

NEVADA STATE BOARD OF PHARMACY

BOARD MEETING

October 14-15, 2020

Zoom

<https://zoom.us/j/5886256671>

Meeting ID: 5886256671

Please do not remove the book from the meeting room.



Nevada State Board of Pharmacy

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Date Posted: September 30, 2020

AMENDED AGENDA

◆ PUBLIC NOTICE ◆

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, October 14, 2020 at 9:00 am. The meeting will continue, if necessary, on Thursday October 15, 2020 at 9:00 am or until the Board concludes its business at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

Via Videoconference at Zoom:

<https://zoom.us/j/5886256671>

or

Via Teleconference at 1 (669) 900-6833
 Meeting ID: 588 625 6671

Please Note:

In regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety and welfare of the public.

The Nevada State Board of Pharmacy may address agenda items out of sequence to accommodate persons appearing before the Board or to aid in the efficiency or effectiveness of the meeting;

The Nevada State Board of Pharmacy may combine two or more agenda items for consideration; and

The Nevada State Board of Pharmacy may remove an item from the agenda or delay discussion relating to an item on the agenda at any time.

Public comment is welcomed by the Board, but will be heard during the public comment item and may be limited to three minutes per person. You may call into the videoconference by following the link or calling the phone number listed above. The president may allow additional time to a given speaker as time allows and in his or her sole discretion.

Public comment may also be submitted to the Board at pharmacy@pharmacy.nv.gov.

Prior to the commencement and conclusion of a contested case or a quasi judicial proceeding that may affect the due process rights of an individual the board may refuse to consider public comment. See NRS 233B.126. Please be aware that after the quasi-judicial board or commission has rendered a decision in the contested case and, assuming this happens before adjournment, the board or commission may entertain public comment on the proceeding at that time.

1. Call to Order and Roll Call – Establishment of Quorum
2. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

◆ CONSENT AGENDA ◆

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of September 2-3, Minutes (**FOR POSSIBLE ACTION**)
4. 4.1 Applications for Out-of-State Pharmacy License – Non-appearance (**FOR POSSIBLE ACTION**)
 - A. Advanced InfusionCare – Dallas, TX
 - B. ApothecoRX – New York, NY
 - C. Ascension Michigan Pharmacy – Farmington Hills, MI
 - D. Biologics by McKesson – Cary, NC
 - E. Biologics by McKesson – Cary, NC
 - F. Complete Medical Supplies, Inc – Coral Springs, FL
 - G. divvyDOSE – Moline, IL
 - H. Eagle Pharmacy – Virginia Beach, VA
 - I. Galaxy Pharmacy – Long Beach, CA
 - J. LA Pharmacy LLC – Alhambra, CA
 - K. Magnolia Pharmacy – Cumming, GA
 - L. MedWiseRx – Tucson, AZ
 - M. MK Pharmacy – Houston, TX
 - N. Morris Apothecary LLC – Parsippany, NJ
 - O. Pharmxpress Pharmacy – Tampa, FL
 - P. Princeton Medical Pharmacy LLC – Princeton, NJ
 - Q. Spring Creek Pharmacy, LLC – Edmond, OK
- 4.2 Application for Out-of-State Compounding Pharmacy License – Non-appearance (**FOR POSSIBLE ACTION**)
 - R. Lucile Packard Children’s Hospital Outpatient Pharmacy – Palo Alto, CA
 - S. Saveway Market Pharmacy – Salmon, ID

4.3 Applications for Out-of-State Medical, Devices, Equipment and Gases License – Non-appearance (**FOR POSSIBLE ACTION**)

- T. Bonds Therapeutics LLC – Columbiana, OH
- U. Capital Medical Corporation – Tallahassee, FL
- V. DJO, LLC – Carlsbad, CA
- W. Gordian Medical, Inc. – Irvine, CA
- X. Gordian Medical II, Inc. – Spring, TX
- Y. Gordian Medical IV, Inc. – Riverside, CA
- Z. Gordian Medical V, Inc. – Houston, TX
- AA. Gordian Medical VI, Inc. – Irvine, CA
- BB. Hanger Clinic – Salt Lake City, UT
- CC. Mendtronix Inc. – Poway, CA
- DD. Nexel Health – Katy, TX
- EE. Next Level Medical Supply LLC – Ft. Lauderdale, FL
- FF. Permobil, Inc. – Lebanon, TN
- GG. SourceMark, LLC – Hebron, KY

4.4 Applications for Nevada Medical, Devices, Equipment and Gases License – Non-appearance (**FOR POSSIBLE ACTION**)
None

4.5 Applications for Out-of-State Wholesaler License – Non-appearance (**FOR POSSIBLE ACTION**)

Background Check Not Required by Law.

4.5.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))
None

4.5.2 Manufacturer (NAC 639.593(7)(d))

- HH. Exelead, Inc. – Indianapolis, IN
- II. RVL Pharmaceuticals, Inc. – Sayreville, NJ
- JJ. Slayback Pharma, LLC – Princeton, NJ
- KK. Time-Cap Laboratories, Inc. – Melville, NY
- LL. QED Therapeutics, Inc. – Brisbane, CA

4.5.3 Publicly Traded (NAC 639.593(7)(a))

- MM. McKesson Medical-Surgical Government Solutions LLC – Henrico, VA
- NN. McKesson Medical-Surgical Minnesota Supply Inc. – Henrico, VA

4.5.4 VAWD-Accredited (NAC 639.593(7)(c))

- OO. MD Logistics, LLC – Plainfield, IN

PP. RxCrossroads 3PL LLC – Mason, OH

4.5.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

QQ. MD Logistics, LLC – Plainfield, IN

RR. MD Logistics, LLC – Plainfield, IN

4.5.5 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

SS. Rhythm Pharmaceuticals, Inc. – Boston, MA

4.5.6 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

TT. McKesson Medical-Surgical Inc. – Clear Brook, VA

UU. McKesson Medical-Surgical Inc. – Rock Hill, SC

VV. McKesson Specialty Distribution, LLC

WW. McKesson Specialty Distribution, LLC

4.5.7 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**

XX. SC Wholesale – St. George, UT

4.6 Application for Nevada Compounding Pharmacy License – Non-appearance
(FOR POSSIBLE ACTION)

YY. Renown Pharmacy – Reno, NV

4.7 Application for Ambulatory Surgery Center License- Non-appearance **(FOR POSSIBLE ACTION)**

ZZ. Affordable Excellence Surgery Center – Las Vegas, NV

AAA. Desert Orthopaedic Pain Center – Las Vegas, NV

BBB. First Specialty Surgery Center – Las Vegas, NV

CCC. Signature Surgery Center – Las Vegas, NV

DDD. Ultimate Specialty Surgery Center – Las Vegas, NV

4.8 Application for Nevada Pharmacy License – Non-appearance **(FOR POSSIBLE ACTION)**

EEE. All City Pharmacy LLC – Las Vegas, NV

◆ REGULAR AGENDA ◆

5. Disciplinary hearings pursuant to NRS 639.247. Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties.

(FOR POSSIBLE ACTION)

A. Katherine Kuehl, RPH	(19-035-RPH-B-S)
B. Lily Akana, PT	(19-075-PT-S)
C. Ashley Carrier, APRN	(19-089-CS-S)
D. Theodore Herrera	(19-079-IN-S)
E. Jerald Clyde, RPH	(19-061-RPH-S)
F. Smith's Pharmacy #366	(19-061-PH-S)
G. Abdel M. Khalek, MD	(19-003-CS-A-S)
H. Robert Chancellor, MD	(19-003-CS-B-S)
I. Lindsay Hoffman, PA-C	(19-003-CS-C-S)
J. Bernard Kofi Addo-Quaye, MD	(19-242-CS-A-S)
K. Mukwel Aiyuk, APRN	(19-242-CS-B-S)
L. Jeff Chen, MD	(20-001-CS-N)
M. Kirash Mirkia, MD	(19-090-CS-S-A)

6. Appeal hearings for citation and fine pursuant to NRS 639.2895(2). Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties. **(FOR POSSIBLE ACTION)**

Vinay Kumar Bararia, MD (19-003-CS-D-S)

7. Petition for Reinstatement of Pharmacist Registration and Request to Appear Before the Board – Appearance. Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties. **(FOR POSSIBLE ACTION)**

Daniel Niel, RPH

8. Applications for Pharmacist Registration by Examination – Appearance. Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties. **(FOR POSSIBLE ACTION)**

Michael Shimoide

9. Applications for Pharmaceutical Technician in Training Registration– Appearance. Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties. **(FOR POSSIBLE ACTION)**

- A. Gina Chiofolo
- B. Jasmine McLaurie

10. Application for Veterinarian Authority to Dispense Drugs Registration – Appearance. Note: The Board may convene in closed session to consider the character, alleged

misconduct, professional competence or physical or mental health of any of the below named parties. **(FOR POSSIBLE ACTION)**

- A. Carrie Lambert, DVM
- B. Melissa Tyson, DVM

11. Applications for Out-of-State Compounding Pharmacy License – Appearance **(FOR POSSIBLE ACTION)**

- A. APS Pharmacy – Palm Harbor, FL
- B. Carolina Infusion – Ridgeland, SC
- C. Hunt Valley PharmaLAB – Cockeysville, MD
- D. Olympia Pharmacy – Orlando, FL
- E. Option Care – Roseville, MN
- F. Pope Shenouda LLC – Holiday, FL
- G. Procure Pharmaceutical Services – Burgettstown, PA

12. Application for Nevada Medical, Devices, Equipment and Gases License – Appearance **(FOR POSSIBLE ACTION)**

- A. ActiveStyle, Inc. – Reno, NV
- B. Evolve Prosthetics & Orthotics – Henderson, NV
- C. First Care Medical Supply LLC – Las Vegas, NV
- D. Nevada Limb & Brace, LLC – Henderson, NV

13. Application for Nevada Wholesaler License – Appearance **(FOR POSSIBLE ACTION)**
None

14. Applications for Out-of-State Wholesaler License – Appearance **(FOR POSSIBLE ACTION)**

Background Check Not Required by Law.

14.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))
None

14.2 Manufacturer (NAC 639.593(7)(d))

- A. Sheffield Pharmaceuticals LLC – New London, CT
- B. Sun Pharmaceuticals Industries, Inc. – Billerica, MA
- C. Zydus Pharmaceuticals (USA) Inc. – Pennington, NJ

14.3 Publicly Traded (NAC 639.593(7)(a))
None

14.4 VAWD-Accredited (NAC 639.593(7)(c))
None

14.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))
None

14.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))
None

14.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))
None

14.8 **Background checks completed in compliance with NRS 639.500. Disqualifying Events.**

D. Apnar Pharma LP – Chino, CA

14.9 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**
None

15. Application for Out-of-State Outsourcing Facility – Appearance (**FOR POSSIBLE ACTION**)

- A. Optum Compounding Services, LLC – Phoenix, AZ
- B. Imprimis NJOF, LLC – Ledgewood, NJ
- C. KRS Global Biotechnology, Inc. – Boca Raton, FL
- D. Nephron Sterile Compounding Center, LLC – West Columbia, SC
- E. Olympia Pharmacy – Orlando, FL
- F. QuVa Pharma, Inc. – Sugar Land, TX
- G. QuVa Pharma, Inc. – Temple, TX
- H. Sincerus Florida, LLC – Pompano Beach, FL
- I. Wedgewood Connect, LLC – San Jose, CA

16. Application for Nevada Pharmacy License – Appearance (**FOR POSSIBLE ACTION**)

Plus One Pharmacy, LLC – Las Vegas, NV

17. Request for Pharmacist Applicant to Retake the Nevada MPJE Exam – Appearance: (**FOR POSSIBLE ACTION**)

Sathish Ariarra Cariappa

18. Application for Advanced Practice Registered Nurse Prescribe Registration – Appearance. Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties. (**FOR POSSIBLE ACTION**)

Natalie Wynn, APRN

19. Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Appearance **(FOR POSSIBLE ACTION)**
 - A. KayLynn Bowman, RPH
 - B. James Kim, RPH
20. Approval of Revised Wholesaler Application **(FOR POSSIBLE ACTION)**
21. Rehearing of Order in Case No. 20-008-PT-S on Application of Jevons Wang pursuant to NRS 639.252 **(FOR POSSIBLE ACTION)**
22. Applications for Controlled Substance Registration– Appearance. Note: The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties. **(FOR POSSIBLE ACTION)**

Kim Kemmerly, DMD
23. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).
24. Executive Secretary Report:
 - A. Financial Report
 - B. Issuance of Temporary Licenses and Registrations
 - C. Meetings with Other Health Care Regulatory Boards
 - D. COVID-19 Response
 - Emergency Regulation Update
 - E. Licensing Software Update
 - F. Licensing Activities Report
 - G. PMP Integration

◆ PUBLIC HEARING ◆

Thursday October 15, 2020 – 9:00 am

25. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION):**

Amendment of Nevada Administrative Code (NAC) 453.510 Schedule I; 453.550 Schedule V. The proposed amendment adds certain substances to schedule 1; provides that certain drug products are not a controlled substance; and removes certain drug products from schedule V. (LCB File No. R090-20)

◆ WORKSHOP ◆

Thursday October 15, 2020 – 9:00 am

26. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2)
(FOR POSSIBLE ACTION):
- A. **Amendment of Nevada Administrative Code (NAC) 639.501 Inspections; provision of self-assessment form.** The proposed amendment to NAC 639.501 will remove the requirement to complete an assessment of workplace and modifies the requirement of an annual inspection.
 - B. **Amendment of Nevada Administrative Code (NAC) 639.** The proposed amendment adds a new section thereto authorizing the issuance of a citation to and assessment of an administrative fine against a registered pharmacist and a licensed pharmacy pursuant to NRS 639.2895 for a prescription misfill in violation of Nevada law in certain instances.
 - C. **Amendment of Nevada Administrative Code (NAC) 639.010 Definitions, (NAC) 639.403 Application required for pharmacist to engage in practice of pharmacy at site other than licensed pharmacy; exemption for pharmacists who administer immunizations, (NAC) 639.406 Hearing to approve or deny application from pharmacist, (NAC) 639.409 Grounds for revocation, suspension or placement of restrictions on approval granted to pharmacist to practice pharmacy at site other than licensed pharmacy, (NAC) 639.412 Application for licensed pharmacy to use services of one or more pharmacists at site other than licensed pharmacy, (NAC) 639.415 Hearing to approve or deny application from licensed pharmacy, (NAC) 639.418 Grounds for revocation, suspension or placement of restrictions on approval granted to licensed pharmacy to use services of one or more pharmacists at site other than licensed pharmacy.** The proposed amendment to these regulations will modify the locations where a pharmacist may practice pharmacy.
27. Date and Location of Next Scheduled Board Meeting:
- December 2-3, 2020 – Las Vegas, NV
28. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)
29. Adjournment

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 985

Damonte Ranch Parkway, Suite 206, Reno, NV, 89521, or call Kristopher Mangosing at (775) 850-1440, as soon as possible.

Supporting materials or additional information regarding the meeting may be obtained from Shirley Hunting at (775) 850-1440, email shunting@pharmacy.nv.gov or 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521.

No Continuing Education credit, will be given for attending this Board meeting.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

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July 22, 2020



State Board of Pharmacy

This letter has been sent to every Board of Pharmacy in the United States as this is a Nationwide CVS Problem

Attn: Executive Director

Let me start by saying to the Board, **OPEN YOUR EYES!!!!** Who will protect the Pharmacist and Technicians against unfair, understaffed, over worked, unrealistic expectations, if you don't?

As a Pharmacist working for CVS in Maryland, I cry on my way home and pray to GOD that I haven't made any mistakes that could cause harm to my innocent patients. When a Pharmacist works a grueling 13 or 14-hour shift, demand dictates that we check a prescription every 45 seconds. CVS does not allocate any time for the Pharmacist to have a break to eat, if we are lucky, we can grab a small snack at our station. In these long shifts, because of the work that is demanded by CVS I am lucky to go to the bathroom once, that is inhumane and degrading, not to mention very unhealthy. Food and rest even for 15 minutes fuels the brain, lack of fluid intake can lead to dehydration.

The American Psychiatric Association is particularly concerned about CVS, America's eighth-largest company, which it says routinely ignores doctors' explicit instructions to dispense limited amounts of medication to mental health patients. The pharmacy's practice of providing three-month supplies may inadvertently lead more patients to attempt suicide by overdosing, the association said.

"Clearly it is financially in their best interest to dispense as many pills as they can get paid for," said Dr. Bruce Schwartz, a psychiatrist in New York and the group's president. CVS paid its President and Chief Executive Officer, Larry J. Merlo \$21.9 million in total compensation for 2018 and \$36.5 million in 2019.

FOR WHAT AND WHY, what does Larry Merlo do that is worth that much money, when every CVS pharmacy is understaffed! Most of my Pharmacist colleagues have not had a raise in 3-4 years! But it is not all about the money, it's about the way we are treated if we voice our concerns. We are then targeted by our District Leader in unimaginable ways, threatening phone calls, texts and nasty snarky emails. As a CVS Pharmacist, you are expected to be on duty 24/7, 365 days a year, even if you are on vacation! I am not the only Pharmacist that is concerned, we are afraid to speak up and lose our jobs. And now with everything else we have to do, we are a COVID test center! Jeopardizing the health and wellbeing of our staff. Our technician hours have been taken away for this testing because we cannot process 40 tests in a day. This is Utterly ridiculous!

The amount of busywork we must do while verifying prescriptions is absolutely dangerous. Mistakes are going to be made, and the patients are going to be the ones suffering. In turn, the Pharmacist will be written up and very possibly terminated. Not to mention trying to live with the fact that they made a mistake that injured a patient, or even the unimaginable, caused someone to die...just because we are understaffed and too BUSY!

At CVS, we have the following stations: 10 telephone lines that ring constantly, Drop Off, Production Stations 1 and 2, Drive thru COVID testing, Drive thru Pick up, In store Pick up with 3 registers and customer pick up lines, Consultation, Immunization station, Visual Verify (RPH only) station, Bagging of prescriptions (RPH only). That is 8 technician stations and 1 Pharmacist station. In an ideal situation, we should have a minimum of 4 technicians

and 1-2 Pharmacists all day, every day. Most days we are lucky to have 5 technicians with various schedules throughout the day. On the weekend we are lucky to have 2 technicians to man all of those stations,

1 Pharmacist and the added burden of 150 or more telephone calls that have to be made. CVS wants to cut us to only 1 technician and 1 Pharmacist on the weekends. How are we to prevent mistakes when we are this understaffed?

We have a workstation assignment screen that pops up on the computer every 2 hours. It is there to assure corporate that we are doing everything under the sun in our day. One such day, in a 2-hour period the Pharmacist duties were as follows:

Drop off - QT – this is taking prescriptions from the customer and inputting the new prescriptions, Pick up, Drive thru, Production (which is filling the prescriptions), calling Dr. offices to ask to refill prescriptions that the patient DID NOT ASK FOR, PCQ calls - this is calling the customer and asking them to pick up their prescriptions. IN ADDITION to: Answering Dr. Calls, administering immunizations, helping customers with questions about their medications or OTC products, and vitamins. Oh, and verifying the prescriptions, bagging those prescriptions. Handling customer complaints about the long lines, the wait on a new dropped off prescription, checking email, completing tasks in the HUB, answering texts from the DL, monitoring the temperature of the outside COVID testing boxthe list goes on and on and it MUST STOP.

This crisis is not just in Maryland, it is in all the states that CVS operates. Here are just a few examples from customers:

Mr. X said he waited on hold with CVS for 40 minutes last summer, after discovering his antidepressant prescription had been refilled with another drug. Mr. X, 47, suspected something was wrong when he felt short of breath and extremely dizzy. Looking closely at the medication — and turning to Google — he figured out it was estrogen, not an antidepressant, which patients should not abruptly quit. "It was very apparent they were very understaffed," Mr. X said, recalling long lines inside the Las Vegas store and at the drive-through when he picked up the prescription.

For Al W..., the medication mix-up meant a pounding headache, nausea and dizziness. In September, Ms. W..., a 17-year-old from Connecticut, was about to take another asthma pill when she realized CVS had mistakenly given her blood pressure medication intended for someone else.

E W 38, landed in an emergency room, his eyes swollen and burning after he put drops in them for five days in November 2018 to treat a mild irritation. A Walgreens in Illinois had accidentally supplied him with ear drops — not eye drops.

For M Scl n, 85, the error was discovered only when she was dying in a Florida hospital in December 2018. A Publix pharmacy had dispensed a powerful chemotherapy drug instead of the antidepressant her doctor had prescribed. She died about two weeks later.

Just a few examples from Pharmacists

The day before W Hi quit his job as a pharmacist at CVS, he worked a 13-hour shift with no breaks for lunch or dinner. As the only pharmacist on duty that day at the Leland, N.C., store, Dr. Hi filled 552 prescriptions — about one every 43 seconds — while counseling patients, giving shots, making calls and staffing the drive-through, he said. Partway through his shift the next day, in December 2018, he called his manager. "I said, 'I am not going to work in a situation that is unsafe.' I shut the door and left," said Dr. h who now runs an independent pharmacy. Dr. Hi felt that the multitude of required tasks distracted from

his most important jobs: filling prescriptions accurately and counseling patients. He had begged his district manager to schedule more pharmacists, but the request was denied, he said.

As a happily retired pharmacist - 14-hour shifts and never eating, sitting or peeing is EVERYDAY for CVS pharmacists and staff. It is inhumane and needs to stop.

The public has no idea about the poor working conditions we endure. I also refrain from drinking because I do not have time to use the restroom. Breaks? Oh, that's nonexistent. I work 13-hour shifts with no breaks. Is that really comprehended? Have I complained? Yes. The answer I get is simple. Just take a break they tell me. Right! The minute I try to sit down the phone rings. It's a doctor calling in a script. I sit back down. Now it's a question from a patient "oh what can I take for my stuffy nose". Next... red basket customer doesn't want to wait. Sit back down again. Shingles shot now. It's never ending, and I only come back to an overload of prescription to fill because I sat down for 5 minutes. I fill over 400 prescriptions a day with no pharmacist overlap. Think about that people and make sure you double check everything. Oh, and please don't yell at me and call corporate because you didn't get the service you deserve. We only get reprimanded and written up. I'm hanging on a thread now just waiting to get fired.

As the husband of a pharmacist, they absolutely do lose sleep over it. She is constantly being hounded on for failing to meet impossible metrics while being understaffed (which they know). Part of the issue with understaffing is the fact that pharmacy technician wages start below that of a fast food or convenience store employee, yet they are expected to carefully handle potentially dangerous medications. The whole system is a mess.

As a former pharmacy tech, I can tell you that yes...it follows you home. You fill and count and label and stand there while people scream at you in your dreams, just like on the job. You remember random half-finished tasks from the time you leave until you walk back in the door. It's incredibly stressful and is steadily getting worse.

A year or 2 ago, Maryland sent out a survey about working conditions and to my knowledge nothing has been addressed. So WHY was that survey conducted? Below are just a few of the examples of the poor staffing concerns for CVS.

CVS Fined for Prescription Errors and Poor Staffing at Pharmacies

New York Times, July 16, 2020

Regulators faulted four locations in Oklahoma, a rare action that followed complaints at drugstore chains across the country.

In a rare public rebuke of the nation's largest retail pharmacy chain, state regulators in Oklahoma cited and fined CVS for conditions found at four of its pharmacies, including inadequate staffing and errors made in filling prescriptions.

While the fine of \$125,000 on Wednesday was small for CVS Health — it paid its chief executive \$36.5 million in total compensation last year and is the country's fifth-largest company — the move validated concerns raised at multiple drugstore chains across the country by pharmacists and technicians who say understaffed workplaces are putting the public at risk.

CVS also agreed to distribute a memo to its pharmacists in the state, highlighting a law that requires them to take action if working conditions in their pharmacies could lead to problems safely filling prescriptions. The memo is to make clear that they are not to face retaliation for documenting and reporting such issues.

In a statement, a CVS spokesman said the company agreed to the terms to “avoid the time and expense of a protracted hearing process and to foster a positive working relationship” with the Oklahoma State Board of Pharmacy. The spokesman said the action did not constitute an admission of guilt by the company on all counts.

The state board inspected the four pharmacies from mid-2019 to early this year after receiving multiple complaints about errors and overwhelmed staff members.

One of those errors occurred last year when a developmentally disabled teenager received one-fourth of his prescribed dose of anticonvulsant medication from a CVS in Owasso, a suburb north of Tulsa, according to a complaint filed by the board. The boy took the incorrect dosage for 18 days, during which his seizures became uncontrollable, causing him to fall and hit his head, said his father, A B

The convulsions were “nonstop” and “violent,” Mr. B said. “You have no idea what kind of shame we feel about this — that we couldn’t figure out what was going on.”

As part of its agreement on Wednesday, CVS will pay a \$75,000 fine for that incident — the highest amount allowed under state law for this case — and its Owasso pharmacy will remain on probation for two years. While pleased the board had addressed the matter, the boy’s parents said they were worried that the action was not strong enough, and that it could allow other patients to be harmed in the future unless CVS made substantial changes to its business.

“A \$75,000 fine? That is nothing to them,” said the teenager’s mother, R B. “These things are going to keep happening if they don’t fix their staffing issues.”

Pharmacists in dozens of states have accused CVS, Walgreens and other major pharmacy chains of putting the public at risk of medication errors because of poorly staffed and chaotic workplaces, The New York Times reported in January.

In letters to state pharmacy boards and in interviews with The Times, pharmacists said they struggled to keep up with an increasing number of tasks — filling prescriptions, giving flu shots, tending the drive-through, answering phones and calling patients — while racing to meet corporate performance metrics they characterized as excessive and unsafe.

The pharmacy chains, including CVS, have pushed back on employees’ complaints, saying staffing is sufficient and errors are rare.

Most state investigations focus on pharmacists, not conditions in their workplaces. In Oklahoma, the state board has begun investigating broader workplace issues when responding to complaints and doing routine inspections.

In mid-January, two board compliance officers went to a CVS in Bartlesville, Okla., to investigate a complaint of a mislabeled prescription. There, they “witnessed a chaotic scene including the phones ringing almost all of the time, along with constant foot traffic and drive thru traffic,” according to a complaint filed against CVS.

The officers discussed the error with the head pharmacist, noting that she said “she had lost a considerable amount of her support staff, and that the pharmacy was operating with little help, so she was not terribly surprised that an error could have occurred.”

In an audit, the officers found an error rate of nearly 22 percent, or 66 errors out of 305 prescriptions. Some of the mistakes were minor and would not affect a patient — such as the incorrect name of a prescribing physician — but others were more significant, like instructions for medications that were unclear or substantially different from what they should have been.

Days later, a prescriber complained of insufficient staffing at a pharmacy in Moore, about 10 miles south of Oklahoma City, saying calls were placed on hold for up to 60 minutes. Compliance officers reported finding one pharmacist and one technician who had fallen behind on work.

The officers recorded a 6 percent error rate, according to the complaint. Some of the errors were substantial, including the wrong dose of an antibiotic for a 1-year-old, the incorrect frequency for an antiviral drug (every two hours instead of 12) and multiple errors involving the frequency of a narcotic.

There were several reported errors involving testosterone; in one case, the dose was doubled for a female patient. The compliance officers also noted mistakes related to blood pressure, gastric disorder and steroid medications that had been dispensed to or entered for the wrong patients.

Errors were also flagged in a complaint about a pharmacy in Choctaw, east of Oklahoma City, in February. Inspectors said a computer screen showed more than 99 prescriptions waiting to be filled and more than 99 calls needing to be made.

When asked about the backlog, the pharmacist said that employees were several days to weeks behind, according to the complaint, adding that they had been given an extra 17 hours of technician help but could not find anyone who would work only 17 hours.

Similar staffing concerns were detailed in the case involving the disabled teenager. The pharmacist on duty that day, according to the complaint, was responsible for checking 194 prescriptions in a six-hour shift, about one every two minutes.

The store's lead pharmacist told the board that he had no control over staffing, and that while he complained about the issue to his district leader, she also had no power to make changes.

That district leader, Al D , who is a pharmacist, told The Times in an interview this week that "district leaders were repeatedly voicing their concerns about the budgets" for staffing at CVS pharmacies last year.

Dr. Di said that many pharmacies in her 19 stores were short-staffed, that customer complaints were on the rise and that she was worried about patient safety. She had worked for CVS for almost six years until November, when, she said, she was terminated for a policy violation involving another employee, although she believes she may have been retaliated against by the company because of the board's investigation.

In its statement on Wednesday, M D , the CVS spokesman, said that "if a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith." He added that any suggestion the company retaliated against a district leader was false.

In addition to the fines, the state board said it "strongly recommended" that the company follow through on nearly a dozen recommendations for all of its Oklahoma pharmacies, including increased training for technicians and changes to how staffing needs were determined.

The board also advised eliminating tasks that might overburden pharmacists and removing some metrics they are required to meet. Phone calls pharmacists often must make, it said, could be outsourced to a corporate call center.

Mr. Di said the company would review the board's recommendations, noting that CVS had reduced its overall metrics this year and was planning to increase staffing in the fall to help handle vaccines for flu season.

Understaffing at Pharmacy Chains Puts Patients at Risk

ASH Clinical News, FRIDAY, FEBRUARY 7, 2020

Pharmacists at large U.S. retail chains like Walgreens, CVS, and Rite Aid, are filing complaints with state regulatory boards about working in understaffed and chaotic environments, which they argue are putting them at risk of making medication errors.

Pressure from pharmacy benefit managers (PBMs) may be to blame for understaffing at chain pharmacies, and poor performance caused by pharmacists who are rushing to meet corporate metrics may be putting the public at risk.

"When a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith," CVS said in a statement. Walgreens claims it made "clear to all pharmacists that they should never work beyond what they believe is advisable." Both companies declined to provide data about errors.

State boards and lawmakers are trying to keep companies accountable, with some adopting laws to introduce lunch breaks or limit the number of technicians each pharmacist can supervise. However, when a medication mistake is reported to a board, the board almost always acts against the pharmacist, rather than investigating conditions at the company.

Union alleges overwork and understaffing at CVS pharmacies

APhA, May 16, 2016

Teamsters Local 727, the union representing Chicago-area CVS pharmacists, warned of safety risks Tuesday from "management's mistreatment of overworked and understaffed pharmacists," allegations that come as the parties negotiate a new contract.

Teamsters Local 727, the union representing Chicago-area CVS pharmacists, warned of safety risks Tuesday from "management's mistreatment of overworked and understaffed pharmacists," allegations that come as the parties negotiate a new contract. Approximately 150 CVS pharmacists have been working without a contract since their last 3-year agreement expired on May 7. The union claims management has been unresponsive to workers' concerns about quality-of-life issues including uninterrupted breaks, preservation of the 9-hour workday, and the elimination of "superfluous tasks" that take time away from their primary responsibilities. The union has filed unfair labor practice charges against CVS, which said in a statement that it has had a long-standing and productive relationship with Teamsters Local 727 for many years and it looks forward to finalizing a new agreement. "Our pharmacists, including those represented by Local 727, are health care professionals who are given the flexibility to manage their work schedules in collaboration with their pharmacist colleagues to ensure that our pharmacies are properly staffed during operating hours," said spokesman M D "We want to preserve the ability for our pharmacists who choose to work longer shifts to do so."

CVS "skeleton schedule" leaves the pharmacy undermanned all day. No time to complete the behind-the-scenes tasks that are required because you are constantly helping customers and answering phones while being understaffed. Yet you are held accountable for those tasks. During rush hours, you are told to "multi-task" better,

because you can't fill scripts at the same time as serving customer after customer in line. Training is brief and haphazard. Pharmacists tend to be irritable because of lack of breaks and too many demands at once, and they take it out on the techs. Pay scale is lower than competitors. Medical insurance and Rx insurance for full-time workers is costly and doesn't cover well. Most pharm techs are doing their time until they can bail for a better company. Advice to Management

Pay attention to the well-being of your employees and you will have higher morale and lower turnover of employees. Organize your work environment so that there are fewer interruptions for the production and drop-off techs instead of accusing them of not being able to "multi-task" well enough. Consider employing retail sales associates to man the pick-up station to free up the certified techs to safely fill the scripts.

Welcome to a day in the life of a CVS Pharmacist:

My shift today is 8am to 9pm – I am the only Pharmacist on duty today

Today like every other day I arrive for my shift 30 minutes before we open to try to get a small jump on the day and I am NOT paid for that 30 minutes. Today is different in that its WAREHOUSE TRUCK DAY. So before I can even sign on to the computer, I must bring in 40 totes and 30 boxes of vials to the Pharmacy off the sales floor.

I finally get signed onto the computer at 7:50 and I have 7 pages (7 x 15 scripts per page = 105) to QV1 which means to visual verify the prescription for correctness, DUR if any, correct directions and day supply. My staff starts to arrive at 7:55 as there is NO extra time for them to help on TRUCK day due to our hours being cut. I have 7 technician workstations and only 3 technicians to cover all of them. Everyone is in stealth mode because we have 22 COVID-19 tests scheduled every 10 minutes starting at 9:00. This will mean that I am down to 2 technicians to run 7 stations, answer phones and wait on customers. Needless to say my day will be relentless. Here is what I have done today

RTS (14-day scripts return to stock) – 45 this is a technician function but since I only have 2 I am tasked with it
DR. CALLS – 15

PATIENT CALLS – (they just want to talk with a Pharmacist) 9

REGULAR PHONE CALLS – 9

VOICE MAIL RETREIVAL – 15

QT (entering prescriptions into the system) – 15

CHECK EMAIL – AM and PM

CHECK THE HUB – AM and PM

CII CYCLE COUNTS – 26

CHECK TEMPERATURE ON COVID-19 DROP OFF BOX – 3 times a day

RECORD ALL 3 REFRIGERATOR TEMPERATURES – AM and PM

PCQ CALLS – (14) Pharmacist calls customers to find out when they will pick up their prescriptions

CII ORDER ARRIVES – Check in, record, put away, finish paperwork

CII CYCLE COUNTS – 17 twice today

CII PRESCRIPTIONS – 30 – PHARMACIST FUNCTION ONLY – verify for correctness, open time limited safe wait 3 minutes open safe pull stock bottle, record on hard copy, print hard copy and backtag if it is not a hard copy from patient, verify correctness of the bottle pulled, count 2 times then back count and make sure the numbers are correct in the computer. Check the prescription again for correctness, verify in the computer, bag the prescription.

Pull drugs, scan the bottles in the computer for accuracy, count, label and then check the prescriptions (45)
 WAITING ON CUSTOMERS AT THE REGISTER – 20 BECAUSE CVS CUT MY HOURS
 PATIENT COUNSELING – 25
 OTC RECOMMENDATIONS – 12

MAKING KITS FOR COVID-19 TESTING – 20 (as I have only 2 technicians, I must pull myself away from my Pharmacist duties to make kits because we have 10 cars lined up in our drive thru waiting to be tested

Glue carpet squares down as myself and my technicians have almost fallen, and CVS has yet to send someone to fix the problem even after 3 requests and workorders.

In the midst of all this chaos, I get an email from my DL asking why I didn't complete a certain amount of phone calls!!!!

By this time it is 8:55pm – I am mentally and physically exhausted, I have had nothing to eat, only 2 small bottles of water and only had time to go to the restroom once and that was at 11:50AM. I have checked 537 prescriptions **THAT IS 1 PRESCRIPTION EVERY 41 SECONDS.....** I lock up, set the alarm and walk out the door extremely defeated. I get in my car and sit for the first time in 13-1/2 hours and my feet are killing me. I say a prayer to God that I did everything correct and I caused NO harm to anyone. I cry my way home!

In my opinion, Pharmacists have become nothing but robots in white lab coats. The next time you fill a prescription just look at our faces, we always appear to be in chronic stress, tired and look defeated. This is true of every CVS Pharmacist and Technician. We are all under so much stress that our health and home life suffers because of it. Something must be done to help rectify these horrible working conditions. For many years Pharmacists were regarded as the #1 most respected and trustworthy profession. In 2018 we dropped to #2 and in 2019 we dropped to #3, do you see a trend? I do, and it is because of the unrealistic demands that this company loads on us every day, as they continue to cut hours for staffing. As they cut these hours, it just means that the Pharmacist who is already overwhelmed, must pick up the slack, and that is extremely dangerous. If there is only one person doing all of the work on a single prescription, and God forbid, an error occurs, who is going to catch the error? It's highly unlikely that the error will be caught! Again, putting the patient in harm's way.

Obviously, I am voicing my concerns anonymously, as I am 100% sure that if CVS found out, I would be fired.

This dangerous cycle MUST STOP before it's too late!

If the Board is NOT there to protect the Pharmacists and the patients, who is?

3



NEVADA STATE BOARD OF PHARMACY

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September 2nd & 3rd, 2020
 Minutes

Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

Via Videoconference at Zoom:
<https://zoom.us/j/5886256671>

or

Via Teleconference at 1 (669) 900-6833
 Meeting ID: 588 625 6671

Board Members Present:

Helen Park	Krystal Freitas	Jade Jacobo	Richard Tomasso
Rolf Zakariassen	Wayne Mitchell	Gener Tejero	

Board Staff Present:

David Wuest	Yenh Long	Shirley Hunting	Kristopher Mangosing
Brett Kandt	Courtney Lee	Joe Dodge	Dena McClish
Luis Curras	Leo Basch	Ken Scheuber	Sophia Long
Monica Segedy	Shannon Reichman		

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest announced that this meeting is being held virtually and discussed social distancing protocols.

1. Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board Members were present and a quorum was established.

2. Public Comment September 02, 2020 9:00 AM

There was no Public Comment.

◆ CONSENT AGENDA ◆

3. Approval of July 15-16, 2020, Minutes

President Park noted corrections on page 8 to Dr. Charles Kamen's name and page 23 with Steven McBride's name.

Board Action:

Motion: Krystal Freitas moved to approve the July 15-16, 2020 minutes pending corrections as discussed above.

Second: Wayne Mitchell

Action: Passed unanimously.

4. 4.1 Applications for Out-of-State Pharmacy License – Non-appearance

- A. AdhereRx, Inc. – Gilbert, AZ
- B. Blink Pharmacy Plus – Pittsburgh, PA
- C. Epic Pharmacy – Oklahoma City, OK
- D. First Choice Home Infusion LLC – Hendersonville, TN
- E. LeMed Pharmacy III, LLC
- F. Preferred Pharmacy Inc – Costa Mesa, CA
- G. Solara Medical Supplies LLC – Chula Vista, CA
- H. Stoneview Pharmacy – Gilbert, AZ
- I. Vet Perfect, Inc. – Boca Raton, FL
- J. Vivo Health Pharmacy at Home – Great Neck, NY
- K. Zoetis US LLC – Lee's Summit, MO

4.2 Application for Out-of-State Compounding Pharmacy License – Non-appearance

- L. Burt's Pharmacy, LLC – Newbury Park, CA
- M. Cheveux LLC – Phoenix, AZ

- N. Express Veterinary Pharmacy – Gilbert, AZ
- O. Jungle Jim’s Pharmacy – Fairfield, OH

4.3 Applications for Out-of-State Medical, Devices, Equipment and Gases License – Non-appearance

- P. A Better Choice Medical Supply, LLC – Waterford, MI
- Q. BioTel INR, LLC – Indianapolis, IN
- R. Control Bionics Inc. – Milford, OH
- S. First Nation Group, LLC – Denver, CO
- T. Icon Medical Solutions Corp. – Leominster, MA
- U. Linde Gas North America, LLC – Livingston, TN
- V. Nephron Pharmacy LLC – West Columbia, SC
- W. Nitrous Oxide Corp – Tooele, UT
- X. Nitrous Oxide Corp – Yazoo City, MS
- Y. Recovery DME, Inc. – San Diego, CA
- Z. RGH Enterprises, Inc. – Jacksonville, FL
- AA. Secure Medical Products, Inc. – Deerfield Beach, FL
- BB. Sleep Data Holdings, LLC – San Diego, CA

4.4 Applications for Nevada Medical, Devices, Equipment and Gases License – Non-appearance None

4.5 Applications for Out-of-State Wholesaler License – Non-appearance

Background Check Not Required by Law.

4.5.1 Distributor for Single Manufacturer (NAC 639.593(7)(e)) None

4.5.2 Manufacturer (NAC 639.593(7)(d))

- CC. Acertis Pharmaceuticals, LLC – Langhorne, PA
- DD. Bayshore Pharmaceuticals LLC – Short Hills, NJ
- EE. Estreno Pharmaceuticals, LLC – Sunrise, FL
- FF. Nestle HealthCare Nutrition, Inc. – Bridgewater, NJ
- GG. PCI of Illinois – Rockford, IL
- HH. Praxair Distribution, Inc. – Bethlehem, PA
- II. Profounda, Inc. – Orlando, FL
- JJ. Sovereign Pharmaceuticals, LLC – Fort Worth, TX
- KK. Tusker Medical, Inc. – Menlo Park, CA
- LL. Zealand Pharma US, Inc. – Marlborough, MA

4.5.3 Publicly Traded (NAC 639.593(7)(a))

- MM. BioCryst Pharmaceuticals, Inc. – Durham, NC

NN. RGH Enterprises, Inc. – Jacksonville, FL

4.5.4 VAWD-Accredited (NAC 639.593(7)(c))

OO. NDC Distributors LLC – Brooklyn, NY

4.5.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))
None

4.5.5 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

PP. Apellis Pharmaceuticals, Inc. – Waltham, MA

QQ. AVEO Pharmaceuticals, Inc. – Boston, MA

RR. Dermira, Inc. – Menlo Park, CA

SS. Gamida Cell Inc – Boston, MA

TT. TG Therapeutics, Inc. – Edison, NJ

4.5.6 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))
None

4.5.7 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**

UU. Puragraft – Kingwood, TX

VV. Takeda Pharmaceuticals America, Inc. – Florence, KY

4.6 Application for Nevada Pharmacy License – Non-appearance **(FOR POSSIBLE ACTION)**
None

Krystal Freitas disclosed that she has a business relationship with Consent Agenda Item 4.3P but is able to participate fairly and without bias.

Rolf Zackariassen disclosed that his father had a business relationship with Consent Agenda Item 4FF, that he himself had worked for 4FF, but he is able to participate fairly and without bias.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda.

Second: Wayne Mitchell

Action: Passed unanimously.

5. Discipline

A. Kirash Mirkia, MD

(19-090-CS-S-A)

Brett Kandt prosecuted the case on behalf of the State. Keith Weaver appeared as counsel representing Respondent Kirash Mirkia.

The Board heard oral argument on Respondent's Motion to Dismiss. Mr. Weaver argued that the Nevada statutes are not clear on the authority of APRN's to possess and administer, as demonstrated by the fact that a competitor asking for clarification in the form of an advisory opinion from the Board, and subsequently filed a complaint against Dr. Mirkia that provided the basis for administrative charges, making the action therefor invalid. Mr. Weaver argued that there were no dangerous drugs involved and that the pharmacy from which Dr. Mirkia bought drugs from does not need to be licensed by the Board.

Mr. Kandt responded to the arguments by pointing out that the standard on a motion to dismiss required the Board to accept all factual allegations in the Accusation as true. Mr. Kandt argued that the facts alleged supported the charges, and referenced the specific language of NRS 454.213(1)(c), NRS 454.201 and NAC 639.6915.

Board members ask questions of both attorneys and discussion ensued.

Sophia Long, Deputy Attorney General sitting as Board counsel, advised the Board on the standard for a motion to dismiss.

President Park asked the Board members to consider denying the Motion to Dismiss.

Board Action:

Motion: Richard Tomasso moved to deny the Motion to Dismiss.

Second: Wayne Mitchell

Action: Passed unanimously.

Mr. Kandt and Mr. Weaver stipulated on the record to continue this matter to a future meeting.

B. Victoria Wall, MD

(20-067-CS-S)

Brett Kandt prosecuted the case on behalf of the State. Baron Harmon appeared as counsel representing Respondent Victoria Wall.

Dr. Wall appeared and was sworn by President Park prior to answering questions or offering testimony.

The Board heard oral argument on the prosecution's Motion to Deem the Allegations Admitted and on Respondent's Motion for Continuance. Mr. Kandt argued that the facts were

uncontroverted that on or about May 13, 2009, and during subsequent renewal periods, Dr. Wall requested that her License No. 12154 issued by the Nevada State Board of Medical Examiners (NSBME) be placed on inactive status with an explanation or attestation showing that “you are not practicing or have not practiced medicine in Nevada.” Dr. Wall’s NSBME License No. 12154 to practice in Nevada has been inactive since 2009.

On each renewal application for her Certificate of Registration No. CS15026 for the years 2010, 2012, 2014, 2016, and 2018, Dr. Wall certified to the Board that she held an active and current Nevada license with the NSBME.

Dr. Wall wrote multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive.

On or about June 5, 2020, Board staff served Dr. Wall with an order pursuant to NRS 639.2895(1) to immediately cease and desist prescribing controlled substances for Nevada patients.

On June 14, 2020 Dr. Wall surrendered her DEA Certificate of Registration No. BW8998025 to the U.S. Drug Enforcement Administration by executing a DEA form 104, entitled “Surrender for Cause” (DEA Surrender for Cause).

By executing the DEA Surrender for Cause, Dr. Wall acknowledged in pertinent part the following:

In view of my alleged failure to comply with Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

Ms. Wall’s surrender of her DEA Certificate of Registration No. BW8998025 for cause operated as an immediate suspension of her Certificate of Registration No. CS15026 with the Board pursuant to NRS 639.2107

Mr. Harmon argued that Dr. Wall did not try to willfully deceive the Board. Dr. Wall has completed her continuing education credits for her license. Had she changed her status to active she would have been in compliance with Nevada Law. Mr. Harmon also stated that Dr. Wall was licensed to practice medicine in California during the period in question and that license was in good standing.

Mr. Kandt argued that Dr. Wall had, through counsel, voluntarily surrendered her Certificate of Registration No. CS15026 and is subject to discipline pursuant to NRS 233B.121(6).

Sophia Long stated that should the Board grant the prosecution’s Motion and deem the allegations admitted, Respondent’s Motion for Continuance should be denied.

Mr. Kandt moved to admit Dr. Wall’s Surrender of Cause of her DEA be admitted into the record as Exhibit A. Mr. Harmon had no objection.

President Park admitted into the record Exhibit A.

Mr. Kandt moved to admit into the record Ms. Wall's Notice of Surrender of Controlled Substance Registration with the Nevada Board of Pharmacy as Exhibit B. Mr. Harmon had no objection.

President Park admitted into the record Exhibit B.

Mr. Harmon moved to admit into the record Ms. Wall's Evidence of Good Standing Licensure with the Medical Board of California as Exhibit C. Mr. Kandt had no objection.

President Park admitted Exhibit C into the record.

Mr. Harmon moved to admit into the record Ms. Wall's good standing with the American Board of Ophthalmology as Exhibit D. Mr. Kandt had no objection.

President Park admitted into the record Exhibit D.

Mr. Harmon moved to admit into the record an email from Mr. Harmon to Mr. Kandt dated September 1, 2020, which contains a statement from Dr. Wall as Exhibit E. Mr. Kandt had no objection.

President Park admitted into the record Exhibit E.

Mr. Kandt reiterated in closing that based upon Dr. Wall's responses and judicial admissions, her surrender for cause of her DEA registration and her voluntary surrender of her controlled substance registration, there are no material issues of fact or affirmative defenses, and no basis for a continuance.

Board Action:

Motion: Jade Jacobo moved to grant the prosecution's motion to deem the allegations set forth in paragraphs two through eight of the Accusation as admitted.

Second: Wayne Mitchell

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to deny the Respondent's Motion for Continuance.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action

Motion: Richard Tomasso moved to making findings of fact consistent with paragraphs 1-8 of the Accusation together with a finding that on August 24, 2020, through her legal counsel, Dr. Wall voluntarily surrendered her Certificate of Registration No. CS15026.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action

Motion: Richard Tomasso moved to make conclusions of law consistent with paragraphs 9-29 of the Accusation, including the eight causes of action, and to also conclude as a matter of law that by voluntarily surrendering her Certificate of Registration No. CS15026 while this administrative action was pending, Dr. Wall is subject to discipline pursuant to NRS 233B.121(6).

Second: Rolf Zakariassen

Action: Passed unanimously.

Board Action

Motion: Richard Tomasso moved to fine Dr. Wall \$2,000 for each of the first seven causes of action, for a total of \$14,000 dollars to be paid to the State of Nevada.

Second: Wayne Mitchell

Action: Passed unanimously.

On the basis of that discipline Mr. Kandt moved to admit into the record documentation of \$1,962.87 in attorney's fees and costs incurred in investigating and prosecuting this matter as Exhibit F. Mr. Harmon had no objection.

President Park admitted into the record Exhibit F.

Board Action:

Motion: Richard Tomasso moved that Dr. Wall pay \$1,962.87 to partially reimburse the Board for documented attorney's fees and costs incurred in investigating and prosecuting this matter, the Board finding that these expenses were reasonable, necessary, and actually incurred.

Second: Rolf Zakariassen

Action: Passed unanimously.

C. Katherine Kuehl

(19-035-RPH-B-S)

This item was continued.

D. Walmart Pharmacy #10-3728

(18-096-PH-S)

Ms. Freitas recused herself from participation in this matter due to a friend who is involved in this matter.

Ms. Jacobo disclosed that this case has respondents who were past employers and co-workers, but she is able to participate fairly and without bias.

Brett Kandt prosecuted the case on behalf of the State. Shelley Tustison, Health and Wellness Compliance for Walmart, John Castro, pharmaceutical technician subpoenaed to appear, and Hal Taylor, legal counsel for Walmart, appeared before the Board.

President Park swore in Ms. Tustison and Mr. Castro prior to answering questions or offering testimony.

Mr. Kandt summarized the facts of the case where a data entry error by a pharmaceutical technician resulted in the dispensing of two unauthorized refills of a prescription. Registered pharmacist Jessica Huey verified as correct the two unauthorized refills. Pursuant to NRS 639.3230(5), NAC 639.702, and NAC 639.945(2), Walmart #10-3728 is responsible for each of the above stated allegations. Mr. Kandt reported that the First Cause of Action against Respondent Gloria Remley had been dismissed and Remley was cited and fined \$1000 pursuant to NRS 639.2895(2) for violating NAC 639.252(2). Remley has paid her fine in full. The Second Cause of Action against Respondent Jessica Huey had been dismissed as well.

Mr. Taylor stated that Mr. Kandt's summary is accurate.

Mr. Kandt presented a proposed Stipulation and Order for the Board's consideration, that Walmart #10-3728 pay a fine of \$1000, and pay \$1000 to partially reimburse the Board for recoverable attorney fees and costs

Board Action:

Motion: Wayne Mitchell moved to approve the Stipulation and Order as presented to the Board.

Second: Rolf Zakariassen

Action: Passed unanimously.

E. Paul Luke

(19-066-PH-S)

Courtney Lee prosecuted the case on behalf of the State. Paul Luke appeared and was sworn by President Park.

Ms. Lee summarized the facts of the case that Mr. Luke was employed by St. Rose Dominican Hospital-San Martin Campus (St. Rose), located in Las Vegas.

In April of 2019, Pharmacist John Glick, Director of Pharmacy for St. Rose, reported Mr. Luke to the Nevada Board of Pharmacy alleging concealment of drugs and pharmacy supply items in a bag from St. Rose with intent to divert.

A subsequent investigation by St. Rose's staff identified a total of at least twenty tablets diverted by Mr. Luke. During the investigation, Mr. Luke admitted to the unlawful diversion activity, and submitted a statement regarding the same. Mr. Luke was terminated on April 5, 2019.

Ms. Lee questioned Mr. Luke about receiving the Notice of Intended Action and Accusation together with the Statement to Respondent and Notice of Hearing mailed to him by the Board. Mr. Luke acknowledged receipt of the accusation.

Ms. Lee stated that the Board does have jurisdiction over this matter as Mr. Luke is a registered pharmacist with the Board and he did receive the accusation.

Ms. Lee questioned Mr. Luke regarding his employment at St. Rose, and asked if he was aware of the investigation by the pharmacist and the Hospital. Mr. Luke stated that he was aware of the investigation. Mr. Luke admitted diversion of medications.

Mr. Luke read into the record an apology letter. Ms. Lee moved to admit into the record Mr. Luke's apology letter as Exhibit 1.

President Park admitted into the record Exhibit 1.

Board Action:

Motion: Jade Jacobo moved to make findings of fact consistent with paragraphs 1-6 of the Accusation.

Second: Wayne Mitchell

Action: Passed unanimously.

Board action

Motion: Jade Jacobo moved to make conclusions of law consistent with paragraphs 7-12 of the Accusation.

Second: Wayne Mitchell

Action: Passed unanimously.

Board Action:

Motion: Wayne Mitchell moved to revoke Paul Luke's Certificate of Registration No. 15314, and stay the revocation, and be placed on probation for five years with following conditions; cannot be managing pharmacist, supervising pharmacist must submit a yearly evaluation to the Board, must report the discipline to potential employers.

Second: Rolf Zakariassen

After Board discussion, Wayne Mitchell rescinded the motion, and Rolf Zakariassen agreed.

Board Action:

Motion: Jade Jacobo moved to revoke Paul Luke's Certificate of Registration No. 15314 and that Mr. Luke may not petition for reinstatement for one year.

Second: Richard Tomasso

Aye: Park, Tomasso, Freitas, Jacobo, Zakariassen

Nay: Mitchell, Tejero

Action: Motion carries.

F. Theodore Herrera (19-079-IN-S)

These items were continued.

G. Jerald Clyde, RPH (19-061-RPH-S)

H. Smith's Pharmacy #336 (19-061-PH-S)

These items were continued.

I. Abdel M. Khalek, MD (19-003-CS-A-S)

J. Robert Chancellor, MD (19-003-CS-B-S)

K. Lindsay Hoffman, PA-C (19-003-CS-C-S)

This matter was heard in conjunction with Agenda Item 6A.

Brett Kandt prosecuted the case on behalf of the State. Lindsay Hoffman, Robert Chancellor and Vinay Bararia appeared and were sworn by President Park prior to answering questions or offering testimony.

E. Brent Bryson appeared as counsel representing Ms. Hoffman, Mr. Chancellor, and Mr. Bararia.

Mr. Kandt requested authorization to pursue injunctive relief against the respondents should it be deemed necessary. Mr. Bryson objected, arguing that the requirements for issuing an injunction were not present. Mr. Kandt rebutted that the Board staff would be required to make the necessary showing to a court when seeking injunctive relief. Board counsel Sophia Long concurred with Mr. Kandt.

Board Action:

Motion: Richard Tomasso moved to authorize Board staff to seek injunctive relief if necessary.

Second: Wayne Mitchell.

Action: Passed unanimously.

Mr. Bryson represented that respondents Bararia, Chancellor, and Hoffman had executed written waivers for joint representation. Mr. Kandt canvassed respondents Bararia, Chancellor, and Hoffman individually on the record regarding their joint representation by Mr. Bryson. Bararia knowingly and voluntarily waived any potential conflict and consented to joint representation. Chancellor knowingly and voluntarily waived any potential conflict and consented to joint representation. Hoffman knowingly and voluntarily waived any potential conflict and consented to joint representation.

The parties stipulated on the record to continue this matter.

L. Bernard Kofi Addo-Quaye, MD	(19-242-CS-A-S)
M. Mukwel Aiyuk, APRN	(19-242-CS-B-S)
N. Solomon Joshua, APRN	(19-242-CS-C-S)

This matter was heard in conjunction with Agenda Item 6B.

Courtney Lee prosecuted the case on behalf of the State. John Hunt appeared as counsel representing respondent Victor Bruce. Maria Nutile appeared as counsel representing respondent Bernard Kofi Addo-Quaye. Ms. Lee stated that Lyn Beggs is representing respondent Mukwel Aiyuk. David Krawczyk appeared as counsel representing Mr. Joshua. Solomon Joshua appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Lee provided background on the case regarding Solomon Joshua, who was an independent contractor and/or employed by TrimCare during the relevant timeframes in question. Mr. Joshua is alleged to have unlawfully prescribed controlled substances/dangerous drugs under Dr. Addo-Quaye's name and credentials for at least three patients from October 30, 2018 to December 19, 2018.

Ms. Lee presented a proposed Stipulation and Order for the Board's consideration, that Mr. Joshua shall receive a public reprimand, pay a \$1000 fine to the State of Nevada, pay \$950 to partially reimburse the Board for recoverable attorney's fees and costs, that Mr. Joshua not work with Dr. Bruce, and comply with all State and Federal Laws.

Board Action:

Motion: Krystal Freitas moved to accept the Stipulation and Order regarding Solomon Joshua as presented.

Second: Wayne Mitchell

Action: Passed unanimously.

Courtney Lee requested authorization to pursue injunctive relief against the remaining respondents should it be deemed necessary.

Board Action:

Motion: Richard Tomasso moved to authorize Board Staff to seek injunctive relief if necessary.

Second: Krystal Freitas

Action: Passed unanimously.

The parties stipulated on the record to continue this matter.

6. Appeal hearings for citation and fine pursuant to NRS 639.2895(2).

A. Vinay Kumar Bararia, MD (19-003-CS-D-S)

This Agenda Item was heard in conjunction with Item 5I, 5J, and 5K.

B. Victor Bruce, MD (19-242-CS-D-S)

This Agenda Item was heard in conjunction with Item 5L, 5M, and 5N.

7. Petition for Reinstatement of Controlled Substance Registration and Request to Appear Before the Board – Appearance.

Joyce P. Chang, MD (18-029-CS-S)

Courtney Lee recused herself from participation in this matter.

Joyce P. Chang appeared and was sworn by President Park prior to answering questions or offering testimony. The Board previously entered an Order on October 10, 2018, revoking Dr.

Chang's controlled substance registration, Certificate of Registration No. CS15881, and dispensing practitioner registration, Certificate of Registration No. PD00340. Dr. Chang answered questions and gave testimony regarding her petition for reinstatement of her controlled substance registration. Dr. Chang does not currently have a DEA registration.

Board Action:

Motion: Gener Tejero moved to reinstate Dr. Chang's controlled substance registration without restrictions.

Second: Jade Jacobo

Action: Passed unanimously.

8. Applications for Controlled Substance Registration – Appearance.

A. Roger Belcourt

Roger Belcourt appeared and was sworn by President Park prior to answering questions or offering testimony.

Dr. Belcourt stated that he is here to make disclosures on his application for a Controlled Substance registration.

Ms. Long provided background information on the disclosure for the application; in 1988 he was arrested for self-prescribing controlled substances and discipline ensued. In 1993 he finished a counseling program and has been in additional programs since then. In 2008 Dr. Belcourt had a relapse and self-reported his dependence on a controlled substance.

Dr. Belcourt stated that he had a DEA in California to prescribe controlled substances and has not had issues.

Dr. Belcourt answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the Controlled Substance Registration application for Roger Belcourt.

Second: Rolf Zackariassen

Action: Passed unanimously.

B. Andrew Podley

Andrew Podley appeared and was sworn by President Park prior to answering questions or offering testimony.

Dr. Podley stated that he is here to make disclosures on his application for Controlled Substance Registration.

Dr. Podley disclosed that he was arrested for a DUI in 2018. He was acquitted and charges were dropped. In 2012, Dr. Podley was charged with a misdemeanor- a small amount of cannabis and paraphernalia was in the car when he was pulled over. He stated that he has not been convicted of any felonies or misdemeanors since.

Dr. Podley answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve the Controlled Substance Registration application for Andrew Podley.

Second: Rolf Zakariassen

Action: Passed unanimously.

9. Applications for Pharmacist Registration by Examination – Appearance.

A. Tosin A. Adelakun

Tosin Adelakun appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background information, that in April 2014 he was a passenger in a vehicle that contained marijuana, but the case was later dismissed.

Mr. Adelakun stated that Ms. Long's summary is accurate and the incident occurred before he was considering pharmacy school. Mr. Adelakun stated that he has made significant changes in his personal life to avoid this type of situation in the future.

Mr. Adelakun answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the Application for Pharmacist Registration by Examination for Tosin Adelakun.

Second: Wayne Mitchell

Action: Passed unanimously.

B. Mark Harward

Mark Harward appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background that Mr. Harward in 2012 took money from the cash register. He pled guilty to the accusation. In 2013 he was forced to retire his Florida license and then later reapplied. There were restrictions on his license in Utah but those restrictions have since been lifted.

Mr. Harward stated that he has the opportunity to work at a pharmacy in Nevada and would like the opportunity to be licensed in Nevada.

Mr. Harward answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moves to approve the Application for Pharmacist Registration by Examination for Mr. Harward.

Second: Wayne Mitchell

Action: Passed unanimously.

C. Michael Shimoide

This matter has been continued.

10. Applications for Pharmacist Registration by Reciprocity – Appearance.

Gabriel Castaneda

Gabriel Castaneda appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background information that Mr. Castaneda in 2008 practiced outside his scope of licensure as a pharmaceutical technician in Texas which resulted in discipline.

Mr. Castaneda stated that Ms. Long's summary is accurate and there have been no issues since then.

Mr. Castaneda answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the application for Pharmacist Registration by Reciprocity for Mr. Castaneda.

Second: Wayne Mitchell

Action: Passed unanimously.

11. Application for Advanced Practice Registered Nurse Prescribe Registration – Appearance.

A. Patrick Smith, APRN

Patrick Smith appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Smith disclosed an arrest in 1997 for inhaling fumes, in 2002 he was charged with a misdemeanor for possession of marijuana which was later dismissed, and then in 2005 he was charged with reckless driving which was later dismissed. For the last 15 years he has abstained from alcohol or other substances, and has made changes to avoid encounters with the law in the future.

Mr. Smith answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the application for Advanced Practice Registered Nurse Prescribe Registration for Patrick Smith.

Second: Jade Jacobo

Action: Passed unanimously.

B. Natalie Wynn, APRN

Natalie Wynn appeared and was sworn by President Park prior to answering questions or offering testimony.

Bridget Kelly appeared as counsel representing Ms. Wynn.

Ms. Long provided background on the matter, that Ms. Wynn was arrested on suspicion of driving under the influence, possession of a dangerous drug without a prescription, which was later dropped. In July of 2019 she was charged with a misdemeanor driving under the influence and failing to maintain a travel lane. This case is currently pending.

Ms. Wynn stated that she is a recent graduate and working at a few different locations and provided insight into the events of the arrests and what is being done to rectify the past.

Ms. Wynn answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve the Controlled Substance Registration application for Ms. Wynn pending a positive PRN-PRN evaluation.

Second: Jade Jacobo

Action: Passed unanimously.

12. Application for Physician's Assistant Prescribe Registration – Appearance.

Tammy Hankins, PA

Tammy Hankins appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Hankins disclosed her past criminal history and interactions with law enforcement and other state licensing boards.

Mr. Kandt recommended that full documentation of the various criminal prosecutions and their dispositions, and all administrative charges and dispositions, be provided to the Board for review of application.

President Park offered Ms. Hankins the option to table the application to provide the Board with all legal and administrative documentation from her disclosures.

Ms. Hankins accepted the offer to table the application.

The Board tabled this matter at Ms. Hankins request.

13. Application for Pharmacist Registration Renewal – Appearance.

Mark Robertson

Mark Roberston appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background, that in November 2017 the Arizona Board of Pharmacy received a complaint about a pharmacy and Mr. Robertson was the pharmacist in charge at the time. After investigation the Arizona Board imposed discipline on Mr. Robertson's license.

Mr. Robertson provided insight into the Arizona discipline charges. The pharmacy was expecting to extend their lease which did not happen and they were forced to find a new location. Due to the rush in change of location, the pharmacy did not provide notice of change of address to the Arizona Board of Pharmacy in the required time.

Mr. Robertson answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the Pharmacist Registration Renewal for Mark Robertson.

Second: Wayne Mitchell

Action: Passed unanimously.

14. Applications for Pharmaceutical Technician Registration Renewal – Appearance.

Eyosias Bekele

Eyosias Bekele appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background information, that in 2018 Mr. Bekele received a DUI.

Mr. Bekele disclosed that he was pulled over for driving under the influence, and provided insight into the incident. Community service was completed as well as additional driving classes.

Mr. Bekele answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve the Pharmaceutical Technician Registration Renewal for Eyosias Bekele pending a positive evaluation from PRN-PRN.

Second: Jade Jacobo

Action: Passed unanimously.

15. Application for Advanced Practice Registered Nurse Dispensing Registration – Appearance.

John Phoenix, APRN

John Phoenix appeared and was sworn by President Park prior to answering questions or offering testimony.

Tracy Singh appeared as counsel representing Mr. Phoenix.

Mr. Kandt provided background on the matter. On March 5, 2020, Mr. Phoenix was served with a notice to cease and desist dispensing dangerous drugs, specifically clinical trial medications, for Nevada patients without a valid registration, and was issued a citation and \$5000 fine. He paid the fine and submitted a new application for a dispensing registration. Mr. Phoenix currently holds a limited temporary registration which expires September 3rd, 2020.

Ms. Singh stated that there is no criminal history, there is no substance abuse history, and Mr. Phoenix has been involved in medication research and trials for many years. Mr. Phoenix has tried to stay in compliance with Nevada law and licensure. As his trial medications are related to HIV, the license to dispense is necessary for the clinical trials and clinical studies.

Mr. Phoenix answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve the APRN Dispensing Registration application for John Phoenix.

Second: Krystal Freitas

Action: Passed unanimously.

16. Application for Intern Registration – Appearance.

Dustin Godoy

President Park recused herself from this matter due to her employer's relationship with the respondent.

Dustin Godoy appeared and was sworn by Acting President Wayne Mitchell prior to answering questions or offering testimony.

Mr. Godoy disclosed a DUI that happened in April of 2020. This is the first incident with the law and Mr. Godoy stated that he no longer drinks and will not drink in the future.

Mr. Godoy answered questions to the Board's satisfaction.

Board Action:

Motion: Richard Tomasso moved to approve the Pharmacy Intern Application for Dustin Godoy with no restrictions.

Second: Gener Tejero

Action: Passed unanimously.

17. Applications for Out-of-State Compounding Pharmacy License – Appearance

A. APS Pharmacy – Palm Harbor, FL

Dave Hill, Chief Executive Officer, and George Chrysakis, managing pharmacist, appeared and were sworn by President Park prior to answering questions or offering testimony.

Joe Dodge, Inspector, questioned APS Pharmacy, about but not limited to, products to be shipped into Nevada, specifically sterile compounded medications.

Mr. Dodge questioned Mr. Chrysakis regarding the policies of APS Pharmacy for testing of compounded medications, reporting, consultations, filters, and failed tests. Mr. Chrysakis answered to the best of his ability and suggested that some of these questions be directed to the Quality Assurance department.

Mr. Dodge stated to the Board that some questions have not been answered to his satisfaction.

President Park offered to table this application to a date that the QA Pharmacist is able to attend and present before the Board. The offer was accepted.

The Board tabled this matter at Mr. Hill's request.

B. Sisu Healthcare Solutions, Inc. – Tempe, AZ

Mike Smith, managing pharmacist, appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Smith stated that he emailed a letter of authorization to the Board to appear and speak on behalf of Sisu Health Care Solutions.

Mr. Smith provided the Board with his employment and pharmacy history.

Mr. Dodge questioned Mr. Smith about products to be shipped into the state of Nevada. Mr. Smith stated that IV medications will be the most common sterile compounded medications shipped into Nevada. Mr. Smith provided insight into procedures about safe shipping of sterile compounded medications.

Mr. Dodge questioned Mr. Smith about the operations and intensions of Sisu Health Care Solutions.

Mr. Smith answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the Out-of-State Compounding Pharmacy License application for Sisu Health Care Solutions.

Second: Richard Tomasso

Action: Passed unanimously.

18. Applications for Out-of-State Pharmacy License – Appearance

A. Carepharm Pharmacy, LTC – Houston, TX

Nancy Harris, managing pharmacist, appeared and was sworn by President Park prior to answering questions or offering testimony.

Christopher Miller, attorney, appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background that in 2019 the pharmacy was operating without a managing pharmacist, and that Carepharm Pharmacy was later placed on probation for 2 years, required to pay a fee, and required to follow all State and Federal Laws.

In August of 2020 there was a request to repeal the discipline. The repeal was granted and Carepharm Pharmacy was granted an early release on probation.

Mr. Miller disclosed the reason behind not having a managing pharmacist and what has been done to fix the issue.

Mr. Miller answered questions regarding the services that will be provided to patients in Nevada.

Ms. Harris and Mr. Miller answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the Out-of-State Pharmacy License application for Carepharm Pharmacy, LTC.

Second: Richard Tomasso

Action: Passed unanimously.

B. Script2U LLC – Memphis, TN

C. ScriptHero Pharmacy LLC – Columbus, OH

Roger Morris, attorney representing McKesson, Nick Meza, attorney representing McKesson, Kyle Dresbach, managing pharmacist, and Therese Twomey, managing pharmacist appeared.

Mr. Wuest provided background for these two Agenda Items, that they are part of a large pharmacy company. Because of this there is discipline that needs to be disclosed.

Mr. Morris disclosed the DEA Settlement from 2017 that occurred due to failure to report suspicious ordering. Mr. Morris talked about how future situations will be rectified, such as not filling suspicious orders and working more closely with the DEA when suspicions do arise.

Mr. Morris answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Pharmacy License applications for Script2U LLC and ScriptHero Pharmacy LLC.

Second: Wayne Mitchell

Action: Passed unanimously.

19. Application for Out-of-State Medical, Devices, Equipment and Gases License – Appearance.

Medical Action Industries, Inc. – Arden, NC

President Park swore in Sarah Golas in conjunction with Agenda Item 22E, prior to answering questions or offering testimony.

Mr. Wuest clarified to the Board that the application is not the correct application for this entity.

This item has been continued upon receipt of the correct application.

20. Application for Nevada Medical, Devices, Equipment and Gases License – Appearance

Nevada Prime Healthcare LLC – Reno, NV

Jared Koler, owner, appeared and was sworn by President Park, prior to answering questions and offering testimony.

Ms. Long provided background information, that Mr. Koler has personal history disclosures that need to be made and the application amended to reflect these disclosures.

Mr. Koler stated that he is happy to amend the application to reflect the arrest in 2000 for possession of marijuana in Utah.

Mr. Koler answered questions regarding services to be provided by Nevada Prime Healthcare, as well as products provided, and his personal work history.

Mr. Koler answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the application for Nevada Medical, Devices, Equipment and Gases License for Nevada Prime Healthcare LLC.

Second: Wayne Mitchell

Action: Passed unanimously.

21. Application for Nevada Wholesaler License – Appearance

MD Logistics, LLC – Reno, NV

Robert Grange, Director of Quality and Regulatory Affairs, and Roland Rock, Vice President of the Midwest Region, appeared and were sworn by President Park prior to answering questions or offering testimony.

Ms. Long provided background that MD Logistics, LLC is here for approval of an application for ownership and name change. MD Logistics is VAWD certified.

Mr. Grange stated that a smaller company is being bought out by Nippon Express to better meet the demands of the public.

Mr. Rock stated to the Board that MD Logistics will continue as a wholesale business.

Mr. Grange and Mr. Rock answered questions to the Board's satisfaction. A letter of authorization from Dirk Clark will be provided to the Board of Pharmacy prior to MD Logistics being licensed.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Wholesaler License application for Ownership and Name change, for MD Logistics, LLC.

Second: Jade Jacobo

Action: Passed unanimously.

22. Applications for Out-of-State Wholesaler License – Appearance

Background Check Not Required by Law.

22.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))
None

22.2 Manufacturer (NAC 639.593(7)(d))

A. Aurolife Pharma LLC – Dayton, NJ

Jennifer Schneider, State Licensing Service, appeared and was sworn by President Park prior to answering questions or offering testimony.

A letter of Limited Power of Attorney was sent to Courtney Lee, allowing Ms. Schneider to represent and answer for Aurolife Pharma LLC.

Ms. Schneider disclosed discipline for the owner AuroBindo.

Ms. Schneider answered questions regarding products and controlled substances to be provided to patients in Nevada.

Ms. Schneider answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Wholesaler License for Aurolife Pharma LLC.

Second: Krystal Freitas

Action: Passed unanimously.

B. Clinical Solutions Wholesale, LLC – Franklin, TN

Jami Scannell, Regulatory Specialist, and Christi Throneberry, CEO, appeared and were sworn by President Park prior to answering questions or offering testimony.

Mr. Wuest stated to the Board that Clinical Solutions Wholesale LLC is here to disclose discipline on their application.

Ms. Throneberry stated that in 2014 they had a late renewal on their license which they self-reported. During the time their license was expired, they did ship some medications.

Ms. Throneberry answered questions to the Board's satisfaction.

Board Action:

Motion: Gener Tejero moved to approve the Out-of-State Wholesaler License application for Clinical Solutions Wholesale, LLC.

Second: Jade Jacobo

Action: Passed unanimously.

C. Exelan Pharmaceuticals, Inc. – Boca Raton, FL

Jennifer Schneider, State Licensing Services, and Terri Arndt, Facility Manager, appeared and were sworn by President Park prior to answering questions or offering testimony.

Mr. Wuest stated to the Board that Exelan Pharmaceuticals, Inc. is appearing to disclose disciplinary action on their application.

Ms. Schneider disclosed that Exelan Pharmaceuticals, Inc, received administrative action on their license for improper record keeping in Florida, as well as late notification of change of address. There was also an administrative fine of \$500 for the New Hampshire Board of Pharmacy due to untimely notice of location change.

Ms. Schneider stated that she does have a letter for Limited Power of Attorney to speak on behalf of Exelan Pharmaceuticals which will be sent to Courtney Lee.

Ms. Schneider answered questions to the Board's satisfaction.

Jade Jacobo was excused from the meeting September 3rd, 2020 at 1:30pm.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Wholesaler License application for Exelan Pharmaceuticals, Inc.

Second: Krystal Freitas

Action: Passed unanimously.

D. Mizner BioScience, LLC – Boca Raton, FL

Joseph Anzalone, Chief Operating Officer, and Laura Koman, legal counsel, appeared and were sworn by President Park prior to answering questions or offering testimony.

Mr. Wuest noted to the Board that Mizner BioScience has disclosures to make on their application.

Mr. Anzalone provided the Board with a history of the company and made the appropriate disclosures regarding discipline on licensure in other states. Mr. Anzalone discussed changes made to resolve the issues regarding the past discipline.

Mr. Anzalone answered questions to the Board's satisfaction.

Board Action:

Motion: Gener Tejero moved to approve the Out-of-State Wholesaler License application for Mizner BioScience, LLC.

Second: Wayne Mitchell

Action: Passed unanimously.

22.3 Publicly Traded (NAC 639.593(7)(a))
None

22.4 VAWD-Accredited (NAC 639.593(7)(c))

E. Owens & Minor Distribution, Inc. – Hebron, KY

Sarah Golas, Manager of Licensing, appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Golas stated that there is discipline action dating from 2002 to present. Discipline is related to tardiness on reporting change of Designated Representative in a timely matter. To address the issue Ms. Golas stated that a biannual training for designated representatives has been instituted, as well as policy regarding the reading and signing off Prescription Monitoring Program reports.

Ms. Golas answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Wholesaler License application for Owens & Minor Distribution Inc.

Second: Wayne Mitchell

Action: Passed unanimously.

22.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))
None

22.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))
None

22.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

F. Covetrus North America – Aurora, CO

Hilary Wilson, from the Regulatory and Quality Affairs Department, appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Wilson disclosed the administrative action taken on Covetrus North America and discussed the changes made to rectify the situation.

Ms. Wilson answered questions to the Board's satisfaction.

Board Action:

Motion: Richard Tomasso moved to approve the Agenda Items 22F and 22G.

Second: Gener Tejero

Action: Passed unanimously.

G. Covetrus North America – Southaven, MS

This item was heard with Agenda Item 22F.

22.8 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**

H. Aleracare Wholesale, LLC – Phoenix, AZ

Paul Vasiliauskas, CEO of Aleracare Wholesale, LLC, appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Vasiliauskas disclosed an arrest from 1999 for a DUI charge that has since been closed.

Mr. Wuest stated that this disclosure was consistent with the results of the background check.

Board Action:

Motion: Krystal Freitas moved to approve the application for Aleracare Wholesale, LLC.

Second: Richard Tomasso

Action: Passed unanimously.

I. Janus Trade Group LLC – Eatontown, NJ

Stewart Husney, Eli Abisror, and Michael Antar, co-owners, appeared and were sworn by President Park prior to answering questions or offering testimony.

Mr. Wuest provided background, that Janus Trade Group LLC has some pending litigations and past discipline that needs to be disclosed to the Board.

Mr. Husney disclosed to the Board that one of the litigations involves some money that was lent out and not returned. In 2016 there was a purchase from a company that was not licensed in the State. Discipline occurred.

Mr. Antar and Mr. Abisror answered questions about products sold by Janus Trade Group to the Board's satisfaction.

Board Action:

Motion: Gener Tejero moved to approve the Out-of-State Wholesaler License application for Janus Trade Group LLC.

Second: Krystal Freitas

Action: Passed unanimously.

23. Application for Out-of-State Outsourcing Facility – Appearance

Farmakeio Outsourcing – Southlake, TX

Justin Graves, Quality Director, appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Dodge questioned Mr. Graves regarding products and services provided by Farmakeio and the FDA Inspection that was completed in October of 2019.

Mr. Graves answered questions to the Board's satisfaction.

Board Action:

Motion: Gener Tejero moved to approve the Out-of-State Outsourcing Facility License application for Farmakeio Outsourcing Facility. They are to send the Board correspondence between the facility and DEA.

Second: Wayne Mitchell

Action: Passed unanimously.

24. Application for Nevada Pharmacy License – Appearance

Off-Site Rampart Pharmacy – Winnemucca, NV

Tiffany Love, Chief Operating Officer, and David Simsek, Director of Pharmacy, appeared and were sworn by President Park prior to answering questions or offering testimony.

Mr. Simsek stated that this license would be for emergency purposes only, to allow the hospital and hospital pharmacy to be extended if need be.

Ms. Love and Mr. Simsek answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Pharmacy License application for Off-Site Rampart Pharmacy.

Second: Richard Tomasso

Action: Passed unanimously.

25. Rehearing of Order in Case No. 20-008-PT-S on Application of Jevons Wang pursuant to NRS 639.252

This item has been continued.

26. Discussion and possible action on Bill Draft Request for 2021 Nevada Legislative Session to amend NRS Chapter 639 regarding the licensing and regulation of the practice of pharmacy, including increasing fees for initial licensure and biennial renewal of a wholesaler license, and requiring criminal background checks for initial registration as a pharmacist or pharmaceutical technician.

Mr. Kandt provided overview of the bill draft request, explaining that the Legislature's Sunset Subcommittee recommended that the Board analyze its fee structure and revise fees to the extent necessary to support its operations. Based upon this recommendation the BDR amends NRS 639.170 to increase the maximum statutory fee for the licensure of wholesalers from \$500 to \$1000. Kandt explained that the Governor's Division of Internal Audits in Audit No. 20-05 recommended that criminal background checks be required for pharmacists, pharmaceutical technicians and pharmaceutical technicians in training. This would require statutory authorization and the BDR provides this. The BDR also makes various conforming changes and clarifies existing statutory provisions.

Board Action:

Motion: Richard Tomasso moved to approve the language of the bill draft request.

Second: Krystal Freitas

Action: Passed unanimously.

Rolf Zakariassen and Wayne Mitchell were excused from the meeting, September 3, 2020 at 3:30pm.

27. Discussion and Possible Action on Advisory Opinion pursuant to NAC 639.150 in response to petition submitted by the Nevada Association of Nurse Anesthetists on authority of CRNAs to possess and administer anesthetic agents to patients.

Mr. Kandt reminded the Board that earlier this year the Nevada Association of Nurse Anesthetists submitted a petition for an advisory opinion pursuant to NAC 639.150 on the authority of CRNAs to possess and administer anesthetic agents to patients. The Board at the January meeting directed that he draft a proposed advisory opinion.

Mr. Kandt presented a proposed advisory opinion, that concluded that CRNAs may only possess and administer anesthetic agents to patients “at the direction” of a practitioner or “pursuant to a chart order” and the Board lacks the statutory authority to license CRNAs to select and order anesthetic agents from a licensed institutional pharmacy in order to possess and administer these agents to patients of the medical facility in any manner that conflicts with NRS 453.375(1)(b) and NRS 454.213(1)(c).

Chelsea Adams, from the Nevada Association of Nurse Anesthetists, commented that they are still petitioning for legislative clarification on particular aspects of the law in question.

Board Action:

Motion: Krystal Freitas moved to approve the advisory opinion as offered by legal counsel.

Second: Gener Tejero

Action: Passed unanimously.

28. Discussion and possible action on medical interns and residents’ controlled substance registration fee

Mr. Wuest provided the Board with background that in October of 2019 there was a fee increase for the Controlled Substances Registration for practitioners. The medical schools were unaware of the fee changes and did not budget for this increase for the medical interns and medical residents. Board staff maintained the \$80 fee.

Megan Courtney, UNLV Medical School, stated that Mr. Wuest’s summary is correct and accurate. Ms. Courtney provided the Board with the financial implications to the State if interns and residents were to be required to pay the increased fee of \$200 for a Controlled Substance Registration.

Angela Shaw, representing UNR Medical School, agrees with Ms. Courtney's statement about the implications of a fee increase to the state of Nevada as well as future doctors coming into the state.

Ms. Courtney answered questions to the Board's satisfaction.

Board Action:

Motion: Richard Tomasso moved to keep the Intern and Resident fees for Controlled Substance Registration at \$80 and not increase them to \$200.

Second: Krystal Freitas

Action: Passed unanimously.

29. Annual review to consider and suggest amendments to and deletions from the provisions of NAC 639.501-.5019

Leo Basch, Board Investigator, provided background on the regulations regarding the annual review of NAC 639.501-.5019. He recommended discontinuing the Workplace Assessment Form.

Mr. Wuest agreed with Mr. Basch.

30. Discussion and possible action on approval of Immunize Nevada - Nevada Immunization Learning Exchange - CE Programs

Breanne Van Dyne, Education Manager, appeared and presented potential CE opportunities for pharmaceutical technicians. Immunize Nevada is the only immunizing organization to provide specific immunizing CE's.

Ms. Van Dyne is seeking approval of the CE's in order to secure trainers to provide the in-person training and hands on experience in immunization for the state of Nevada.

Ms. VanDyne answered questions to the Board's satisfaction.

Board Action:

Motion: Richard Tomasso moved to approve the CE program for three years.

Second: Rolf Zakarriassen

Action: Passed unanimously.

31. Approval of Revised Wholesaler Application

This matter has been continued.

32. Petition for Exemption from the requirement of a lavatory with toilet and washbasin within or adjoining the pharmacy. NAC 639.530(4).

Rx2U, LLC. – Las Vegas, NV

Krystal Freitas disclosed that the owner is a former classmate, but she is able to participate fairly and without bias.

Mr. Wuest provided background information that the Board had previously approved a license but upon inspection, the location did not meet the law requirements. The law does present the option to waive the particular issue on the Petition for Exemption of a lavatory with toilet and washbasin within or adjoining the pharmacy.

Maryam Rastkerdar, Pharmacist, appeared to answer questions regarding the petition.

Board discussed the regulation and conferred with Board counsel on the extent of the Board's authority to grant a waiver under NAC 639.530(4).

The Board determined that the variance request cannot be considered as Rx2U, LLC is not a remodeled pharmacy eligible to make the request.

33. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

34. Executive Secretary Report:

- A. Financial Report

Mr. Wuest presented the Financial Report to the Board's satisfaction.

- B. Issuance of Temporary Licenses and Registrations

There were four temporary licenses and registrations issued since the last meeting.

- C. Meetings with Other Health Care Regulatory Boards
- D. COVID-19 Response
 - Emergency Regulation Update

Mr. Wuest reported to the Board that Board Staff has supported the State efforts with Remdesavir. Board staff meets weekly with FEMA and HHS and Amerisource to help allocate the medication to the facilities that are most in need. These efforts will continue through September 2020.

- E. Presentation to GME UNLV
- F. Licensing Software Update

Mr. Wuest presented to the Board updates to the Licensing Software.

G. Licensing Activities Report

Mr. Wuest stated to the Board that license renewals have begun.

H. PMP Integration

President Park thanked the Board staff for their efforts in assisting the state, as well as their efforts in moving the regulation along to allow pharmaceutical technicians the authority to immunize under the supervision of the pharmacist.

◆ PUBLIC HEARING ◆

Thursday September 3, 2020 – 9:00 am

35. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2)

- A. **Amendment of Nevada Administrative Code (NAC) 453.520 Schedule II.** The proposed amendment adds such drug products to the list of controlled substances in schedule II in conformity with the federal regulations of the Uniform Controlled Substances Act. (LCB File No. R084-20)

Mr. Wuest stated that the proposed amendments were requested by the State's crime labs based upon new derivatives of drugs and compounds. Mr. Wuest reminded the Board that this language has already been through workshop.

President Park opened the Public Comment.

There was no Public Comment.

Board Action:

Motion: Jade Jacobo moved to adopt LCB File No. R084-20.

Second: Wayne Mitchell

Action: Passed unanimously.

- B. **Amendment of Nevada Administrative Code (NAC) 639: Pharmaceutical Technician Ability to Administer Immunizations.** The proposed amendment will authorize a pharmaceutical technician with appropriate training to administer immunizations under the direct supervision of a pharmacist. (LCB File No. R142-20)

Ms. Long stated that LCB reverted the routes of administration back to the original draft

language.

President Park opened the floor for Public Comment.

Ms. Long stated that there were some written comments that are available on the Board Website.

Lauren Paul, CVS Health, stated that she is in support of the proposed language.

Mary Staples, National Association of Chain Drug Stores, stated that she is also in favor of the language and to not delay this amendment.

Jessica Langley, Coalition for the Advancement of Pharmacy Technician Practitioners, stated that she is in favor of this amendment and the benefit it will be to the public.

Liz MacMenamin, RAN, stated that she is in favor of the amendment and is in support of allowing technicians to administer immunizations.

Ademola Are, National Community Pharmacist Association, stated that he is in support of the language and thanked the Board for their effort in this amendment.

President Park closed Public Comment.

Mr. Tomasso read into the record a public comment that was against allowing pharmaceutical technicians the authority to administer immunizations.

The Board discussed current policies on direct supervision, and future plans on pharmaceutical technician training as well as continued direct supervision.

Board Action:

Motion: Krystal Freitas moved to adopt LCB File No. R142-20

Second: Richard Tomasso

Action: Passed unanimously.

◆ WORKSHOP ◆

Thursday September 3, 2020 – 9:00 am

36. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2)

Amendment of Nevada Administrative Code (NAC) 639.742, 639.743, 639.744. and 639.745: Dispensing Practitioners. The proposed amendments will modify the supervision of dispensing technician by dispensing practitioners. These amendments

will authorize dispensing practitioners in group practices to share inventory of certain medications and centralize activities. The proposed amendments will increase the fees for the application for an initial registration, and the biennial renewal of a registration, as a registered dispensing technician.

Mr. Wuest presented background on the requested regulation.

President Park opened the floor to Public Comment.

Rupesh Parikh, Comprehensive Cancer Centers, read a prepared statement into the record regarding the ability of group practices to streamline patient care by having one central location of drugs to be dispensed, available to all dispensing doctors listed on the application for the site.

Liz MacMenamin, RAN, commented to the Board that she was present in 2003 when this law was first enacted and the reasoning behind it. By allowing more freedom in dispensing by doctors, they are in essence practicing pharmacy which is out of their scope.

Rachel Dobbs, Vice President of Operations with Activate Healthcare, stated that she is in support of the proposed changes and the potential benefit of efficiency in patient care.

Brad Raghasin, Pharmacist, stated that medications will only be dispensed by licensed practitioners.

The Board discussed the potential benefits of change in patient care and public wellbeing.

The Board directed staff to notice a public workshop.

37. Request for Approval of Change of Managing pharmacist pursuant to NRS 639.220
ACRx Specialty Pharmacy

This matter has been continued.

38. Adoption of Emergency Regulation pursuant to NRS233B.0613

Amendment of Nevada Administrative Code (NAC) 639: Pharmaceutical technician Ability to Administer Immunizations. The proposed emergency amendment in response to COVID-19 will authorize a pharmaceutical technician with appropriate training to administer immunizations under the direct supervision of a pharmacist. (LCB File No. R142-20)

President Park opened the floor to Public Comment.

Dave Wuest provided insight into the emergency regulation.

Liz MacMenamin, RAN, thanked the Board for moving this emergency regulation through quickly to prepare the State for the upcoming flu season and potential COVID-19 vaccine expected to arrive soon.

Mary Staples, National Association for Chain Drug Stores, thanked the Board for their cooperation in pushing the emergency regulation through as quickly as they have.

The Board discussed when this regulation would go into effect and if this regulation will still be in effect during the peak of the flu season.

President Park closed the floor to Public Comment.

Board Action

Motion: Jade Jacobo moved to adopt this emergency regulation.

Second: Rolf Zakariassen.

Action: Passed unanimously.

39. Date and Location of Next Scheduled Board Meeting:

October 14-15, 2020 – Las Vegas, NV

40. Public Comment 4:15 PM

There was no Public Comment.

41. Date and location of Next Scheduled Board Meeting

October 14-15, 2020- Las Vegas, NV

42. Adjournment

4

4A



RECEIVED
8-11-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership - Pages 1,2,6,8

☒ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: 1st America Infusion Services, LLC dba Advanced InfusionCare

Physical Address: 18451 Dallas Parkway, Ste. 130, Dallas, TX 75287

Mailing Address: 625 Highland Colony Parkway, Ste. 105

City: Ridgeland State: MS Zip Code: 39157

Telephone: 1-833-885-5812 Fax: 1-833-885-5813

Toll Free Number: 1-833-885-5812 (Required per NAC 639.708)

E-mail: licensingDALINF@aiscaregroup.com Website: www.aiscaregroup.com

Managing Pharmacist: Marinda Howard License Number: 35480

TYPE OF PHARMACY **AND**

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☒ ☐ Other: Home Infusion

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☒ ☐ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Ford
Print Name of Authorized Person

8-3-2020
Date

Page 2

Board Use Only	Date Processed: _____	Amount: <u>500.00</u>
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APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Georgia

Parent Company if any: Advanced Infusion Solutions Acquisition, LLC

Mailing Address: 623 Highland Colony Parkway, Ste. 100

City: Ridgeland State: MS Zip: 39157

Telephone: 1-877-443-4006 Fax: 1-877-415-4050

Contact Person: Sarah Tew

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a)

N/A	
Name	Address

b)

N/A
Name
Address

c) N/A

Name	Address
------	---------

[illegible]

- 2) Provide the number of shares issued by the corporation. N/A

- | | | |
|----|------------------------------------|-----|
| 3) | What was the price paid per share? | N/A |
|----|------------------------------------|-----|

- 4) What date did the corporation actually receive the cash assets? N/A

- 5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: 0

Name: N/A %: 0

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 5:00 pm

Saturday See* am See* pm

Sunday See* am See* pm

24 Hours See*

*Pharmacist is available 24/7/365

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

**STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA**

I, Michael Ford

Responsible Person of 1st America Infusion Services, LLC dba Advanced InfusionCare

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Ford

Print Name of Authorized Person

8-3-2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Mississippi)
Madison COUNTY) ss.

I, Michael Ford, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Operating Officer for 1st America Infusion Services, dba Advanced InfusionCare (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of- State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Michael Ford, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
 before me, a notary public this
3rd day of August, 2020

Amy P. Vernon
 NOTARY PUBLIC

[Signature]

Name



Control Number : 0572372

STATE OF GEORGIA**Secretary of State****Corporations Division****313 West Tower****2 Martin Luther King, Jr. Dr.****Atlanta, Georgia 30334-1530****CERTIFICATE OF EXISTENCE**

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

1ST AMERICA INFUSION SERVICES, LLC**a Domestic Limited Liability Company**

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number : 17209512
Date Inc/Auth/Filed: 11/01/2005
Jurisdiction : Georgia
Print Date : 05/23/2019
Form Number : 211

*Brad Raffensperger*

Brad Raffensperger
Secretary of State

1st America Infusion Services, LLC dba Advanced InfusionCare ("AIC") is owned and managed by Advanced Infusion Solutions Acquisition, LLC ("Acquisition"). Neither AIC or Acquisition have any officers; however, we are providing a list of managing employees.

Direct Ownership

Advanced Infusion Solutions
Acquisition, LLC
FEIN 80-0910085
Address: 625 Highland Colony Parkway, Ste 100
Ridgeland MS 39157

100%

1st America Infusion Services, LLC dba
Advanced InfusionCare
FEIN 20-3733871
Address: 18451 Dallas Pkwy
Ste. 130
Dallas, TX 75287

1st America Infusion Services, LLC

Manager: Advanced Infusion Solutions Acquisition, LLC

<u>AIC Managing Employees</u>	
CEO:	Simon Castellanos
Home Address:	N. Houston Street, A Dallas, TX
COO:	Michael E. Ford
Home Address:	Canton Road Canton
Divisional V.P.:	Juderal E. Hall, Jr.
Home Address:	Griffin Drive Carrollton, G/
Pharmacist-in-Charge:	Marinda Howard
Home Address:	Hunter Street Lantana, TX

6/2/2020

Texas Pharmacy License # 32946



Texas Pharmacy License # 32946

ADVANCED INFUSIONCARE

License Information

License Status Active
 License # 32946
 Expiration Date 10/31/2021
 Date License Issued 10/21/2019

Address

18451 DALLAS PARKWAY STE 130
 DALLAS, TX 75287
 County DENTON
 Phone (833) 885-5812

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
 Type of Ownership LLC
 Type of Pharmacy Community Independent
 # of Hospital beds

Employment Information

Pharmacist in Charge
 HOWARD, MARINDA RAE

Pharmacy Profile *

Accessible to disabled persons? Yes

Participates in the Texas Medicaid program? No

Translating services (Listed Below If Available)

Spanish
 American Sign Language
 Other

* Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

No Nuclear
 No Out-Patient Prescriptions
 No Ship Prescription Out of State
 No Class D (Expanded Formulary)
 No Class D (Alternative Visit Schedule)
 No Compounding Sterile-Risk Level Low
 No Compounding Sterile-Risk Level Med
 No Compounding Sterile-Risk Level High
 No Compounding Non-Sterile
 No 24 Hour Service
 Yes Closed Door
 No Compounding, Office Use
 No Home Delivery
 Yes Infusion
 No Pharmacist Administered Immunizations
 No Veterinary Prescriptions

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
HOWARD, MARINDA RAE	35480	07/27/1995	02/28/2021	PIC	Active



TEXAS STATE BOARD OF PHARMACY

Texas Pharmacist License # 35480

License Information

HOWARD, MARINDA RAE

License Status Active

License # 35480

Expiration Date 02/28/2021

Date License Issued 07/27/1995

Names

Last Name HOWARD

First Name MARINDA

Middle Name RAE

Other Name

Certificate Name HOWARD, MARINDA RAE

Pharmacist Details

School Graduated PURDUE UNIVERSITY

Graduation Year 1995

Degree at time of licensure BS

License Method Exam

Preceptor No

Prior Disciplinary Order(s)* No

More Pharmacist Details

Specialty Board Certification ✖ Unknown

✖ Data regarding Specialty Board Certification is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder for clarification.

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Remedial Plans

Remedial plans (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Texas Pharmacist Employment Information		
Pharmacy Name	Pharmacy License #	Employment Status
ADVANCED INFUSIONCARE	32946	PIC
Page 1 of 0		View 1 - 1 of 1

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

4B

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ **New Pharmacy** or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,8 ☒ Partnership – Pages 1,2,6,8
☐ Non Publicly Traded Corporation – Pages 1,2,4,8 ☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: West 35th Apothecary LLC dba ApothecoRX

Physical Address: 147 W. 35th St., Suite 2

Mailing Address: 147 W. 35th St., Suite 2

City: New York State: NY Zip Code: 10001

Telephone: 212-706-4096 Fax: 212-706-4097

Toll Free Number: 866-588-7756 (Required per NAC 639.708)

E-mail: W35apothecary@gmail.com Website: _____

Managing Pharmacist: Mercedes Chen License Number: 063448-1

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked
 For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Anush Amin

Print Name of Authorized Person

Date

8/20/20

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

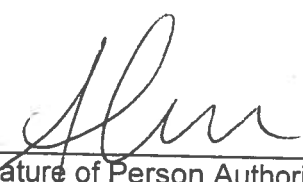
I, Anush Amin

Responsible Person of West 35th Apothecary LLC dba ApothecoRX

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Anush Amin

Print Name of Authorized Person

Date

8/20/20

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP

General _____ Limited ☒

Partnership Name: West 35th Apothecary LLC

Mailing Address: 147 W. 35th St., Suite 2

City: New York State: NY Zip Code: 10001

Telephone Number: 212-706-4096 Fax Number: 212-706-4097

Contact Person: Mercedes Chen

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
List of LLC officers attached		

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: %:

Name: %:

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday Closed am Closed pm
Sunday Closed am Closed pm 24 Hours

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF New Jersey)
Essex COUNTY) ss.

I, Amish Amin, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OFFICER & PRESIDENT for Princeton Medical Pharmacy (the LLC Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Amish Amin, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name Amish Amin

SUBSCRIBED AND SWORN TO
 before me, a notary public this
20 day of August, 20 20
Danielle L. Rocco
 NOTARY PUBLIC

DANIELLE L. ROCCO
 NOTARY PUBLIC OF NEW JERSEY
 Commission # 50118055
 My Commission Expires 12/4/2024

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

SUPERVISING PHARMACIST
JEFFIN A. KURIAN



2018-21

THIS IS TO CERTIFY

WEST 35TH APOTHECARY LLC
147 W. 35TH ST.
SUITE 2
NEW YORK, NY 10001

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-SEVENTH DAY OF AUGUST, 2018.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JULY, 2021.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

036668



Kimberly A. Leonard
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

Officers of West 35th Apothecary LLC**1) Joel Saban – CEO**

Address: Avalon Drive
Buffalo Grove, IL 60089-4685

2) Anush Amin - President

Address: Groff Court
Flemington, NJ 08822-6939

3) James C. Luthin- CFO

Address Schiller Ave.
Wilmette, IL 60091-2329

4) Nikki Baniewicz – Secretary and Treasurer

Address Madison St., #
Hoboken, NJ 07030-6364

ApothecoRX
147 W. 35th St.
Suite 2
New York, NY 10001

The State of New York does not issue license verifications. Per their website (<http://www.op.nysed.gov/opsearches.htm#rx>) and direct communication with the office-

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

Please accept and find enclosed the pharmacy license verification from their official database.



Office of the Professions



Verification Searches

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

Pharmacy Establishment Information *

08/27/2020

Type : PHARMACY**Legal Name :** WEST 35TH APOTHECARY LLC**Trade Name :** APOTHECORX**Street Address :**

147 W. 35TH ST.

SUITE 2

NEW YORK, NY 10001-0000

Registration No : 036668**Date First Registered :** 08/27/18**Registration Begins :** 08/27/18**Registered through :** 07/31/21**Supervisor :** 063448 CHEN MERCEDES**Establishment Status :** ACTIVE**Successor :** NONE

* Use of this online verification service signifies that you have read and agree to the [terms and conditions of use](#). See [HELP glossary](#) for further explanations of terms used on this page.

- Use your browser's back key to return to establishment list.
- You may [search](#) to see if there has been recent disciplinary action against this registered establishment.



State of New York
Department of State } ss:

I hereby certify, that WEST 35TH APOTHECARY LLC a NEW YORK Limited Liability Company filed Articles of Organization pursuant to the Limited Liability Company Law on 03/13/2018, and that the Limited Liability Company is existing so far as shown by the records of the Department.

The Biennial Statement is past due.



*WITNESS my hand and the official seal
of the Department of State at the City of
Albany, this 19th day of August two
thousand and twenty.*

Brendan C. Hughes

*Brendan C Hughes
Executive Deputy Secretary of State*

4C

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,8 ☐ Partnership - Pages 1,2,6,8
☐ Non Publicly Traded Corporation – Pages 1,2,4,8 ☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Affiliated Health Services, Inc. dba Ascension Michigan Pharmacy

Physical Address: 30055 Northwestern Highway Suite 225 Farmington Hills MI 48334

Mailing Address: 30055 Northwestern Highway Suite 225 Farmington Hills MI 48334

City: _____ State: _____ Zip Code: _____

Telephone: 248-865-3770 Fax: 248-865-3771

Toll Free Number: 855-292-1427 (Required per NAC 639.708)

E-mail: CGIANATIEMPO@LICENSELOGIX.COM Website: _____

Managing Pharmacist: Suzanne Noe License Number: 5302032652

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

DEBORAH SOPO
Original Signature of Person Authorized to Submit Application, no copies or stamps

DEBORAH SOPO
Print Name of Authorized Person

8/10/2020
Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: MICHIGAN

Parent Company if any: ASCENSION ST. JOHN HOSPITAL FEIN - 38-2244034

Mailing Address: 22101 MOROSS ROAD DETROIT, MI 48236 USA

City: _____ State: _____ Zip: _____

Telephone: 586-753-1954 Fax: _____

Contact Person: Brooke Johnson

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) _____
Name Address

b) See attached
Name Address

c) _____
Name Address

d) _____
Name Address

- 2) Provide the number of shares issued by the corporation. 200,000
- 3) What was the price paid per share? \$ 1.00
- 4) What date did the corporation actually receive the cash assets? See attached
- 5) Provide a copy of the corporation's stock register evidencing the above information See attached

List any physician shareholders and percentage of ownership.

Name: DIA %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday CLOSED am _____ pm

Sunday CLOSED am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, SUZANNE NOE

Responsible Person of Affiliated Health Services, Inc. DBA Ascension Michigan Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

SUZANNE NOE

Print Name of Authorized Person

8/10/2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Michigan)
Oakland) ss.
COUNTY)

I, SUZANNE NOE, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST for Affiliated Health Services, Inc. DBA Ascension Michigan Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, SUZANNE NOE, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Suzanne Noe SUZANNE NOE
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
12 day of August, 2020.
Barbara Lepri
NOTARY PUBLIC

BARBARA LEPRI
NOTARY PUBLIC, STATE OF MI
COUNTY OF MACOMB
MY COMMISSION EXPIRES Jun 21, 2023
ACTING IN COUNTY OF MACOMB, MI

Posted April 1, 2020

LIMITED POWER OF ATTORNEY FOR APPLICATION FOR PHARMACY LICENSES

Affiliated Health Services, Inc. d/b/a Ascension Michigan Pharmacy ("**Pharmacy**") operates pharmacies which are licensed in several states throughout the United States of America.

Pharmacy has made, constituted, and appointed, and hereby makes, constitutes and appoints Deborah Sopo ("**Agent**"), as the Pharmacy's agent and true and lawful attorney-in-fact for the limited purposes of applying for Pharmacy's pharmacy licenses effective May 5, 2020. Agent may act in this capacity until such time as Pharmacy revokes this Limited Power of Attorney for Application For Pharmacy Licenses (this "**Limited POA**").

Pharmacy recognizes that it remains legally responsible for the licenses and other registrations issued to it during the period in which this Limited POA is in effect. Agent shall follow, abide by, and comply with all federal and state laws governing the application for pharmacy licenses at all times while utilizing this Limited POA.

Additionally, Pharmacy acknowledges, authorizes, ratifies, and confirms any action undertaken and completed by Agent as of January 1, 2020, which if undertaken or completed during the term of this Limited POA would have been within the scope of the authority provided to Agent.

This Limited POA may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement, binding on all of the parties hereto.

IN WITNESS WHEREOF, Pharmacy and Agent have executed this Limited POA as of May 5, 2020 to be effective May 5, 2020.

PHARMACY:

Affiliated Health Services, Inc.

By: Joseph Hurshe
DocuSigned by: D8807C7257734D6

Name: Joseph Hurshe

Title: COO

Date: 5/5/2020

AGENT

Deborah Sopo

By: Deborah Sopo
DocuSigned by: 2C84461E5B054C3

Title: Deborah Sopo Pharmacy Manager

Date: 5/5/2020

NOTARY ACKNOWLEDGEMENT:

State of MICHIGAN

County of MACOMB

The foregoing instrument was acknowledged before me on this 5TH DAY OF MAY 2020 by JOSEPH HURSHE AND DEBORAH SOPO

Notary Public Signature: Kim Skarbo
DocuSigned by: 36CAB45BE098404
 Notary Printed Name: Kim Skarbo

Acting in the County of: MACOMB
My Commission Expires: JUNE 20, 2025

List of Current Corporate Members

Name of Member	Title	City of Residence
Brooke Johnson	Board Chair	Macomb Twonship
Brant Russell	Board Secretary	Rocky River
Selena Schmidt	Board Vice Chair	Shelby Township
Dr. Kevin Grady	Board Treasurer	Grosse Pointe Farms

Nevada Out of State Pharmacy Application

Attachment for Page 4 Items 1-5

1. List top 4 persons to the share were issued by the corporation (name and address)

This is a wholly owned subsidiary of St. John Providence which is headquartered at 28000 Dequindre, Warren, MI 48092 since 2001. However, the original filing was under Ascension St. John Hospital located at 22151 Moross Road, Detroit, MI 48236.

2. Provide the number of shares issued by the corporation: 200,000

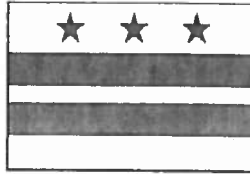
3. What was the price paid per share? \$1.00

4. What date did the corporation actually receive the cash assets? *The entity was formed on 1/11/1980 as a wholly owned entity with the health system and did not receive fixed cash assets as it rolled up within a health system.*

5. Provide a copy of the corporation's stock register evidencing the above information. *Because this entity was a wholly owned entity of a health system, there was no stock register beyond the filing of the articles of incorporation in the state of Michigan.*

Initial File #: C00006700285
Entity Type: For-Profit Corporation

GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF CONSUMER AND REGULATORY AFFAIRS
CORPORATIONS DIVISION



C E R T I F I C A T E

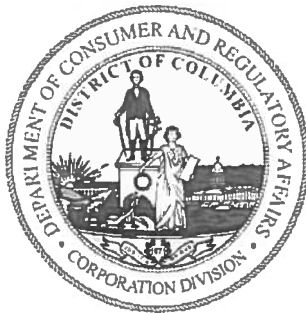
THIS IS TO CERTIFY that all applicable provisions of the District of Columbia Business Organizations Code (Title 29) have been complied with and accordingly, this ***CERTIFICATE OF GOOD STANDING*** is hereby issued to

Affiliated Health Services INC

WE FURTHER CERTIFY that the qualified foreign entity is registered to do business in the District on 07/29/2020 ; that all fees, and penalties owed to the District for entity filings collected through the Mayor have been paid and Payment is reflected in the records of the Mayor; The entity's most recent biennial report required by § 29-102.11 has been delivered for filing to the Mayor; and the entity's registration has not been terminated. This office does not have any information about the entity's business practices and financial standing and this certificate shall not be construed as the entity's endorsement.

IN TESTIMONY WHEREOF I have hereunto set my hand and caused the seal of this office to be affixed as of 8/3/2020 9:37 AM

Business and Professional Licensing Administration



Josef G. Gasimov

JOSEF G. GASIMOV
Superintendent of Corporations,
Corporations Division

Muriel Bowser
Mayor

Tracking #: B7btfQJr

Staff Pharmacists

Pharmacist	License Number	Controlled License	Expiration	Hours per Week
Deborah Sopo	5302022818	5315171372	6/29/2021	40
Suzanne Noe	5302032652	5315124272	6/28/2022	40
Stephanie Dunseith-Zimny	5302038377	531510395	6/30/2020	40
Bonnie Sysling- Salvador	5302027495	5315109604	07/29/2021	40
Deepa Pinkney	5302036976	5315101871	6/24/2011	16

GRETCHEN WHITNER
GOVERNOR

N942390

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
PHARMACY LICENSE

ASCENSION MICHIGAN PHARMACY
30055 NORTHWESTERN HWY STE 225
FARMINGTON HILLS, MI 48334

LICENSE NO.
5301007247

EXPIRATION DATE
9/26/2021

19165090645

THIS DOCUMENT IS DULY
ISSUED UNDER THE LAWS OF
THE STATE OF MICHIGAN

4D

NEVADA STATE BOARD OF PHARMACY
 431 W Plumb Lane – Reno, NV 89509
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ **Ownership Change** (Provide current license number if making changes: **PH 02131**)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership – Pages 1,2,5,7
☒ Non Publicly Traded Corporation – Pages 1,2,4,7 ☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Biologics by McKesson
 Physical Address: 13000 Weston Parkway, Suite 105
 Mailing Address: 11800 Weston Parkway
 City: Cary State: NC Zip Code: 27513
 Telephone: 919-546-9810 Fax: 919-831-0440
 Toll Free Number: 800-850-4306 (Required per NAC 639.708)
 E-mail: pharmacists@biologicsinc.com Website: www.biologicsinc.com
 Managing Pharmacist: Sheila A. Bizune License Number: 18281

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☐ Community
☒ ☐ Other: Specialty/Oncology

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services:

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

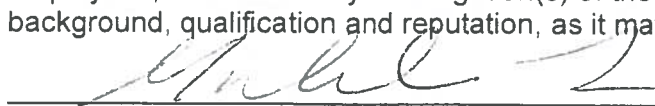
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau

Print Name of Authorized Person

Date

3/12/2020

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: North CarolinaParent Company if any: Physician Reliance Network, LLCMailing Address: 11800 Weston ParkwayCity: Cary State: NC Zip: 27513Telephone: 919-459-4905 Fax: 919-831-0440Contact Person: Michele Coakley

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A - no individuals own shares

Name

Address

b)

Name

Address

c)

Name

Address

d)

Name

Address

2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 8 am 8 pmSaturday N/A am _____ pmSunday N/A am _____ pm

24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

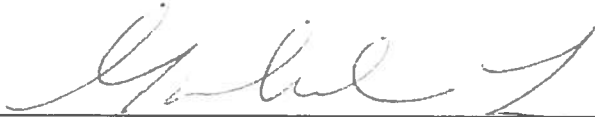
I, Michele Lau

Responsible Person of Biologics, Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau

Print Name of Authorized Person

3/12/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF North Carolina)
) ss.
Wake COUNTY)

I, Sheila A. Bizune, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge for Biologics by McKesson (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Sheila A. Bizune, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Sheila A. Bizune
 Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
12 day of March, 2020.

Drew Hess
 NOTARY PUBLIC





NORTH CAROLINA

Department of the Secretary of State

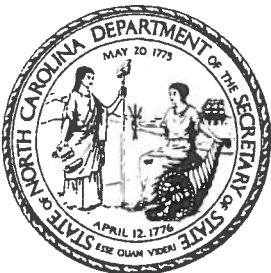
CERTIFICATE OF EXISTENCE

I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify that

BIOLOGICS, INC.

is a corporation duly incorporated under the laws of the State of North Carolina, having been incorporated on the 13th day of January, 1994, with its period of duration being Perpetual.

I FURTHER certify that, as of the date set forth hereunder, the said corporation's articles of incorporation are not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation is not administratively dissolved for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by N.C.G.S. 55-16-22 has been delivered to the Secretary of State; and that the said corporation has not filed articles of dissolution as of the date of this certificate.



Scan to verify online.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 12th day of February, 2020.

Elaine F. Marshall

Secretary of State

Biologics, Inc.
13000 Weston Parkway, Ste. 105
Cary, NC 27513
Disciplinary Action Overview
(Previously Disclosed)

Missouri

Biologics applied for a Missouri pharmacy permit in November, 2003 and Missouri requested certain additional information in January, 2004. Biologics did not respond with the additional information as requested due to oversight during a change in pharmacy management personnel. The pharmacy application automatically expired six months from the date of original filing and Biologics needed to reapply. Solely because of the tardiness in its original pharmacy application, the pharmacy permit subsequently issued to Biologics by the Missouri State Board of Pharmacy on March 31, 2005 was "restricted" for a period of three years. The purpose of the restriction was to require Biologics to continue to comply with applicable Missouri pharmacy rules and regulations. The terms of the discipline were completed as of March 30, 2008. Biologics is currently in good standing with the Missouri Board of Pharmacy.

Texas

In April 2012, the Texas State Board of Pharmacy notified Biologics, Inc. that Biologics, Inc. had failed to include the Missouri restricted license in its 2006 Texas licensure renewal and subsequent Change of Managing Office notice.

In a letter dated June 4, 2012, the Texas Board of Pharmacy notified Biologics, Inc. that its license# 23756 would be sanctioned from May 16, 2012 through August 14, 2015. In addition, an administrative penalty of \$2,000.00 would be assessed. The omission was inadvertent and in the good faith belief that the reason for the restricted license was due to a tardy application in Missouri and not an "act" by the Company or its personnel in Missouri. Biologics now understands that this was an incorrect interpretation. Biologics, Inc. paid the penalty and completed the restricted period. Biologics is currently in good standing with the Texas Board of Pharmacy.

Michigan

In May 2013, the Michigan Department of Licensing and Regulatory Affairs notified Biologics, Inc. of an administrative complaint in relation to the administrative penalty levied by Texas. In a State of Michigan consent order dated August 18, 2013, Michigan issued a reprimand to Biologics' Michigan pharmacy license# 530100834 and levied a fine in the amount of \$500.00. Biologics is currently in good standing with the Michigan Board of Pharmacy.

Montana

In August 2013, the Montana Board of Pharmacy convened a hearing to review the above mentioned disciplinary actions and determine whether it would take reciprocal action. After review of all documentation submitted by Biologics, the Board determined that the case did not justify legal or disciplinary proceedings. Biologics is currently in good standing with the Montana Board of Pharmacy.

Hawaii

On March 16, 2015, Hawaii notified Biologics that it would investigate the above mentioned Michigan and Texas discipline, as it was not notified within 30 days of the orders. Early resolution terms were signed and fee of \$1,500.00 was paid. Biologics is currently in good standing with the Hawaii Board of Pharmacy.

Illinois

In March 2016, Illinois Board of Pharmacy notified Biologics that it would investigate the above mentioned discipline, as it was not notified within 30 days of the orders. A consent order was signed and fee of \$2,000.00 was paid. Biologics is currently in good standing with the Illinois Board of Pharmacy.

Colorado

In an unrelated action in January 2010, Biologics, Inc. was fined five thousand dollars (plus a \$500 surcharge) by the Colorado Board of Pharmacy for a failure to provide a zero report to the Colorado Prescription Drug Monitoring Program for a 10 day reporting period from December 1, 2009 through December 10, 2009. The failure was inadvertent and immediately corrected.

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions.*

In 2009, **McKesson** entered into two stipulations with the Colorado Board of Pharmacy and paid fines due to McKesson’s Colorado distribution centers receiving prescription drugs from entities that were not registered with the Colorado Board of Pharmacy. In both instances, the requirement to accept product only from entities licensed by the Colorado Board, regardless of the state of residence, was a new requirement that was not publicized and many entities were fined by the Board.

On January 19, 2011, **McKesson** signed an Agreed Findings of Fact, Conclusion of Law and Final Order with the Oklahoma Board of Pharmacy, concerning its Oklahoma distribution center. The Oklahoma Board of Pharmacy alleged the McKesson Oklahoma distribution center distributed controlled substances to an unlicensed pharmacy. The pharmacy had been issued a DEA registration and, when McKesson verified the license, it was listed on the Board’s website with a license number. However, the pharmacy was awaiting an inspection for final approval. The Board’s website did not reflect that the license was pending approval. A \$3,000 fine was paid; however, McKesson made no admissions or denials.

In May 2011, **McKesson** entered into a stipulation with the Colorado Board of Pharmacy and paid a fine due to one of its Colorado distribution center not timely notifying the Colorado Board of Pharmacy that its designated representative had changed.

In August 2012, **McKesson** entered into a private consent order with the Georgia Board of Pharmacy due to the Georgia Drugs and Narcotics Agency discovering a carrier hired by McKesson leaving the truck unlocked while making deliveries on two separate occasions to Georgia pharmacies.

In 2012 **Physician Sales & Service (PSS)** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy for partnering with Green VaHey Med (GVM) to furnish compounded medications to PSS clients/customers by PSS sales reps ordering compounded medications through the unlicensed entity GVM who brokered the manufacturing of these products at USP for PSS client/customers while GVM invoiced, billed, and collected payments and split the profits 50/50 with PSS. The fine was \$500.00.

In 2013, **McKesson** entered into a consent order with the Virginia Board of Pharmacy based on the discovery of McKesson product in a non-McKesson warehouse that did not have proper security or temperate controls. Without McKesson's knowledge, an independent courier had placed McKesson customer returns in a warehouse used by the courier. After a default on the lease, McKesson was informed that its product was in the warehouse, but when McKesson attempted to retrieve the product, the owner of the warehouse denied entry. The Virginia Board was informed of the issue and ultimately held McKesson responsible for the courier's activity. A \$4,000 penalty was assessed against McKesson's Landover, Maryland distribution center (this facility closed as of May 31, 2012).

McKesson Patient Care Solutions Inc. (MPCS) is licensed as a pharmacy in New Jersey and is in good standing with the New Jersey State Board of Pharmacy. Based upon a routine inspection on 8/2/2013, MPCS was fined on 11/20/2014 for the following citations: 1.) a copy of a pharmacy technician's license was displayed instead of the original license; 2.) wording on MPCS' pharmacy labels required an update from "use by" to "discard after"; and 3.) some samples of prescriptions did not record patient allergy information.

In 2014 **McKesson** disclosed to the Michigan Board of Pharmacy final agency orders from Colorado, Georgia and Oklahoma that were issued between 2009 and 2012. , The Michigan Board of Pharmacy subsequently filed a complaint alleging that it is a violation of Michigan pharmacy law for a licensee to be the subject of administrative action in another state and asked McKesson to prove compliance with the agency orders in Colorado, Georgia, and Oklahoma. McKesson promptly supplied proof of compliance to the Michigan Board of Pharmacy. The Michigan Board of Pharmacy determined that McKesson had accepted responsibility in Colorado, Georgia, and Oklahoma and taken corrective measures to prevent re-occurrences of the issues that gave rise to those agency orders and the matter was resolved via consent order, pursuant to which McKesson accepted a reprimand and a fine.

In 2014, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning its Landover, Maryland distribution center (the "Landover DC") that had closed in May 2012. The Final Consent Order resolved allegations that, from January 2008 – November 2009, McKesson's Landover DC purchased approximately \$2.95 million of prescription drugs/devices from a wholesale distributor that was not licensed in Maryland. McKesson paid a \$30,000 fine in November 2014.

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson's Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In 2015 **McKesson Medical-Surgical Minnesota Supply Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy for selling hypodermic needles and syringes, classified as dangerous devices to an entity not licensed by the board. McKesson paid \$5,000 fine. The fine is related to a non-disciplinary action.

Oncology Rx Care Advantage, L. P., a wholly-owned subsidiary of McKesson Corporation entered into a consent agreement with the State of Maine with respect to a delay in filing of a PIC Change Application and error therein.

In April 2016 the **McKesson Medical-Surgical Inc.** Clear Brook, VA facility, which is a wholly-owned subsidiary of McKesson Corporation, was fined by the California Board of Pharmacy for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In September 2016, **McKesson Medical Surgical, Inc.** entered into a Consent Agreement for a \$2,750 fine with the Louisiana Board of Drug and Device concerning its St. Rose, Louisiana distribution center (the "St. Rose DC"). McKesson Medical Surgical, Inc agreed that it failed to maintain copies of current licenses for customers that are shipped or sold drugs or devices, or, if customer licenses are maintained offsite, by failing to maintain at the licensed distribution location a list of customer names, addresses, license numbers, and license expiration dates for all customers that are shipped or sold drugs or devices.

In 2016 **McKesson Specialty Distribution LLC** was fined by the California Board of Pharmacy related to the fact that McKesson Specialty Distribution LLC delivered dangerous drugs to an entity not licensed by the board. McKesson paid \$3,000 fine. The fine is related to a non-disciplinary action.

In 2016 January in response to California Board of Pharmacy fine **McKesson Specialty Distribution LLC** was fined by the Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics for failing to operate in compliance with applicable state law. McKesson paid the \$1,500 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Packaging Services, a business unit of McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that McKesson Packaging Services failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since February 2, 2016 fully licensed. McKesson paid a \$500 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy at its Clear Brook, VA location for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Minnesota Supply Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy related to the fact that

its distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since July 1, 2016 fully licensed. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In April 2017 the Hawaii Regulated Industries Complaints Office (RICO) received a request for Investigation from the Hawaii Board of Pharmacy after **Oncology Rx Care Advantage, LP** (Oncology Rx) reported disciplinary action taken by the State of Maine. Like most state boards of pharmacy, the Hawaii Board of Pharmacy can reciprocally discipline based on orders from other states under Hawaii Revised Statutes 43 6B-19 (13). This error, which the Hawaii Board never alleged to be intentional, has since been corrected. Oncology Rx paid \$500 as an administrative fine.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In 2017 **Oncology Rx Care Advantage, L. P.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy related to the fact that its distribution center failed to timely notify the state of California when their pharmacist-in-charge left the

company. The new pharmacist-in-charge is now and has been since March, 2016 fully licensed. McKesson paid \$750 fine. The fine is related to a non-disciplinary action.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled

substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson**'s distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On November 7, 2018, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Denver, Colorado distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid November 29, 2018. The Board released McKesson Medical-Surgical Inc. from the terms and conditions of the December 6, 2018, Stipulation and Final Agency Order and restored the Registration to unencumbered status.

In December of 2018, **MPCS** finalized a Consent Agreement with the Florida Agency for Health Care Administration ("AHCA") concerning a Final Audit Report ("Report") from AHCA indicating that it determined that MPCS was overpaid for claims which were in whole or in part not covered by Florida Medicaid. Upon review of additional documentation submitted by MPCS, AHCA agreed to accept payment of three hundred four dollars and eighty-five cents (\$304.85) in full settlement of any alleged overpayment, fine, and costs arising from the above-referenced Report. Specifically, MPCS agreed to pay a total overpayment of one hundred eight dollars and eighty-four cents (\$108.84), a fine of twenty-one dollars and seventy-seven cents (\$21.77), and

costs of one hundred seventy-four dollars and twenty-four cents (\$174.24) to resolve any and all issues related to any alleged overpayments. MPCS tendered payment of three hundred four dollars and eighty-five cents (\$304.85) on November 13, 2018, and the parties fully executed the Consent Agreement as of December 3, 2018.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On March 1, 2019, the Ohio Board of Pharmacy sent a Notice of Opportunity for Hearing to the McKesson Medical-Surgical Inc. distribution center in Urbancrest, OH, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The allegations relate to an investigation that McKesson Medical-Surgical Inc. shipped dangerous drugs to an unlicensed site in September 2017. A monetary penalty of \$4,5000 was imposed and paid on March 27, 2019.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and

Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Repeval with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Repeval, agreed to pay \$4,000 in investigative fees.

On July 31, 2019 **McKesson Medical-Surgical Inc.** received a citation from the California Board of Pharmacy regarding it's Urbancrest, OH location for failure to report a new Designated Representative within 30 days of change. No fine was assessed.

On August 29, 2019 **McKesson** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("**McKesson St. Louis**").

On August 5, 2019 the California State Board of Pharmacy issued a Citation and Fine of \$250.00 to **McKesson Specialty Distribution, LLC** at its facility located at 4100 Quest Way, Memphis, TN to resolve the delinquent notification of a change in the Designated Representative in 2016. The fine is related to a non-disciplinary action.

On August 5, 2019 the California State Board of Pharmacy issued a Citation and Fine of \$250.00 to **McKesson Specialty Distribution, LLC** at its facility located at 4100 Quest Way, Memphis, TN to resolve the delinquent notification of a change in the Designated Representative in 2018. The fine is related to a non-disciplinary action.

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of \$1,150.00.

On November 21, 2019 **RxCrossroads Third Party Logistics Division** was fined by the California Board of Pharmacy related to the fact that its Louisville, KY distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since May 2018 fully licensed. **RxCrossroads** paid \$750 fine. The fine is related to a non-disciplinary action.

On January 7, 2020 **McKesson** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

On January 14, 2020 **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of \$1,000 was imposed and paid on January 14, 2020.

Effective June 1, 2018, McKesson acquired Medical Specialties Distributors, LLC. Prior to the acquisition the following actions occurred:

In May of 2015, First Choice Medical Supply, LLC ("First Choice"), a wholly-owned subsidiary of McKesson Corporation, was cited and fined by the California Board of Pharmacy in connection with its Phoenix, Arizona distribution center. First Choice was cited for selling, shipping, mailing or delivering dangerous drugs and/or devices to its Fresno, California distribution center prior to obtaining a non-resident wholesaler permit. In connection with the citation, First Choice paid a \$5,000 fine. The fine is related to a non-disciplinary action.

In May of 2015, First Choice Medical Supply, LLC ("First Choice"), a wholly-owned subsidiary of McKesson Corporation, was cited and fined by the California Board of Pharmacy in connection with its Gresham, Oregon distribution center. First Choice was cited for selling, shipping, mailing or delivering dangerous drugs and/or devices to its Fresno, California distribution center prior to obtaining a non-resident wholesaler permit. In connection with the citation, First Choice paid a \$5,000 fine. The fine is related to a non-disciplinary action.

In May of 2015, First Choice Medical Supply, LLC ("First Choice"), a wholly-owned subsidiary of McKesson Corporation, was cited and fined by the California Board of Pharmacy in connection with its Fresno, California distribution center. First Choice was cited for acting as a wholesaler of dangerous drugs and/or devices prior to obtaining a wholesale license from the California Board of Pharmacy. The company was also cited for transferring, selling, or delivering a dangerous drug or device into the State of Nevada without a license issued by the Nevada Board of Pharmacy. In connection with the former citation, First Choice paid a \$5,000 fine. The fine is related to a non-disciplinary action.

In November of 2017, the Illinois Department of Financial and Professional Regulation issued a wholesale drug distributor license to Medical Specialties Distributors, LLC ("MSD"), a wholly-owned subsidiary of McKesson Corporation, subject to the terms and conditions of a Non-Disciplinary Consent Order. The Consent Order resolved allegations that MSD shipped five orders of prescription drugs into the State of Illinois from August 2015 to December 2015 without an active wholesale drug distributor license. MSD agreed to pay a \$5,000 non-disciplinary fee in connection with the allegations.

In February of 2018, Outpatient Infusion Systems, Inc. ("OIS"), a wholly-owned subsidiary of McKesson Corporation, entered into a Consent Agreement with the Arkansas Board of

Pharmacy concerning its Irving, Texas distribution center. The Consent Agreement resolved allegations that, from January 1, 2017 to June 1, 2017, OIS' Irving distribution center was operating without a valid Medical Equipment/Medical Gas license. OIS agreed to pay a settlement amount of \$2,500 in connection with allegations. The Consent Agreement is related to a non-disciplinary action.

Effective August 23, 2017, McKesson acquired BDI Pharma, Inc. Prior to the acquisition the following actions occurred

The Maryland Board of Pharmacy issued a subpoena to BDI Pharma, Inc. on April 4, 2017 requesting copies of invoices from 1998 until mid-1999 for prescription drugs shipped into Maryland in order to carry out health oversight activities. BDI Pharma, Inc provided information indicating that it distributed certain prescription plasma drug products into Maryland in 1998-1999 prior to obtaining a Maryland wholesale distributor permit. The Maryland Board of Pharmacy concluded that BDI Pharma was subject to discipline in accordance Md. Code Ann., 1-Health Occ. § 12-6C-03 and 12-6C-11 and ordered BDI Pharma, Inc to pay a FINE in the amount of \$5,000.00. BDI Pharma, Inc. paid the \$5,000 fine.

Effective May 13, 2016, McKesson acquired Labsco Holdings Inc. and its subsidiary, Laboratory Supply Company. Prior to the acquisition the following actions occurred:

In December 2005, the Florida Department of Health revoked/suspended Laboratory Supply Company's Jacksonville, FL distribution center license for failure of a Certified Designated Representative candidate to pass the exam. The candidate passed the exam in January 2006 and the distribution center license was returned to good standing. The distribution center has since been closed.

In February 2010, Laboratory Supply Company's distribution center located in Louisville, KY entered into an agreed order with the Kentucky Board of Pharmacy and paid a \$500 fine. The fine was for operating out of a new location without first filing a new application.

In April 2011, a Laboratory Supply Company distribution center located in Indiana had its license placed on indefinite suspension for not being accredited by VAWD which is required under Indiana law for any distributor selling drugs. The settlement was in April 2011 and the Indiana distribution center has since been closed.

In April, 2016, the South Carolina Board of Pharmacy fined Laboratory Supply Company \$5,000 for shipping legend product into South Carolina without a license. The fine was paid and the distribution center applied for and was granted a license.



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March 19, 2020

VIA UPS

Mr. Dave Wuest
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Ste 206
Reno, NV 89521

RE: Parent Level Change in Ownership - Biologics, Inc. dba Biologics by McKesson
13000 Weston Pky., Ste. 105 - **Current Permit Number(s): PH02131**
11800 Weston Parkway - **Current Permit Number(s): PH03800**

Dear Mr. Wuest:

We previously notified you of a transaction involving the above referenced permit holder, Biologics, Inc. dba Biologics by McKesson. Specifically, McKesson will be undergoing an internal multi-step transaction and re-organization effective **April 1, 2020** that impacts the parent company of Biologics, Inc. As the Board is aware, the current parent company of Biologics, Inc. is AORT Holdings Company, Inc. and the grandparent company is Physician Reliance Network, LLC. After the transaction, the parent company of Biologics, Inc. will be Physician Reliance Network, LLC. Essentially, the only effect of the transaction is that the current parent company, AORT Holdings Company, Inc. will no longer be in the chain of ownership, and the current grandparent entity will be the parent company. For ease of review, we have enclosed a change of ownership applications and the appropriate fees for processing.

Importantly, there are no changes to the direct operating entity of Biologics, Inc. The Tax ID, pharmacist-in-charge and all other organizational and operational facets will remain unchanged. Currently, the North Carolina Board is processing the ownership change applications for these facilities and once the new permits are received, we will forward them to you for your records.

Please feel free to contact me at 602-229-5530 or amy.cotton@quarles.com if you have any questions or would like any additional information regarding this transaction. Thank you for your consideration.

Very truly yours,

Amy Cotton Peterson

Encls.

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NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ **Ownership Change** (Provide current license number if making changes: **PH 03800**)

Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,7

☐ Partnership - Pages 1,2,5,7

☒ Non Publicly Traded Corporation – Pages 1,2,4,7

☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Biologics by McKesson

Physical Address: 11800 Weston Parkway

Mailing Address: Same as above.

City: Cary State: NC Zip Code: 27513

Telephone: 919-546-9810 Fax: 919-831-0440

Toll Free Number: 800-850-4306 (Required per NAC 639.708)

E-mail: pharmacists@mckesson.com Website: https://biologics.mckesson.com

Managing Pharmacist: Charles Shaw License Number: 23346

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
- ☐ ☒ Hospital (# beds)
- ☐ ☒ Internet
- ☐ ☒ Nuclear
- ☐ ☒ Ambulatory Surgery Center
- ☐ ☒ Community
- ☒ ☐ Other: Specialty/Oncology

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
- ☐ ☒ Parenteral **
- ☐ ☒ Parenteral (outpatient)
- ☐ ☒ Outpatient/Discharge
- ☐ ☒ Mail Service
- ☐ ☒ Long Term Care
- ☐ ☒ Sterile Compounding **
- ☐ ☒ Non Sterile Compounding
- ☐ ☒ Mail Service Sterile Compounding **
- ☐ ☒ Other Services:

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau

Print Name of Authorized Person

3/12/2020
Date

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Board Use Only

Date Processed: _____

Amount: 600.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: North Carolina
 Parent Company if any: Physicians Reliance Network, LLC
 Mailing Address: 11800 Weston Parkway
 City: Cary State: NC Zip: 27513
 Telephone: 919-459-4905 Fax: 919-831-0440
 Contact Person: Michele Coakley

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?
 - a) N/A - no individuals own shares.

Name
Address
 - b) _____

Name
Address
 - c) _____

Name
Address
 - d) _____

Name
Address
- 2) Provide the number of shares issued by the corporation. N/A
- 3) What was the price paid per share? N/A
- 4) What date did the corporation actually receive the cash assets? N/A
- 5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____
 Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 8 pm Saturday N/A am _____ pm
 Sunday N/A am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Michele Lau

Responsible Person of Biologics, Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau

Print Name of Authorized Person

3/12/2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF North Carolina)
Wake) ss. COUNTY)

I, Charles Shaw, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge for Biologics by McKesson (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

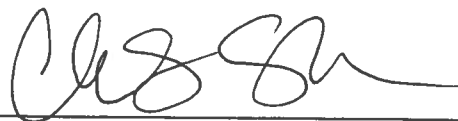
3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

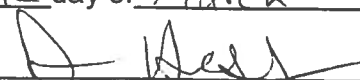
5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Charles Shaw, do hereby swear under penalty of perjury that the assertions of this affidavit are true.


 Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
12 day of March, 2020.


 NOTARY PUBLIC



While Biologics, Inc. dba Biologics by McKesson located at 11800 Weston Parkway, Cary, North Carolina has no disciplinary actions, Biologics by McKesson located at 13000 Weston Parkway, Ste. 105, Cary, North Carolina has the following previous discipline.

Biologics, Inc.

13000 Weston Parkway, Ste. 105

Cary, NC 27513

Disciplinary Action Overview

(Previously Disclosed)

Missouri

Biologics applied for a Missouri pharmacy permit in November, 2003 and Missouri requested certain additional information in January, 2004. Biologics did not respond with the additional information as requested due to oversight during a change in pharmacy management personnel. The pharmacy application automatically expired six months from the date of original filing and Biologics needed to reapply. Solely because of the tardiness in its original pharmacy application, the pharmacy permit subsequently issued to Biologics by the Missouri State Board of Pharmacy on March 31, 2005 was "restricted" for a period of three years. The purpose of the restriction was to require Biologics to continue to comply with applicable Missouri pharmacy rules and regulations. The terms of the discipline were completed as of March 30, 2008. Biologics is currently in good standing with the Missouri Board of Pharmacy.

Texas

In April 2012, the Texas State Board of Pharmacy notified Biologics, Inc. that Biologics, Inc. had failed to include the Missouri restricted license in its 2006 Texas licensure renewal and subsequent Change of Managing Office notice.

In a letter dated June 4, 2012, the Texas Board of Pharmacy notified Biologics, Inc. that its license# 23756 would be sanctioned from May 16, 2012 through August 14, 2015. In addition, an administrative penalty of \$2,000.00 would be assessed. The omission was inadvertent and in the good faith belief that the reason for the restricted license was due to a tardy application in Missouri and not an "act" by the Company or its personnel in Missouri. Biologics now understands that this was an incorrect interpretation. Biologics, Inc. paid the penalty and completed the restricted period. Biologics is currently in good standing with the Texas Board of Pharmacy.

Michigan

In May 2013, the Michigan Department of Licensing and Regulatory Affairs notified Biologics, Inc. of an administrative complaint in relation to the administrative penalty levied by Texas. In a State of Michigan consent order dated August 18, 2013, Michigan issued a reprimand to Biologics' Michigan pharmacy license# 530100834 and levied a fine in the amount of \$500.00. Biologics is currently in good standing with the Michigan Board of Pharmacy.

Montana

In August 2013, the Montana Board of Pharmacy convened a hearing to review the above mentioned disciplinary actions and determine whether it would take reciprocal action. After

review of all documentation submitted by Biologics, the Board determined that the case did not justify legal or disciplinary proceedings. Biologics is currently in good standing with the Montana Board of Pharmacy.

Hawaii

On March 16, 2015, Hawaii notified Biologics that it would investigate the above mentioned Michigan and Texas discipline, as it was not notified within 30 days of the orders. Early resolution terms were signed and fee of \$1,500.00 was paid. Biologics is currently in good standing with the Hawaii Board of Pharmacy.

Illinois

In March 2016, Illinois Board of Pharmacy notified Biologics that it would investigate the above mentioned discipline, as it was not notified within 30 days of the orders. A consent order was signed and fee of \$2,000.00 was paid. Biologics is currently in good standing with the Illinois Board of Pharmacy.

Colorado

In an unrelated action in January 2010, Biologics, Inc. was fined five thousand dollars (plus a \$500 surcharge) by the Colorado Board of Pharmacy for a failure to provide a zero report to the Colorado Prescription Drug Monitoring Program for a 10 day reporting period from December 1, 2009 through December 10, 2009. The failure was inadvertent and immediately corrected.

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions.*

In 2009, **McKesson** entered into two stipulations with the Colorado Board of Pharmacy and paid fines due to McKesson’s Colorado distribution centers receiving prescription drugs from entities that were not registered with the Colorado Board of Pharmacy. In both instances, the requirement to accept product only from entities licensed by the Colorado Board, regardless of the state of residence, was a new requirement that was not publicized and many entities were fined by the Board.

On January 19, 2011, **McKesson** signed an Agreed Findings of Fact, Conclusion of Law and Final Order with the Oklahoma Board of Pharmacy, concerning its Oklahoma distribution center. The Oklahoma Board of Pharmacy alleged the McKesson Oklahoma distribution center distributed controlled substances to an unlicensed pharmacy. The pharmacy had been issued a DEA registration and, when McKesson verified the license, it was listed on the Board’s website with a license number. However, the pharmacy was awaiting an inspection for final approval. The Board’s website did not reflect that the license was pending approval. A \$3,000 fine was paid; however, McKesson made no admissions or denials.

In May 2011, **McKesson** entered into a stipulation with the Colorado Board of Pharmacy and paid a fine due to one of its Colorado distribution center not timely notifying the Colorado Board of Pharmacy that its designated representative had changed.

In August 2012, **McKesson** entered into a private consent order with the Georgia Board of Pharmacy due to the Georgia Drugs and Narcotics Agency discovering a carrier hired by McKesson leaving the truck unlocked while making deliveries on two separate occasions to Georgia pharmacies.

In 2012 **Physician Sales & Service (PSS)** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy for partnering with Green VaHey Med (GVM) to furnish compounded medications to PSS clients/customers by PSS sales reps ordering compounded medications through the unlicensed entity GVM who brokered the manufacturing of these products at USP for PSS client/customers while GVM invoiced, billed, and collected payments and split the profits 50/50 with PSS. The fine was \$500.00.

In 2013, **McKesson** entered into a consent order with the Virginia Board of Pharmacy based on the discovery of McKesson product in a non-McKesson warehouse that did not have proper security or temperate controls. Without McKesson's knowledge, an independent courier had placed McKesson customer returns in a warehouse used by the courier. After a default on the lease, McKesson was informed that its product was in the warehouse, but when McKesson attempted to retrieve the product, the owner of the warehouse denied entry. The Virginia Board was informed of the issue and ultimately held McKesson responsible for the courier's activity. A \$4,000 penalty was assessed against McKesson's Landover, Maryland distribution center (this facility closed as of May 31, 2012).

McKesson Patient Care Solutions Inc. (MPCS) is licensed as a pharmacy in New Jersey and is in good standing with the New Jersey State Board of Pharmacy. Based upon a routine inspection on 8/2/2013, MPCS was fined on 11/20/2014 for the following citations: 1.) a copy of a pharmacy technician's license was displayed instead of the original license; 2.) wording on MPCS' pharmacy labels required an update from "use by" to "discard after"; and 3.) some samples of prescriptions did not record patient allergy information.

In 2014 **McKesson** disclosed to the Michigan Board of Pharmacy final agency orders from Colorado, Georgia and Oklahoma that were issued between 2009 and 2012. , The Michigan Board of Pharmacy subsequently filed a complaint alleging that it is a violation of Michigan pharmacy law for a licensee to be the subject of administrative action in another state and asked McKesson to prove compliance with the agency orders in Colorado, Georgia, and Oklahoma. McKesson promptly supplied proof of compliance to the Michigan Board of Pharmacy. The Michigan Board of Pharmacy determined that McKesson had accepted responsibility in Colorado, Georgia, and Oklahoma and taken corrective measures to prevent re-occurrences of the issues that gave rise to those agency orders and the matter was resolved via consent order, pursuant to which McKesson accepted a reprimand and a fine.

In 2014, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning its Landover, Maryland distribution center (the "Landover DC") that had closed in May 2012. The Final Consent Order resolved allegations that, from January 2008 – November 2009, McKesson's Landover DC purchased approximately \$2.95 million of prescription drugs/devices from a wholesale distributor that was not licensed in Maryland. McKesson paid a \$30,000 fine in November 2014.

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson's Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In 2015 **McKesson Medical-Surgical Minnesota Supply Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy for selling hypodermic needles and syringes, classified as dangerous devices to an entity not licensed by the board. McKesson paid \$5,000 fine. The fine is related to a non-disciplinary action.

Oncology Rx Care Advantage, L. P., a wholly-owned subsidiary of McKesson Corporation entered into a consent agreement with the State of Maine with respect to a delay in filing of a PIC Change Application and error therein.

In April 2016 the **McKesson Medical-Surgical Inc.** Clear Brook, VA facility, which is a wholly-owned subsidiary of McKesson Corporation, was fined by the California Board of Pharmacy for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In September 2016, **McKesson Medical Surgical, Inc.** entered into a Consent Agreement for a \$2,750 fine with the Louisiana Board of Drug and Device concerning its St. Rose, Louisiana distribution center (the "St. Rose DC"). McKesson Medical Surgical, Inc agreed that it failed to maintain copies of current licenses for customers that are shipped or sold drugs or devices, or, if customer licenses are maintained offsite, by failing to maintain at the licensed distribution location a list of customer names, addresses, license numbers, and license expiration dates for all customers that are shipped or sold drugs or devices.

In 2016 **McKesson Specialty Distribution LLC** was fined by the California Board of Pharmacy related to the fact that McKesson Specialty Distribution LLC delivered dangerous drugs to an entity not licensed by the board. McKesson paid \$3,000 fine. The fine is related to a non-disciplinary action.

In 2016 January in response to California Board of Pharmacy fine **McKesson Specialty Distribution LLC** was fined by the Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics for failing to operate in compliance with applicable state law. McKesson paid the \$1,500 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Packaging Services, a business unit of McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that McKesson Packaging Services failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since February 2, 2016 fully licensed. McKesson paid a \$500 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy at its Clear Brook, VA location for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Minnesota Supply Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy related to the fact that

its distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since July 1, 2016 fully licensed. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In April 2017 the Hawaii Regulated Industries Complaints Office (RICO) received a request for Investigation from the Hawaii Board of Pharmacy after **Oncology Rx Care Advantage, LP** (Oncology Rx) reported disciplinary action taken by the State of Maine. Like most state boards of pharmacy, the Hawaii Board of Pharmacy can reciprocally discipline based on orders from other states under Hawaii Revised Statutes 43 6B-19 (13). This error, which the Hawaii Board never alleged to be intentional, has since been corrected. Oncology Rx paid \$500 as an administrative fine.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In 2017 **Oncology Rx Care Advantage, L. P.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy related to the fact that its distribution center failed to timely notify the state of California when their pharmacist-in-charge left the

company. The new pharmacist-in-charge is now and has been since March, 2016 fully licensed. McKesson paid \$750 fine. The fine is related to a non-disciplinary action.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled

substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson**'s distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On November 7, 2018, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Denver, Colorado distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid November 29, 2018. The Board released McKesson Medical-Surgical Inc. from the terms and conditions of the December 6, 2018, Stipulation and Final Agency Order and restored the Registration to unencumbered status.

In December of 2018, **MPCS** finalized a Consent Agreement with the Florida Agency for Health Care Administration ("AHCA") concerning a Final Audit Report ("Report") from AHCA indicating that it determined that MPCS was overpaid for claims which were in whole or in part not covered by Florida Medicaid. Upon review of additional documentation submitted by MPCS, AHCA agreed to accept payment of three hundred four dollars and eighty-five cents (\$304.85) in full settlement of any alleged overpayment, fine, and costs arising from the above-referenced Report. Specifically, MPCS agreed to pay a total overpayment of one hundred eight dollars and eighty-four cents (\$108.84), a fine of twenty-one dollars and seventy-seven cents (\$21.77), and

costs of one hundred seventy-four dollars and twenty-four cents (\$174.24) to resolve any and all issues related to any alleged overpayments. MPCS tendered payment of three hundred four dollars and eighty-five cents (\$304.85) on November 13, 2018, and the parties fully executed the Consent Agreement as of December 3, 2018.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On March 1, 2019, the Ohio Board of Pharmacy sent a Notice of Opportunity for Hearing to the McKesson Medical-Surgical Inc. distribution center in Urbancrest, OH, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The allegations relate to an investigation that McKesson Medical-Surgical Inc. shipped dangerous drugs to an unlicensed site in September 2017. A monetary penalty of \$4,5000 was imposed and paid on March 27, 2019.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and

Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees.

On July 31, 2019 **McKesson Medical-Surgical Inc.** received a citation from the California Board of Pharmacy regarding its Urbancrest, OH location for failure to report a new Designated Representative within 30 days of change. No fine was assessed.

On August 29, 2019 **McKesson** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("**McKesson St. Louis**").

On August 5, 2019 the California State Board of Pharmacy issued a Citation and Fine of \$250.00 to **McKesson Specialty Distribution, LLC** at its facility located at 4100 Quest Way, Memphis, TN to resolve the delinquent notification of a change in the Designated Representative in 2016. The fine is related to a non-disciplinary action.

On August 5, 2019 the California State Board of Pharmacy issued a Citation and Fine of \$250.00 to **McKesson Specialty Distribution, LLC** at its facility located at 4100 Quest Way, Memphis, TN to resolve the delinquent notification of a change in the Designated Representative in 2018. The fine is related to a non-disciplinary action.

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of \$1,150.00.

On November 21, 2019 **RxCrossroads Third Party Logistics Division** was fined by the California Board of Pharmacy related to the fact that its Louisville, KY distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since May 2018 fully licensed. **RxCrossroads** paid \$750 fine. The fine is related to a non-disciplinary action.

On January 7, 2020 **McKesson** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

On January 14, 2020 **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of \$1,000 was imposed and paid on January 14, 2020.

Effective June 1, 2018, McKesson acquired Medical Specialties Distributors, LLC. Prior to the acquisition the following actions occurred:

In May of 2015, First Choice Medical Supply, LLC ("First Choice"), a wholly-owned subsidiary of McKesson Corporation, was cited and fined by the California Board of Pharmacy in connection with its Phoenix, Arizona distribution center. First Choice was cited for selling, shipping, mailing or delivering dangerous drugs and/or devices to its Fresno, California distribution center prior to obtaining a non-resident wholesaler permit. In connection with the citation, First Choice paid a \$5,000 fine. The fine is related to a non-disciplinary action.

In May of 2015, First Choice Medical Supply, LLC ("First Choice"), a wholly-owned subsidiary of McKesson Corporation, was cited and fined by the California Board of Pharmacy in connection with its Gresham, Oregon distribution center. First Choice was cited for selling, shipping, mailing or delivering dangerous drugs and/or devices to its Fresno, California distribution center prior to obtaining a non-resident wholesaler permit. In connection with the citation, First Choice paid a \$5,000 fine. The fine is related to a non-disciplinary action.

In May of 2015, First Choice Medical Supply, LLC ("First Choice"), a wholly-owned subsidiary of McKesson Corporation, was cited and fined by the California Board of Pharmacy in connection with its Fresno, California distribution center. First Choice was cited for acting as a wholesaler of dangerous drugs and/or devices prior to obtaining a wholesale license from the California Board of Pharmacy. The company was also cited for transferring, selling, or delivering a dangerous drug or device into the State of Nevada without a license issued by the Nevada Board of Pharmacy. In connection with the former citation, First Choice paid a \$5,000 fine. The fine is related to a non-disciplinary action.

In November of 2017, the Illinois Department of Financial and Professional Regulation issued a wholesale drug distributor license to Medical Specialties Distributors, LLC ("MSD"), a wholly-owned subsidiary of McKesson Corporation, subject to the terms and conditions of a Non-Disciplinary Consent Order. The Consent Order resolved allegations that MSD shipped five orders of prescription drugs into the State of Illinois from August 2015 to December 2015 without an active wholesale drug distributor license. MSD agreed to pay a \$5,000 non-disciplinary fee in connection with the allegations.

In February of 2018, Outpatient Infusion Systems, Inc. ("OIS"), a wholly-owned subsidiary of McKesson Corporation, entered into a Consent Agreement with the Arkansas Board of

Pharmacy concerning its Irving, Texas distribution center. The Consent Agreement resolved allegations that, from January 1, 2017 to June 1, 2017, OIS' Irving distribution center was operating without a valid Medical Equipment/Medical Gas license. OIS agreed to pay a settlement amount of \$2,500 in connection with allegations. The Consent Agreement is related to a non-disciplinary action.

Effective August 23, 2017, McKesson acquired BDI Pharma, Inc. Prior to the acquisition the following actions occurred

The Maryland Board of Pharmacy issued a subpoena to BDI Pharma, Inc. on April 4, 2017 requesting copies of invoices from 1998 until mid-1999 for prescription drugs shipped into Maryland in order to carry out health oversight activities. BDI Pharma, Inc provided information indicating that it distributed certain prescription plasma drug products into Maryland in 1998-1999 prior to obtaining a Maryland wholesale distributor permit. The Maryland Board of Pharmacy concluded that BDI Pharma was subject to discipline in accordance Md. Code Ann., 1-Health Occ. § 12-6C-03 and 12-6C-11 and ordered BDI Pharma, Inc to pay a FINE in the amount of \$5,000.00. BDI Pharma, Inc. paid the \$5,000 fine.

Effective May 13, 2016, McKesson acquired Labsco Holdings Inc. and its subsidiary, Laboratory Supply Company. Prior to the acquisition the following actions occurred:

In December 2005, the Florida Department of Health revoked/suspended Laboratory Supply Company's Jacksonville, FL distribution center license for failure of a Certified Designated Representative candidate to pass the exam. The candidate passed the exam in January 2006 and the distribution center license was returned to good standing. The distribution center has since been closed.

In February 2010, Laboratory Supply Company's distribution center located in Louisville, KY entered into an agreed order with the Kentucky Board of Pharmacy and paid a \$500 fine. The fine was for operating out of a new location without first filing a new application.

In April 2011, a Laboratory Supply Company distribution center located in Indiana had its license placed on indefinite suspension for not being accredited by VAWD which is required under Indiana law for any distributor selling drugs. The settlement was in April 2011 and the Indiana distribution center has since been closed.

In April, 2016, the South Carolina Board of Pharmacy fined Laboratory Supply Company \$5,000 for shipping legend product into South Carolina without a license. The fine was paid and the distribution center applied for and was granted a license.



NORTH CAROLINA

Department of the Secretary of State

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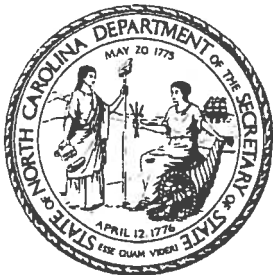
CERTIFICATE OF EXISTENCE

I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify that

BIOLOGICS, INC.

is a corporation duly incorporated under the laws of the State of North Carolina, having been incorporated on the 13th day of January, 1994, with its period of duration being Perpetual.

I FURTHER certify that, as of the date set forth hereunder, the said corporation's articles of incorporation are not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation is not administratively dissolved for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by N.C.G.S. 55-16-22 has been delivered to the Secretary of State; and that the said corporation has not filed articles of dissolution as of the date of this certificate.



Scan to verify online.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 12th day of February, 2020.

Elaine F. Marshall

Secretary of State

4F

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,8 ☐ Partnership – Pages 1,2,6,8
☒ Non Publicly Traded Corporation – Pages 1,2,4,8 ☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Complete Medical Supplies, Inc
 Physical Address: 4001 NW 124 Avenue, Coral Springs, FL 33065-2405
 Mailing Address: 4001 NW 124 Avenue, Coral Springs, FL 33065-2405
 City: Coral Springs State: Florida Zip Code: 33065-2405
 Telephone: 877.748.1977 Fax: 877.748.1985
 Toll Free Number: 877.748.1977 (Required per NAC 639.708)
 E-mail: ssturrup@acsmedical.com Website: acsmedical.com
 Managing Pharmacist: Scott K Sturrup License Number: N/A- DME Company

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☒ ☐ Other: Mail Order DME

All boxes must be checked
 For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☒ ☐ Other Services: consumable medical supplies and legend device (Aspira drain).

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Scott K Sturup

Print Name of Authorized Person

08/19/2020

Date

Page 2

Board Use Only

Date Processed: _____

Amount: 600.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Florida Type text here

Parent Company if any: N/A

Mailing Address: 4001 NW 124 Avenue, Coral Springs, FL 33065-2405

City: Coral Springs State: Florida Zip: 33065-2405

Telephone: 877.748.1977 Fax: 877.748.1985

Contact Person: Scott K Sturup

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?
 - a) Scott K Sturup, Owner President- 50% 0 NV Way, Parkland, FL 33076-3752
Name Address
 - b) Sandra L Hettinger, Owner/ VP- 50% Vestal Way, Coral Springs, FL 33071-5855
Name Address
 - c) _____
Name Address
 - d) _____
Name Address
- 2) Provide the number of shares issued by the corporation. 2
- 3) What was the price paid per share? N/A
- 4) What date did the corporation actually receive the cash assets? N/A
- 5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 5 pm Saturday oncall am _____ pm

Sunday oncall am _____ pm 24 Hours oncall

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

Florida

I, Scott K Sturup

Responsible Person of Complete Medical Supplies, Inc

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Scott K Sturup
Print Name of Authorized Person

08/19/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Florida)
) ss.
Broward COUNTY)

I, Scott K Sturup, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President/Owner/Person Responsible for Complete Medical Supplies, Inc (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

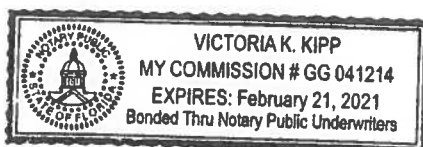
FURTHER AFFIANT SAYETH NOT.

I, Scott K Sturup, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

 Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
19 day of Aug, 2020.

Victoria K Kipp
 NOTARY PUBLIC



State of Florida

Department of State

I certify from the records of this office that COMPLETE MEDICAL SUPPLIES, INC. is a corporation organized under the laws of the State of Florida, filed on May 24, 1999.

The document number of this corporation is P99000047998.

I further certify that said corporation has paid all fees due this office through December 31, 2020, that its most recent annual report/uniform business report was filed on January 29, 2020, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Twentieth day of August, 2020*



Randy R. Lee
Secretary of State

Tracking Number: 1505555062CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>

Florida Non- Licensure Requirement Summary

Complete Medical Supplies, Inc. is NOT required to obtain a Florida HME License, per Florida State Regulations. The below is extracted from Florida State Regulation (attached) and supported by the document in its entirety.

Complete Medical Supplies, Inc. is a Medicare/ Medicaid certified and ACHC Accredited Durable Medical Equipment Provider distributing only disposable medical supplies such as diabetic, ostomy, urological, wound care supplies and prosthetic drain/ dressing kits.

Please know that classification of all devices are assigned by FDA and fall under Class I for minimal risk, Class II for greater risk or and Class III for highest risk. The higher the classification, the more stringent applicable regulations as there is greater concern for the potential to harm the patient. Keep in mind that the Aspira Prosthetic Drain/ Dressing System is classified by FDA as a Class II Medical Device and that is labeled as a Legend Device (see attached initial filing by Bard, now Merit). Also know that a diabetic monitor is also classified by the FDA as a Class II medical device.

The specific Exemption Rule that supports Complete Medical Supplies' position as "exempt" from having a DME/ HME License in Florida is below as extracted by the attached:

Page 2:

Aspen State Regulation Set: O 3.02 Home Medical Equipment

59A-25.002(2), F.S., **Home medical equipment locations that do not require a license:** Diabetic monitors and disposable supplies, e.g., diabetic, ostomy, urological and wound care supplies have been identified as equipment and supplies that do not require services as defined in Section 400.925(9), F.S.; therefore, locations that supply these items only will not require a HME license.

Note: Above clearly lists Diabetic monitors as an exempt item from licensure requirement although it is a Class II Device. However, as this does not address exemption for the Aspira Prosthetic Drain/ Dressing Kit, it defaults to specifics applicable to Home Medical Equipment. The definition for Home Medical Equipment per State of Florida is below. The definition clearly states "prosthetics are NOT included" and therefore exempt.

Page 3 and 4:

ST - 00002 – Definitions

Title Definitions

Statute or Rule: 400.925 FS; 59A-25.001 FAC

Type Memo Tag

Regulation Definition

400.925 Definitions.-As used in this part, the term:

(6) " **Home medical equipment** " includes any product as defined by the Federal Drug Administration's Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need.

BROWARD COUNTY LOCAL BUSINESS TAX RECEIPT

115 S. Andrews Ave., Rm. A-100, Ft. Lauderdale, FL 33301-1895 – 954-831-4000
 VALID OCTOBER 1, 2020 THROUGH SEPTEMBER 30, 2021

DBA: COMPLETE MEDICAL SUPPLIES INC
 Business Name: Receipt #: 378-6564
 Business Type: WHOLESALE/DISTRIBUTOR (MEDICAL SUPPLY DISTRIBUTOR)
 Owner Name: SCOTT STURRUP
 Business Location: 4001 NW 124 AVE
 CORAL SPRINGS
 Business Phone: 954-748-1966
 Business Opened: 09/01/2000
 State/County/Cert/Reg:
 Exemption Code:

Rooms Seats Employees Machines Professionals

Number of Machines:		For Vending Business Only			Vending Type:	
		Transfer Fee	NSF Fee	Penalty	Prior Years	Collection Cost
Tax Amount	45.00	0.00	0.00	0.00	0.00	0.00
						Total Paid
						45.00

THIS RECEIPT MUST BE POSTED CONSPICUOUSLY IN YOUR PLACE OF BUSINESS

THIS BECOMES A TAX RECEIPT

WHEN VALIDATED

This tax is levied for the privilege of doing business within Broward County and is non-regulatory in nature. You must meet all County and/or Municipality planning and zoning requirements. This Business Tax Receipt must be transferred when the business is sold, business name has changed or you have moved the business location. This receipt does not indicate that the business is legal or that it is in compliance with State or local laws and regulations.



FOR PROVIDERS.
BY PROVIDERS.

July 1, 2019

Complete Medical Supplies, Inc.
Scott Sturup
4001 NW 124th Ave.
Coral Springs, FL 33065

Dear Complete Medical Supplies, Inc.:

Thank you for submitting a Plan of Correction (POC) addressing to the deficiencies found during your on-site survey. Accreditation Commission for Health Care (ACHC) conducted an extensive evaluation of your POC, and has concluded that the plan meets the intent of compliance with the ACHC Accreditation Standards.

On behalf of ACHC, it is my pleasure to inform you that Complete Medical Supplies, Inc. has been **approved for accreditation** for the DMEPOS Program. Your accreditation is effective August 2, 2019 through August 1, 2022. Of course, maintaining accreditation is contingent upon continued compliance with ACHC Accreditation Standards during this period. In granting accreditation, ACHC finds that your company has demonstrated that it operates at a level of quality, integrity, and effectiveness consistent with its standards.

Again, congratulations on being awarded accreditation. It is an achievement of which your organization can be proud and one that demonstrates your commitment to quality in the provision of care.

Should you have any questions, please contact your organization's Account Advisor, Almee Pope.

Sincerely,

Timothy Safley MBA, RRT, RCP
Program Director

4G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ **Ownership Change** (Provide current license number if making changes: PH 03440
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership – Pages 1,2,6,8

☒ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: divvyMED, LLC d/b/a divvyDOSE

Physical Address: 4300 44th Ave., Moline, IL 61265

Mailing Address: 4300 44th Ave.

City: Moline State: IL Zip Code: 61265

Telephone: (844) 693-4889 Fax: (309) 807-2462

Toll Free Number: (844) 693-4889 (Required per NAC 639.708)

E-mail: csteffen@divvydose.com Website: www.divvydose.com

Managing Pharmacist: Christine Steffen License Number: IL 051.299426

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
- ☐ ☒ Hospital (# beds)
- ☒ ☐ Internet
- ☐ ☒ Nuclear
- ☐ ☒ Ambulatory Surgery Center
- ☒ ☐ Community
- ☐ ☒ Other:

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
- ☐ ☒ Parenteral **
- ☐ ☒ Parenteral (outpatient)
- ☐ ☒ Outpatient/Discharge
- ☒ ☐ Mail Service
- ☐ ☒ Long Term Care
- ☐ ☒ Sterile Compounding **
- ☐ ☒ Non Sterile Compounding
- ☐ ☒ Mail Service Sterile Compounding **
- ☐ ☒ Other Services:

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Karen E. Peterson, Secretary

Print Name of Authorized Person

Date

9/8/20

Page 2

Board Use Only

Date Processed: _____

Amount:

500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: Penzo Enterprises, LLCMailing Address: McConnor ParkwayCity: Schaumburg State: IL Zip: 60173Telephone: (952) 205-1000 Fax: _____Contact Person: Karen Peterson

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A, Penzo Enterprises, LLC is owned 100% by OptumRx Holdings, LLC
Name Addressb) N/A
Name Addressc) N/A
Name Addressd) N/A
Name Address2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____Name: N/A %: _____**Hours of Operation for the pharmacy:**Monday thru Friday 8 am 6 pm Saturday N/A am N/A pmSunday N/A am N/A pm 24 Hours N/AA Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF ILLINOIS)
COOK COUNTY) ss.)

I, Karen Peterson, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary for DivvyMed, LLC dba DivvyDose (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Karen Peterson, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Karen Peterson
 Name Karen Peterson

SUBSCRIBED AND SWORN TO
 before me, a notary public this
8 day of SEPT, 2020.

Kelly L. Mace-Levin
 NOTARY PUBLIC



STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Karen Peterson

Responsible Person of DivvyMed, LLC dba DivvyDose

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Karen Peterson

Print Name of Authorized Person

Date

9/8/20

Karen Elizabeth Peterson, Secretary of DivvyMed, LLC and Penzo Enterprises, LLC
Disciplinary History

Karen Peterson paid a fine to the Oregon Board of Pharmacy in 1998 to settle discipline related to a prescription misfill. The only information available on the Board's website is the Consent Order and Notice of Proposed Disciplinary Action. A copy is attached.



Signed by: Karen Peterson



Date

MAY 08 1998

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

BOARD OF PHARMACY

In the Matter of the
Pharmacist License of

Case No. 97-0069 (A)

KAREN (BOHMER) PETERSON, R.Ph.

CONSENT ORDER

Licensee

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action regarding the licensee in the above-captioned matter; and

WHEREAS, the above-noted Notice of Proposed Disciplinary Action together with a Notice of Rights was duly served on the licensee as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice of Proposed Disciplinary Action without further proceedings thereon; and

WHEREAS, the licensee is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the licensee admits that the facts alleged in the above-noted Notice of Proposed Disciplinary Action are true, that the licensee's conduct, as admitted, violated the statutes and rules cited in the Notice, and that legal cause exists pursuant to ORS 689.405 for disciplinary action by the Board; and

WHEREAS, the licensee consents to the disciplinary action as set forth herein;

///

NOW THEREFORE THE FOLLOWING DISCIPLINE IS HEREBY ORDERED:

1. The licensee shall pay to the Board a civil penalty in the amount of \$300, said payment to be made within thirty days from the date of this Consent Order;

2. Failure of the licensee to pay the civil penalty as required under this Consent Order may, after notice and hearing, result in further disciplinary action including license revocation.

DATED this 8th day of May, 1998.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

BY:

Gary Schnabel, R.N., R.Ph.
Compliance Director

CONSENT

I hereby acknowledge that I have read and understand the above-noted Notice of Proposed Disciplinary Action and Notice of Rights and the terms of the Consent Order. I agree to the Board entering the Consent Order.

Date

5/1/98

Karen (Bohmer) Peterson, R.Ph.
Licensee

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the
Pharmacist License of

KAREN BOHMER, R.Ph.
Licensee

) Case No. 97-0069 (A)
)
)
) NOTICE OF PROPOSED
) DISCIPLINARY ACTION
)
)

The Oregon Board of Pharmacy proposes to take disciplinary action against you pursuant to ORS 689.445 because you violated the Oregon Pharmacy Act and the Board of Pharmacy rules as follows:

On 1/9/97 you dispensed Depakote 250mg for a Depakote 500mg prescription in violation of OAR 855-041-0065, which is grounds for discipline pursuant to ORS 689.405(1)(e)(B).

On 1/18/97 you dispensed lithium 300mg for a thioridazine 100mg prescription in violation of OAR 855-041-0065, which is grounds for discipline pursuant to ORS 689.405(1)(e)(B).

On 4/25/97 you dispensed Lamictal 100mg for a Lamictal 25mg prescription in violation of OAR 855-041-0065, which is grounds for discipline pursuant to ORS 689.405(1)(e)(B).

On 6/4/97 you dispensed Depakote 250mg for a Depakote 500mg prescription in violation of OAR 855-041-0065, which is grounds for discipline pursuant to ORS 689.405(1)(e)(B).

DATED this 8 day of January, 1998.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

BY: _____
Gary Schnabel, R.N., R.Ph.
Compliance Director

NOTICE OF PROPOSED DISCIPLINARY ACTION

List of Members, Officers, and Managers of DivvyMed, LLC and Penzo Enterprises, LLC

Upon the closing of the transaction, Penzo Enterprises, LLC will be the sole member of DivvyMed, LLC and OptumRx Holdings, LLC will be the sole member of Penzo Enterprises, LLC.

The new officers, directors, and managers of **DivvyMed, LLC** will include:

List of Officers, Directors and Managers	Title and Registered Pharmacist numbers (if any)	Home Address
Jeffrey David Grosklags	Manager	Timberwolf Circle NW, Prior Lake, MN 55372
John Michael Prince	Manager, President	Harrington Road, Wayzata, MN 55391
Karen Elizabeth Peterson	Secretary IL R.PH 051293213	V. Seminary Ave. Wheaton, IL 60187
Peter Marshall Gill	Treasurer	Sherwood Bluff, Eden Prairie, MN 55437
Heather Anastasia Lang	Assistant Secretary	Mount Curve Road, Eden Prairie, MN 55347
David John Oberg	Assistant Secretary	Deep Waters Court, Simi Valley, CA 93065
Arvind Movva	CEO	N. Seeley Ave., Chicago, IL 60625

The new officers, directors, and managers of **Penzo Enterprises, LLC** will include:

List of Officers, Directors and Managers	Title and Registered Pharmacist numbers (if any)	Home Address
Jeffrey David Grosklags	Manager	Timberwolf Circle NW, Prior Lake, MN 55372
John Michael Prince	Manager, CEO, President	Harrington Road, Wayzata, MN 55391
Karen Elizabeth Peterson	Secretary IL R.PH 051293213	W. Seminary Ave. Wheaton, IL 60187
Peter Marshall Gill	Treasurer	Sherwood Bluff, Eden Prairie, MN 55437
Heather Anastasia Lang	Assistant Secretary	Mount Curve Road, Eden Prairie, MN 55347
David John Oberg	Assistant Secretary	Deep Waters Court, Simi Valley, CA 93065

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DIVVYMED, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF MAY, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DIVVYMED, LLC" WAS FORMED ON THE TWENTY-FOURTH DAY OF NOVEMBER, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



5646047 8300

SR# 20203466190

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 202880002

Date: 05-05-20

File Number

0508197-1



To all to whom these Presents Shall Come, Greeting:

I, Jesse White, Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that

DIVVYMED, LLC, A DELAWARE LIMITED LIABILITY COMPANY HAVING OBTAINED ADMISSION TO TRANSACT BUSINESS IN ILLINOIS ON FEBRUARY 05, 2015, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A FOREIGN LIMITED LIABILITY COMPANY ADMITTED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.



In Testimony Whereof, I hereto set
my hand and cause to be affixed the Great Seal of
the State of Illinois, this 30TH
day of MARCH A.D. 2020 .

Jesse White

SECRETARY OF STATE

Authentication #: 2009001278 verifiable until 03/30/2021

Authenticate at: <http://www.cyberdriveillinois.com>





divvyDOSE

divvyDOSE Pharmacist List

Allen Koster	IL 051.293392	Full-Time
Jake Vroman	IL 051.294393	Full-Time
Christine Steffen	IL 051.299426	Full-Time
Andrew Peterson	IL 051.291572	Full-Time
Katheryne Stack	IL 051.297168	Full-Time
Debra Slifka	IL 051.300149	Part-Time
Amanda French	IL 051.292771	Full-Time
Daniel French	IL 051.293558	Full-Time
Emily Kwak	IA 20822	Full-Time
Melissa Williams	IA 23148	Full-Time

First Name	Last Name	Worker Category Description	Location City	License/Certification ID	Category Description	Expiration Date
Brian	Bedoun	Full Time	Moline	49255371/DSM7B4Y7	Certified Pharmacy Technician	01/09/2021
Noah	Eads	Full Time	Moline	49249858/30051722	Certified Pharmacy Technician	08/31/2021
Nikeia	Patel	Full Time	Moline	49244766/30053631	Certified Pharmacy Technician	09/30/2021
John	Petersen	Full Time	Moline	49253075/A6D6S3F9	Certified Pharmacy Technician	02/28/2022
Amy	Jones	Full Time	Moline	49266736/F9R6R7E3	Certified Pharmacy Technician	02/16/2022
Isaac	Smith	Full Time	Moline	49255837/Y9J2T6K8	Certified Pharmacy Technician	03/01/2022
Krystle	Clark	Full Time	Moline	49,257183/J2D3H3L8	Certified Pharmacy Technician	05/03/2022
Megan	Dunaway	Full Time	Moline	49,266171/6001070000000000	Certified Pharmacy Technician	10/31/2020
Dawna	Ewoldt	Full Time	Moline	49218203/4901070000000000	Certified Pharmacy Technician	12/31/2021
Kaci	Korhals	Full Time	Moline	48250632/5401070000000000	Certified Pharmacy Technician	11/30/2020
Shayla	Smith	Full Time	Moline	10098939/49,243404	Certified Pharmacy Technician	03/31/2021
Chrisiti	Rungdahl	Full Time	Moline	4924301/GSL2Z7G7	Certified Pharmacy Technician	01/03/2022
Sara	Tilp	Full Time	Moline	49252727/A6C2S4S6	Certified Pharmacy Technician	03/02/2021
Jessica	Oler	Full Time	Moline	49245685/E8C3M8S3	Certified Pharmacy Technician	03/28/2022
Cassy	Rula	Full Time	Moline	49199817/5701070000000000	Certified Pharmacy Technician	02/28/2022
Amanda	Smith	Full Time	Moline	49260827/H5B2Z2E5	Certified Pharmacy Technician	02/28/2022
Gabrielle	Hill	Part Time	Moline	49,222546/10040684	Certified Pharmacy Technician	03/31/2022
Kevin	Millroy	Full Time	Moline	49228180/30019137	Certified Pharmacy Technician	08/31/2020
Rachel	Pappas	Full Time	Moline	49261829/P8QSB7N9	Certified Pharmacy Technician	06/04/2022
Angela	Chase	Full Time	Moline	49222558/10046465	Certified Pharmacy Technician	07/31/2022
Cindy	Goeden	Full Time	Moline	49263689/W5P9M3X7	Certified Pharmacy Technician	02/16/2022
Jamie	Rebello	Full Time	Moline	49263338/X4T4D6X4	Certified Pharmacy Technician	02/27/2022
Angela	Kirchner	Full Time	Moline	49,239393/6040508	Certified Pharmacy Technician	06/14/2022
Jennifer	Paxton	Full Time	Moline	49248918,W6C9T2T6	Certified Pharmacy Technician	01/30/2022
Sabrina	Armstrong	Full Time	Moline	49246756/N3L5F4D8	Certified Pharmacy Technician	08/02/2021
Sarah	Davis	Full Time	Moline	49255416/P8D3S6C2	Certified Pharmacy Technician	02/28/2022
Devon	Hurley	Full Time	Moline	49243196/P4C2C5F7	Certified Pharmacy Technician	04/08/2022
Stephanie	Nelson	Full Time	Moline	49230840/30008443	Certified Pharmacy Technician	05/31/2022
Elizabeth	Selby	Full Time	Moline	04922784/1/30005574	Certified Pharmacy Technician	03/31/2021
Courtney	Arnold	Full Time	Moline	49256629/30097056	Certified Pharmacy Technician	04/30/2021
Sydney	Shearer	Full Time	Moline	49246743/30063377	Certified Pharmacy Technician	02/28/2022
Gladys	Cole	Full Time	Moline	49251439/L5H3G7G8	Certified Pharmacy Technician	05/04/2021
Sunnie	McCollam	Full Time	Moline	49255456/K9J8H9E5	Certified Pharmacy Technician	02/16/2022
Keili	Holmes	Full Time	Moline	49251544/S3X4S3R8	Certified Pharmacy Technician	03/15/2022
Ariel	McDowell	Full Time	Moline	49244083/30030936	Certified Pharmacy Technician	01/31/2021

Ashley	Punty	Full Time	Moline	49253532	Registered Pharmacy Technician- IL	03/31/2021
Melissa	Dzekunskas	Full Time	Moline	49267288	Registered Pharmacy Technician- IL	03/31/2021
Vickie	Hemm	Full Time	Moline	49270570	Registered Pharmacy Technician- IL	03/31/2021
Kalli	Majewski	Part Time - College	Moline	49267903	Registered Pharmacy Technician- IL	03/31/2021
Meatle	Sanfilippo	Full Time	Moline	49271663	Registered Pharmacy Technician- IL	03/31/2021
Brittany	Short	Part Time	Moline	49266436	Registered Pharmacy Technician- IL	03/31/2021
Susan	Perez	Part Time - College	Moline	49273535	Registered Pharmacy Technician- IL	03/31/2021
Stephen	Moeller	Full Time	Moline	49270512	Registered Pharmacy Technician- IL	05/31/2021
Joella	Jones	Full Time	Moline	49162668	Registered Pharmacy Technician- IL	03/31/2021
Emilee	Dowd	Part Time - College	Moline	49267127	Registered Pharmacy Technician- IL	03/31/2021
Starla	Lawton	Full Time	Moline	48119813	Registered Pharmacy Technician- IL	03/31/2021
Jodi	Kennedy	Full Time	Moline	49264111	Registered Pharmacy Technician- IL	03/31/2021
Kitty	Laaman	Full Time	Moline	49264308	Registered Pharmacy Technician- IL	03/31/2021
Danielle	Stone	Full Time	Moline	49264638	Registered Pharmacy Technician- IL	03/31/2021
Lisa	Woods	Full Time	Moline	49268377	Registered Pharmacy Technician- IL	03/31/2021
Elisha	Lindsey	Full Time	Moline	49266443	Registered Pharmacy Technician- IL	03/31/2021
Christopher	Steele	Full Time	Moline	49266114	Registered Pharmacy Technician- IL	03/31/2021
Abbigail	Yodts	Part Time - College	Moline	49267093	Registered Pharmacy Technician- IL	03/31/2021
Rachel	Kelley	Full Time	Moline	49266952	Registered Pharmacy Technician- IL	03/31/2021
Laure	Gorterman	Full Time	Moline	49267913	Registered Pharmacy Technician- IL	03/31/2021
Mary	Gassman	Full Time	Moline	49267989	Registered Pharmacy Technician- IL	03/31/2021
Jessica	Eversole	Full Time	Moline	49266649	Registered Pharmacy Technician- IL	03/31/2021
Tim	Wright	Full Time	Moline	49266113	Registered Pharmacy Technician- IL	03/31/2021
Danielle	Raymond	Full Time	Moline	49266640	Registered Pharmacy Technician- IL	03/31/2021
Susan	Sherman	Full Time	Moline	49266657	Registered Pharmacy Technician- IL	03/31/2021
Joanna	Martinez	Part Time	Moline	49265976	Registered Pharmacy Technician- IL	03/31/2021
Sarah	Coulter	Full Time	Moline	49272645	Registered Pharmacy Technician- IL	03/31/2021
Nicole	Cram	Full Time	Moline	49267142	Registered Pharmacy Technician- IL	03/31/2021
Adriyela	Bradford	Full Time	Moline	49259116	Registered Pharmacy Technician- IL	03/31/2021
Genevieve	Aretlanes	Full Time	Moline	49268074	Registered Pharmacy Technician- IL	03/31/2021
Cynthia	Gustafson	Part Time	Moline	49268523	Registered Pharmacy Technician- IL	03/31/2021
Annette	Eversole	Part Time - College	Moline	49259943	Registered Pharmacy Technician- IL	03/31/2021
Jenna	Taylor	Part Time - College	Moline	49259984	Registered Pharmacy Technician- IL	03/31/2021
Alexandria	Wilder	Part Time	Moline	49260584	Registered Pharmacy Technician- IL	03/31/2021
Zachary	Chriswell	Full Time	Moline	49260625	Registered Pharmacy Technician- IL	03/31/2021
Michelle	Wetterow	Full Time	Moline	49262732	Registered Pharmacy Technician- IL	03/31/2021
			Moline	49262081	Registered Pharmacy Technician- IL	03/31/2021

Chasity	Rasnake	Full Time	Moline	49259467	Registered Pharmacy Technician- IL	03/31/2021
Heather	Kilby	Full Time	Moline	49262752	Registered Pharmacy Technician- IL	03/31/2021
Garrett	Salger	Full Time	Moline	49263690	Registered Pharmacy Technician- IL	03/31/2021
Shelly	Meier	Full Time	Moline	49263207	Registered Pharmacy Technician- IL	03/31/2021
Ariana	Alcantar	Part Time - College	Moline	49267129	Registered Pharmacy Technician- IL	03/31/2021
Teanna	Randolph	Part Time	Moline	49267401	Registered Pharmacy Technician- IL	03/31/2021
Spencer	Mason	Full Time	Moline	49268513	Registered Pharmacy Technician- IL	03/31/2021
Adam	Uhde	Full Time	Moline	49267393	Registered Pharmacy Technician- IL	03/31/2021
Jillian	Shellabarger	Full Time	Moline	49267996	Registered Pharmacy Technician- IL	03/31/2021
Andrew	Burger	Full Time	Moline	49264103	Registered Pharmacy Technician- IL	03/31/2021
Ryne	Beusseling	Full Time	Moline	49263691	Registered Pharmacy Technician- IL	03/31/2021
Mary	Wingert	Full Time	Moline	49127817	Registered Pharmacy Technician- IL	03/31/2021
Summer	Lowery	Full Time	Moline	49263945	Registered Pharmacy Technician- IL	03/31/2021
Makayla	Combs	Part Time - College	Moline	49264119	Registered Pharmacy Technician- IL	03/31/2021
Abby	Wingate	Full Time	Moline	49275259	Registered Pharmacy Technician- IL	03/31/2021
Vanessa	Lynn	Part Time - College	Moline	49275260	Registered Pharmacy Technician- IL	03/31/2021
Blake	Lewis	Full Time	Moline	49262488	Registered Pharmacy Technician- IL	03/31/2021
Mario	MacDonald Huerta	Full Time	Moline	49271346	Registered Pharmacy Technician- IL	03/31/2021
Alexander	Dailing	Full Time	Moline	49272646	Registered Pharmacy Technician- IL	03/31/2021
Daniela	Anderson	Full Time	Moline	49272808	Registered Pharmacy Technician- IL	03/31/2021
Amanda	Crocker	Full Time	Moline	49271470	Registered Pharmacy Technician- IL	03/31/2021
Imma	dajesus	Full Time	Moline	49271015	Registered Pharmacy Technician- IL	03/31/2021
Karen	Cardenas	Full Time	Moline	49256978	Registered Pharmacy Technician- IL	03/31/2021
Victoria	Castelluccio	Full Time	Moline	49274575	Registered Pharmacy Technician- IL	03/31/2021
Emma	Baldwin	Part Time - College	Moline	49272916	Registered Pharmacy Technician- IL	03/31/2021
Sarah	Meyers	Part Time - College	Moline	49272762	Registered Pharmacy Technician- IL	03/31/2021
Courtney	Pool	Full Time	Moline	49274561	Registered Pharmacy Technician- IL	03/31/2021
Sandra/Eitzabel	Gonzalez	Part Time	Moline	49270979	Registered Pharmacy Technician- IL	03/31/2021
Rae	Pooley	Part Time - College	Moline	49273806	Registered Pharmacy Technician- IL	03/31/2021
Garrett	Schmidt-McCormack	Full Time	Moline	49274730	Registered Pharmacy Technician- IL	03/31/2021
Mary	Brandt	Full Time	Moline	49274431	Registered Pharmacy Technician- IL	03/31/2021
Katherine	Salazar	Full Time	Moline	49274216	Registered Pharmacy Technician- IL	03/31/2021
Emma	Wiegmann	Part Time - College	Moline	49273718	Registered Pharmacy Technician- IL	03/31/2021
Zana	Danner	Part Time - College	Moline	30127771	Certified Pharmacy Technician	03/31/2022
Theo	Daggett	Full Time	Moline	49275262	Registered Pharmacy Technician- IL	03/31/2021
Isabella	Koutsopanagos	Part Time - College	Moline	49275253	Registered Pharmacy Technician- IL	03/31/2021

Madison	Dutton	Full Time	Moline	just submitted	new employee	pending
Jordan	MacNeill	Part Time - College	Moline	just submitted	new employee	pending
Alex	Pearson	Full Time	Moline	just submitted	new employee	pending
Erin	Antonson	Part Time - College	Moline	just submitted	new employee	pending
Jordan	MacNeill	Part Time - College	Moline	just submitted	new employee	pending
Shalynn	Burrage	Full Time	Moline	just submitted	new employee	pending
Katelyn	Laraja	Full Time	lowa City	3002776	new employee	pending
Safa	Gadoura	Full Time	lowa City	P2D8F8S8	Certified Pharmacy Technician	12/31/2020
Mindy	Eischeid	Full Time	lowa City	30037743	Certified Pharmacy Technician	11/15/2021
Abigail	Whitaker	Part Time - College	lowa City	30130078	Certified Pharmacy Technician	03/31/2021
Taylor	Reising	Part Time - College	lowa City	N2S5F6P4	Certified Pharmacy Technician	06/30/2022
Esnee	Belzer	Part Time - College	lowa City	30109134	Certified Pharmacy Technician	08/02/2021
Mandy	Heifman	Part Time - College	lowa City	28644	Certified Pharmacy Technician	08/31/2021
Jessica	May	Part Time - College	lowa City	30078534	Pharmacy Technician Trainee	09/30/2020
Jasmine	Howell	Part Time - College	lowa City	7585	Certified Pharmacy Technician	08/31/2022
Chi	Nesah	Part Time - College	lowa City	7320	RPH Intern	05/31/2024
Sanya	Hassan	Part Time - College	lowa City	7595	RPH Intern	05/31/2023
Jasmina	Arnaul	Part Time - College	lowa City	7531	RPH Intern	05/31/2024
Lucas	Dinh	Part Time - College	lowa City	7537	RPH Intern	05/31/2024
Matthew	Hamilton	Part Time - College	lowa City	7591	RPH Intern	05/31/2024
Emoryan	Foxe	Part Time - College	lowa City	7597	RPH Intern	05/31/2024
Travis	Johnsion	Part Time - College	lowa City	7561	RPH Intern	05/31/2024
Nicholas	Garza	Part Time - College	lowa City	7596	RPH Intern	05/31/2024
Kamel	Shahid	Part Time - College	lowa City	7558	RPH Intern	05/31/2024
Keaton	Higgins	Part Time - College	lowa City	7612	RPH Intern	05/31/2024
Reunina	Cufurovic	Part Time - College	lowa City	7546	RPH Intern	05/31/2024
Elise	Chang	Part Time - College	lowa City	7543	RPH Intern	05/31/2024
Keirstin	Broadway	Part Time - College	lowa City	7529	RPH Intern	05/31/2024
Kamyla	Vargas Freyles	Part Time - College	lowa City	7568	RPH Intern	05/31/2024
Diana	Theusch	Part Time - College	lowa City	6750	RPH Intern	05/31/2021
Ann	Mwangi	Part Time - College	lowa City	7316	RPH Intern	05/31/2023
Katlyn	Fier	Part Time - College	lowa City	7276	RPH Intern	05/31/2023
Jaywin	Patel	Part Time - College	lowa City	7429	RPH Intern	05/31/2021
Ayah	Taha	Part Time - College	lowa City	7554	RPH Intern	05/31/2024

*APPLICATION FOR CERTIFICATION AS A PROVIDER OF
INTERNET PHARMACY SERVICES*

*Addendum to Pharmacy Application
(Only required if providing internet services)*

GENERAL INFORMATION

Name of Nevada license pharmacy: divvyMED, LLC d/b/a divvyDOSE

Nevada license number: PH03440

Websites in use or intended to be used: www.divvydose.com

Affiliated websites (websites that link to or otherwise direct users to your website):

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered by NABP) certified? Please provide a copy with application. Yes ☒ No ☐

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☐ No ☐

PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:
- A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☐ No ☐
- B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☐ No ☐
- C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☐ No ☐
- D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☐ No ☐
- E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☐ No ☐
- F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☐ No ☐
- G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☐ No ☐
- H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☐ No ☐
- I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☐ No ☐
- J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☐ No ☐
3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☐ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☐ No ☐
5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☐ No ☐
6. Does the pharmacy comply with applicable federal and state laws regarding the following:
- A) To the dispensing of prescription drugs? Yes ☐ No ☐
- B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☐ No ☐
- C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs? Yes ☐ No ☐
7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☐ No ☐
8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia*, 25th edition, 2002, which is hereby adopted by reference? Yes ☐ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.


 Signature of Owner Karen Peterson, Secretary,
 DivvyMed, LLC

9/8/20
 Date

Digital Pharmacy



NABP
Accredited
Digital Pharmacy

ISSUED TO

DIVVYMED, LLC dba DIVVYDOSE on the 27 March 2020

ISSUED BY



National Association of Boards of Pharmacy

NABP is a not for profit association that protects public health by assisting its member boards of pharmacy for the purpose of protecting the public health and offers programs that promote safe pharmacy practices for the benefit of consumers.

DESCRIPTION

Digital Pharmacy Accreditation signifies to patients and payers that the pharmacy has an Internet presence and that the pharmacy meets the highest standards of pharmacy care and complies with the licensing requirements of its state and each state to which it practices pharmacy. A Digital Pharmacy Accreditation seal lets patients know that they are on a safe site. For additional information regarding the accreditation program or to identify accredited locations, please visit the Criteria link below.

CRITERIA

<https://nabp-pharmacy/programs/digital-pharmacy>

TAGS

📌 Digital-Pharmacy

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PENZO ENTERPRISES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF MAY, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PENZO ENTERPRISES, LLC" WAS FORMED ON THE TWENTY-FOURTH DAY OF NOVEMBER, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



5646044 8300

SR# 20203466193

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature of Jeffrey W. Bullock in black ink, written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 202880003

Date: 05-05-20



NABP Solutions Licensing <licensing@nabp.solutions>

NV Notice of Pending Transaction re: NR pharmacy DivvyMED LLC

NABP Solutions Licensing <licensing@nabp.solutions>
To: pharmacy@pharmacy.nv.gov
Bcc: NABP Solutions Licensing <licensing@nabp.solutions>

Wed, Jun 17, 2020 at 2:36 PM

Nevada State Board of Pharmacy,

I am writing to provide notice of a pending transaction involving Nevada nonresident pharmacy DivvyMED, LLC.

DivvyMED owns and operates a pharmacy doing business as DivvyDose located at 4300 44th Ave., Moline, IL 61265 and holds a nonresident pharmacy license in the State of Nevada, License No. PH03440. Attached please find the notice letter that details the pending transaction.

- **Current ownership.** DivvyMED, LLC (DivvyMED) is currently owned 99% by Penzo Enterprises, LLC (Penzo) and 1% by an individual owner.
- **Ownership upon change.** Upon closing the transaction, DivvyMED will continue to be owned by Penzo (which will own all 100% of DivvyMED), and OptumRx Holdings LLC will own 100% of Penzo.
- **Corporate officers, managers, and directors will change.** Other than the CEO of DivvyMED who will remain the same, the officers, directors, and managers of both DivvyMED and Penzo will change.
- **All remaining pharmacy operations and store level management will remain the same.** Specifically, the following will remain the same upon the transaction closing:
 - Corporate form of the parent Penzo;
 - Corporate form of pharmacy DivvyMED;
 - Pharmacy name;
 - Tax identification number;
 - Location;
 - NPI;
 - Service offerings;
 - Staff;
 - Pharmacist-in-charge; and
 - Chief Executive Officer

We will follow up with the required documentation for the Board's review. Please review the attached correspondence for additional detail and please do not hesitate to reach out with any questions. Thank you.

Marty

MARTY ALLAIN | Executive Director

(p) 847-261-4004

(e) marty@nabp.solutions

NABP SOLUTIONS | www.nabp.solutions

Navigating the road to compliance.



Notice of Change of Control.6.17.20_NV.pdf
262K



faegredrinker.com

Jay A. Warmuth
Partner
jay.warmuth@faegredrinker.com
+1 612 766 8856 direct

Faegre Drinker Biddle & Reath LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, Minnesota 55402
+1 612 766 7000 main
+1 612 766 1600 fax

June 17, 2020

VIA ELECTRONIC MAIL

Nevada Board of Pharmacy

Re: **Notice of Change of Control - Parent Company**
divvyMED, LLC

Dear Nevada Board of Pharmacy:

We are writing to notify you of a pending transaction involving Penzo Enterprises, LLC ("**Penzo**"), a Delaware limited liability company and parent company of divvyMED, LLC, a Delaware limited liability company (the "**Pharmacy**"). The Pharmacy (i) is a direct subsidiary of Penzo and (ii) holds the corresponding permit(s) and/or license(s) set forth on Exhibit A hereto in your state.

Please note that the operating entity of the Pharmacy will remain intact with the same tax identification number, location, NPI, pharmacist-in-charge, and the operations of the Pharmacy will remain materially the same after the transaction. Furthermore, there are no current plans to make any material change in the Pharmacy's business operations or corporate structure.

Upon the closing of the pending transaction, the Pharmacy will become an indirect, wholly-owned subsidiary of UnitedHealth Group Incorporated, a publicly traded Delaware corporation ("**UHG**"), and OptumRx Holdings, LLC, a Delaware limited liability company and an indirect wholly-owned subsidiary of UHG ("**OptumRx**") (together, the "**Acquiring Parties**"). A simplified pre- and post-closing organizational chart is attached as Exhibit B for ease of reference.

More specifically, pursuant to an Agreement and Plan of Merger dated as of June 15, 2020 (the "**Agreement**") and certain other agreements contemplated thereby, (i) Arvind Movva, an individual, will contribute his one percent (1%) ownership interest in the Pharmacy to Penzo and (ii) Dakota Merger Sub LLC, a Delaware limited liability company and a direct wholly-owned subsidiary of OptumRx ("**Merger Sub**"), will merge with and into Penzo (the "**Merger**"). Immediately upon consummation of the Merger, the separate corporate existence of Merger Sub will cease, and Penzo will continue as the surviving company and as a direct wholly-owned subsidiary of OptumRx (the "**Contemplated Transaction**"). Following the Contemplated

June 17, 2020

Transaction, the Pharmacy will remain a direct subsidiary of Penzo, Penzo will become a direct wholly-owned subsidiary of OptumRx, and UHG accordingly will become the ultimate parent company of Penzo and the Pharmacy.

The Contemplated Transaction is subject to certain customary closing conditions. There are no current plans or proposals to merge or consolidate the Pharmacy with any person or persons, or make any other material change in any of the Pharmacy's business operations or corporate structure.

Additionally, as a result of the Contemplated Transaction, the Pharmacy will undergo changes to certain executive officers and directors. We have enclosed a complete list of the anticipated executive officers and directors of the Pharmacy, which list is attached hereto as Exhibit C.

We appreciate your time and attention to this filing. Please do not hesitate to contact me at (612) 766-8856 or jay.warmuth@faegredrinker.com, or Arvind Movva at (309) 429-6276 or amovva@divvyDOSE.com with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Jay A. Warmuth", with a stylized flourish at the end.

Jay A. Warmuth

Enclosures

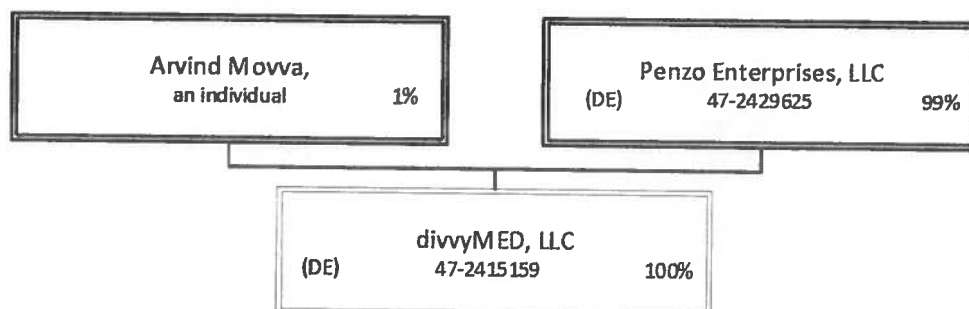
Exhibit A
Pharmacy Permit(s) and License(s)

Nevada Nonresident Pharmacy License

PH03440

Exhibit B Organization Chart

Simplified Pre-Closing Organizational Chart



June 17, 2020

Simplified Post-Closing Organizational Chart

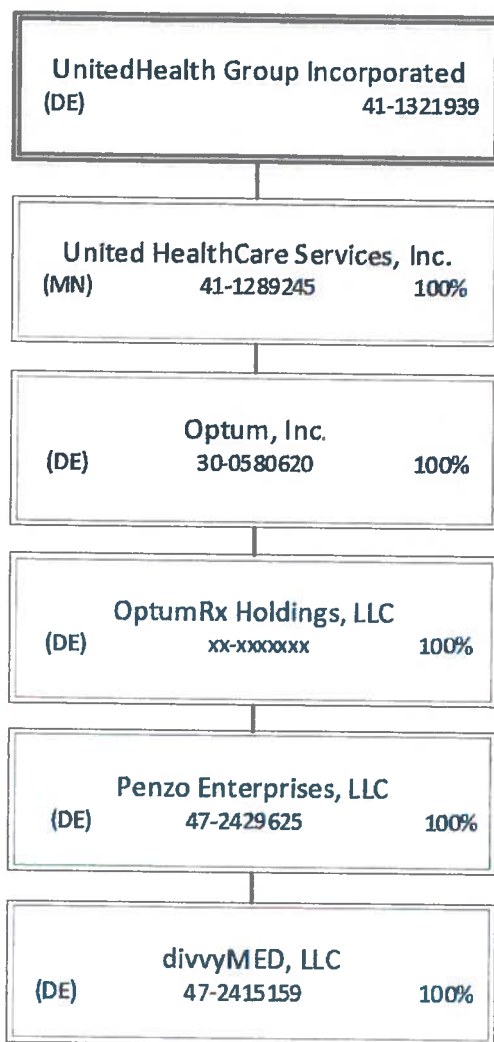


Exhibit C

Post-Closing Executive Officers and Directors

The Pharmacy will have the following post-closing executive officers and directors:

Managers	
Name	Title
Grosklags, Jeffrey David	Manager
Prince, John Michael	Manager

Officers	
Name	Title
Movva, Arvind	Chief Executive Officer
Prince, John Michael	President
Peterson, Karen Elizabeth	Secretary
Gill, Peter Marshall	Treasurer
Lang, Heather Anastasia	Assistant Secretary
Oberg, David John	Assistant Secretary

4H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership - Pages 1,2,6,8

☒ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: AG Pharmacy LLC dba Eagle Pharmacy

Physical Address: 3322 Holland Road Ste A Virginia Beach VA 23452

Mailing Address: 3322 Holland Road Ste A

City: Virginia Beach State: VA Zip Code: 23452

Telephone: 800-828-9469 Fax: 757-689-4339

Toll Free Number: 800-828-9469 (Required per NAC 639.708)

E-mail: vabeachrxpharmacy@gmail.com Website: N/A

Managing Pharmacist: Adrienne M. Gautier License Number: 0202217377

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☒ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting.

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Adrienne Gautier

Original Signature of Person Authorized to Submit Application, no copies or stamps

Adrienne M. Gautier

Print Name of Authorized Person

Date

7/21/2020

Page 2

Board Use Only

Date Processed: _____

Amount:

500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: Delaware

Parent Company if any: _____

Mailing Address: 3322 Holland Road Ste ACity: Virginia BeachState: VAZip: 23452Telephone: 800-828-9469Fax: 757-689-4339Contact Person: Adrienne M. Gautier

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Adrienne M. GautierCottage Dr Luling LA 70070

Name

Address

b) _____

Name

Address

c) _____

Name

Address

d) _____

Name

Address

2) Provide the number of shares issued by the corporation. 1003) What was the price paid per share? .014) What date did the corporation actually receive the cash assets? 06/21/2019

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 9 am 6 pmSaturday - am - pmSunday - am - pm24 Hours -

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Adrienne M. Gautier

Responsible Person of AG Pharmacy LLC dba Eagle Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Adrienne M. Gautier
Original Signature of Person Authorized to Submit Application, no copies or stamps

Adrienne M. Gautier

Print Name of Authorized Person

7/21/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF VIRGINIA)
VIRGINIA BEACH COUNTY) ss.)

I, Adrienne M. Gautier, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner for AG Pharmacy LLC dba Eagle Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

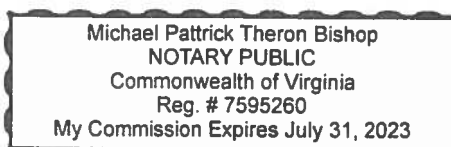
FURTHER AFFIANT SAYETH NOT.

I, Adrienne M. Gautier, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Adrienne M. Gautier
 Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
21st day of JULY, 2020.

[Signature]
 NOTARY PUBLIC





Virginia Department of Health Professions License Lookup

Current as of 07/10/2020 14:59

License Information

License Number	0201004915
Occupation	Pharmacy
Name	Eagle Pharmacy
Address	3322 Holland Road, Suite A Virginia Beach, VA 23452
Initial License Date	08/15/2019
Expire Date	04/30/2021
License Status	Current Active
Additional Public Information*	No

[Back to License Lookup Result](#)

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.

[Back to License Lookup](#)

LISTING OF SECURITY FEATURES ON REVERSE SIDE

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Caroline D. Juran
Executive Director
(804) 367-4456

BOARD OF PHARMACY

Pharmacy Permit

Eagle Pharmacy

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
www.dhp.virginia.gov/pharmacy

3322 Holland Road, Suite A
Virginia Beach VA 23452

Number
0201004915

Pharmacist in Charge
Adrienne Margaret Gautier
0202217377

To verify the status of this registration, visit our website www.dhp.virginia.gov, which is a primary source verification of the credential issued by the Commonwealth of Virginia. To File a Complaint About a Licensee, Call: 1-800-533-1560



STATE CORPORATION COMMISSION

Richmond, June 21, 2019

This is to certify that the certificate of organization of

AG PHARMACY LLC

was this day issued and admitted to record in this office and that the said limited liability company is authorized to transact its business subject to all Virginia laws applicable to the company and its business. Effective date: June 21, 2019



State Corporation Commission
Attest:

Joel H. Peck
Clerk of the Commission

Owner Information:**Adrienne M. Gautier****' Cottage Dr****Luling, LA 70070****DOB .**

41



RECEIVED

7-23-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)

Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership - Pages 1,2,6,8

☐ Non Publicly Traded Corporation – Pages 1,2,4,8

☒ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Galaxy Pharmacy

Physical Address: 1245 E Anaheim st

Mailing Address: same as Above

City: Long Beach State: CA Zip Code: 90813

Telephone: (562) 599-1301 Fax: (562) 599-1305

Toll Free Number: 833-613-1231 (Required per NAC 639.708)

E-mail: Galaxypharmacy@gmail.com Website: N/A

Managing Pharmacist: Kenny Vo License Number: 56364

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
- ☐ ☒ Hospital (# beds _____)
- ☐ ☒ Internet
- ☐ ☒ Nuclear
- ☐ ☒ Ambulatory Surgery Center
- ☐ ☒ Community
- ☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
- ☐ ☒ Parenteral **
- ☐ ☒ Parenteral (outpatient)
- ☐ ☒ Outpatient/Discharge
- ☒ ☐ Mail Service
- ☐ ☒ Long Term Care
- ☐ ☒ Sterile Compounding **
- ☐ ☒ Non Sterile Compounding
- ☐ ☒ Mail Service Sterile Compounding **
- ☒ ☐ Other Services: limited Retail
non-control mail service only

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Authorized Person

Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Kenny Vo
 Business Name: Galaxy Pharmacy
 Current Business Address: 1295 E. Anaheim St
 City: Long Beach State: CA Zip Code: 90813
 Telephone: (562) 599-1301 Fax: (562) 599-1305

List any physician shareholders and percentage of ownership.

Name: Kenny Vo %: 100
 Name: _____ %: _____
 Name: _____ %: _____
 Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday 9 am 2 pm
 Sunday — am — pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Kenny Vo
Responsible Person of Galaxy Pharmacy
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Kenny Vo
Print Name of Authorized Person

Date

7/15/2020

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
Los Angeles) ss. COUNTY)

I, Kenny Vo, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the owner for Galaxy Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Kenny Vo, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name 

SUBSCRIBED AND SWORN TO
 before me, a notary public this
16 day of May, 2020.


 NOTARY PUBLIC





Secretary of State Certificate of Status

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

Entity Name: GALAXY PHARMACY, INC
File Number: C3653599
Registration Date: 03/06/2014
Entity Type: DOMESTIC STOCK CORPORATION
Jurisdiction: CALIFORNIA
Status: ACTIVE (GOOD STANDING)

As of July 14, 2020 (Certification Date), the entity is authorized to exercise all of its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.



IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 15, 2020.

A handwritten signature in black ink, reading "Alex Padilla".

ALEX PADILLA
Secretary of State

Certificate Verification Number: BY6B6VY

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at bebizfile.sos.ca.gov/certification/index.



State of California

Secretary of State

S

Statement of Information

(Domestic Stock and Agricultural Cooperative Corporations)

FEES (Filing and Disclosure): \$25.00.

If this is an amendment, see instructions.

IMPORTANT – READ INSTRUCTIONS BEFORE COMPLETING THIS FORM

1 CORPORATE NAME

GALAXY PHARMACY, INC

2 CALIFORNIA CORPORATE NUMBER

C3653599

This Space for Filing Use Only

No Change Statement (Not applicable if agent address of record is a P.O. Box address. See instructions.)

3 If there have been any changes to the information contained in the last Statement of Information filed with the California Secretary of State, or no statement of information has been previously filed, this form must be completed in its entirety.

☐ If there has been no change in any of the information contained in the last Statement of Information filed with the California Secretary of State, check the box and proceed to Item 17

Complete Addresses for the Following (Do not abbreviate the name of the city. Items 4 and 5 cannot be P.O. Boxes.)

4 STREET ADDRESS OF PRINCIPAL EXECUTIVE OFFICE

1295 E. ANAHEIM ST

CITY

LONG BEACH

STATE

CA

ZIP CODE

90813

5 STREET ADDRESS OF PRINCIPAL BUSINESS OFFICE IN CALIFORNIA, IF ANY

1295 E. ANAHEIM ST

CITY

LONG BEACH

STATE

CA

ZIP CODE

90813

6 MAILING ADDRESS OF CORPORATION, IF DIFFERENT THAN ITEM 4

CITY

STATE

ZIP CODE

Names and Complete Addresses of the Following Officers (The corporation must list these three officers. A comparable title for the specific officer may be added, however, the preprinted titles on this form must not be altered.)

7 CHIEF EXECUTIVE OFFICER/

ADDRESS

KENNY T. VO

TACOMA ST

CITY

GARDEN GROVE

STATE

CA

ZIP CODE

8 SECRETARY

ADDRESS

KENNY T. VO

TACOMA ST

CITY

GARDEN GROVE

STATE

CA

ZIP CODE

9 CHIEF FINANCIAL OFFICER/

ADDRESS

KENNY T. VO

TACOMA ST

CITY

GARDEN GROVE

STATE

CA

ZIP CODE

Names and Complete Addresses of All Directors, Including Directors Who are Also Officers (The corporation must have at least one director. Attach additional pages, if necessary.)

10 NAME

KENNY T. VO

ADDRESS

TACOMA ST

CITY

GARDEN GROVE

STATE

CA

ZIP CODE

11 NAME

ADDRESS

CITY

STATE

ZIP CODE

12 NAME

ADDRESS

CITY

STATE

ZIP CODE

13 NUMBER OF VACANCIES ON THE BOARD OF DIRECTORS, IF ANY

Agent for Service of Process If the agent is an individual, the agent must reside in California and Item 15 must be completed with a California street address, a P.O. Box address is not acceptable. If the agent is another corporation, the agent must have on file with the California Secretary of State a certificate pursuant to California Corporations Code section 1505 and Item 15 must be left blank.

14 NAME OF AGENT FOR SERVICE OF PROCESS

KENNY T. VO

15 STREET ADDRESS OF AGENT FOR SERVICE OF PROCESS IN CALIFORNIA, IF AN INDIVIDUAL

TACOMA ST

GARDEN GROVE

STATE

CA

ZIP CODE

Type of Business

16 DESCRIBE THE TYPE OF BUSINESS OF THE CORPORATION

RETAIL SALES - PHARMACY

17 BY SUBMITTING THIS STATEMENT OF INFORMATION TO THE CALIFORNIA SECRETARY OF STATE, THE CORPORATION CERTIFIES THE INFORMATION CONTAINED HEREIN, INCLUDING ANY ATTACHMENTS, IS TRUE AND CORRECT

DATE

KENNY T. VO

CEO

TYPE/PRINT NAME OF PERSON COMPLETING FORM

TITLE

SIGNATURE

SI-200 (REV 01/2013)

APPROVED BY SECRETARY OF STATE



State of California Secretary of State

S

Statement of Information

(Domestic Stock and Agricultural Cooperative Corporations)

FEES (Filing and Disclosure): \$25.00.

If this is an amendment, see instructions.

IMPORTANT – READ INSTRUCTIONS BEFORE COMPLETING THIS FORM

FV33038

FILED

In the office of the Secretary of State
of the State of California

MAR-16 2018

1. CORPORATE NAME

GALAXY PHARMACY, INC

2. CALIFORNIA CORPORATE NUMBER

C3653599

This Space for Filing Use Only

No Change Statement (Not applicable if agent address of record is a P.O. Box address. See instructions.)

3. If there have been any changes to the information contained in the last Statement of Information filed with the California Secretary of State, or no statement of information has been previously filed, this form must be completed in its entirety.

☒ If there has been no change in any of the information contained in the last Statement of Information filed with the California Secretary of State, check the box and proceed to Item 17.

Complete Addresses for the Following (Do not abbreviate the name of the city. Items 4 and 5 cannot be P.O. Boxes.)

4. STREET ADDRESS OF PRINCIPAL EXECUTIVE OFFICE	CITY	STATE	ZIP CODE
5. STREET ADDRESS OF PRINCIPAL BUSINESS OFFICE IN CALIFORNIA, IF ANY	CITY	STATE	ZIP CODE
6. MAILING ADDRESS OF CORPORATION, IF DIFFERENT THAN ITEM 4	CITY	STATE	ZIP CODE

Names and Complete Addresses of the Following Officers (The corporation must list these three officers. A comparable title for the specific officer may be added; however, the preprinted titles on this form must not be altered.)

7. CHIEF EXECUTIVE OFFICER/	ADDRESS	CITY	STATE	ZIP CODE
8. SECRETARY	ADDRESS	CITY	STATE	ZIP CODE
9. CHIEF FINANCIAL OFFICER/	ADDRESS	CITY	STATE	ZIP CODE

Names and Complete Addresses of All Directors, Including Directors Who are Also Officers (The corporation must have at least one director. Attach additional pages, if necessary.)

10. NAME	ADDRESS	CITY	STATE	ZIP CODE
11. NAME	ADDRESS	CITY	STATE	ZIP CODE
12. NAME	ADDRESS	CITY	STATE	ZIP CODE

13. NUMBER OF VACANCIES ON THE BOARD OF DIRECTORS, IF ANY:

Agent for Service of Process If the agent is an individual, the agent must reside in California and Item 15 must be completed with a California street address, a P.O. Box address is not acceptable. If the agent is another corporation, the agent must have on file with the California Secretary of State a certificate pursuant to California Corporations Code section 1505 and Item 15 must be left blank.

14. NAME OF AGENT FOR SERVICE OF PROCESS

15. STREET ADDRESS OF AGENT FOR SERVICE OF PROCESS IN CALIFORNIA, IF AN INDIVIDUAL CITY STATE ZIP CODE

Type of Business

16. DESCRIBE THE TYPE OF BUSINESS OF THE CORPORATION

17. BY SUBMITTING THIS STATEMENT OF INFORMATION TO THE CALIFORNIA SECRETARY OF STATE, THE CORPORATION CERTIFIES THE INFORMATION CONTAINED HEREIN, INCLUDING ANY ATTACHMENTS, IS TRUE AND CORRECT.

03/16/2018

KENNY VO

CEO

DATE

TYPE/PRINT NAME OF PERSON COMPLETING FORM

TITLE

SIGNATURE

Galaxy Pharmacy

1295 E Anaheim St , Long Beach, CA 90813

July 15, 2020

To: Nevada State Board of Pharmacy

Re: Galaxy Pharmacy

The purpose of this letter is to clarify and facilitate the approval process for Galaxy Pharmacy to obtain licensure for state of Nevada. Galaxy pharmacy operates as a local community pharmacy in Long Beach, California. Galaxy is not a mail order pharmacy. On occasions, our customers relocate and or travels. We are requesting Nevada Board of Pharmacy to grant us licensure to help us facilitate and optimize our patient care without interruptions.

Sincerely,



Kenny Vo, CEO

Galaxy Pharmacy

Renewal Certificate

Retail Pharmacy Permit

BOARD OF PHARMACY 195
1625 NORTH MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834
(916) 574-7900

LICENSE NO. PHY 52022
RECEIPT NO. 92180424

VALID UNTIL OCTOBER 01, 2020

GALAXY PHARMACY
1295 E ANAHEIM ST
LONG BEACH CA 90813

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (12/31/05) PHY

Remove your new Pocket License
from the receipt portion and keep
on your person.

Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

CUT HERE



CUT HERE
Board of Pharmacy
2720 Gateway Oaks Drive,
Suite 100
Sacramento, CA 95833
(916) 518-3100



CUT HERE

I M P O R T A N T

REGISTERED PHARMACIST

LICENSE NO RPH 56364

EXPIRATION 04/30/22

KENNY THAN VO
1295 E. ANAHEIM ST
LONG BEACH CA 90813

1. Please include your License Number with any correspondence to this office.
2. Notify the Board of Pharmacy of any name or address change in writing.
3. Report any loss immediately in writing to the Board
4. Please sign and carry the Pocket License with you.
KENNY THAN VO

Signature _____

RECEIPT NO

00830360

LICENSE NO

EXPIRATION

RECEIPT NO

RPH 56364

04/30/22

00830360

Please retain this receipt in a safe location.

PPHRPH 09/30/19

Candy Nally

From: Galaxy Pharmacy <galaxypharmacy1@gmail.com>
Sent: Tuesday, August 18, 2020 10:03 AM
To: Candy Nally
Subject: Re: Toll Free Number

Goodmorning Candy, sorry about that our toll-free number is **1(833)613-1231** if there is anything else that we need to provide? Thank you so much.

On Wed, Aug 12, 2020 at 3:52 PM Candy Nally <cnally@pharmacy.nv.gov> wrote:

We are in receipt of your out-of-state pharmacy application. Nevada law NAC 639.708 requires a toll free number for all out-of-state pharmacies. Please provide the required toll free number. The application cannot be placed on an agenda until the toll free number has been received.

If you have any questions, please feel free to contact us.

Thanks,

Candy M. Nally

Licensing Specialist

Nevada State Board of Pharmacy

cnally@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

4J

8-11-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,7

☒ Partnership – Pages 1,2,5,7

☐ Non Publicly Traded Corporation – Pages 1,2,4,7

☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: LA Pharmacy LLC

Physical Address: 1048 South Garfield Avenue, Suite 101, Alhambra, CA 91801

Mailing Address: 1048 South Garfield Avenue, Suite 101

City: Alhambra State: CA Zip Code: 91801

Telephone: 626-281-7870 Fax: 626-281-7020

Toll Free Number: 888-700-1048 (Required per NAC 639.708)

E-mail: pharmacyLA@truepill.com Website: N/A

Managing Pharmacist: Thuy Nguyen License Number: CA # 66092

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☐ ☐ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☐ Other Services: _____

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Siddharth Viswanathan

Print Name of Authorized Person

Date

2/20/2020

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIPGeneral ☒ Limited ☐

Partnership Name: LA Pharmacy LLC

Mailing Address: 1048 South Garfield Avenue, Suite 101

City: Alhambra State: CA Zip Code: 91801

Telephone Number: 626-281-7870 Fax Number: 626-281-7020

Contact Person: Siddharth Viswanathan

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
<u>Truepill Inc</u>	<u>G</u>	<u>100%</u>
<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>

List names of 4 largest partners and percentage of ownership:

Name: Truepill Inc %: 100%

Name: %:

Name: %:

Name: %:

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: %:

Name: %:

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday closed am pm

Sunday closed am pm 24 Hours

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Siddharth Viswanathan

Responsible Person of LA Pharmacy LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Siddharth Viswanathan

Print Name of Authorized Person

2/20/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF _____)
 _____) ss.
 _____ COUNTY)

I, Siddharth Viswanathan, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Officer for LA Pharmacy LLC (the

Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Siddharth Viswanathan, do hereby swear under penalty of perjury that the assertions of this affidavit are true.


 Name _____

SUBSCRIBED AND SWORN TO
 before me, a notary public this
 ____ day of _____, 20____.

See Attached Notary Certificate

 NOTARY PUBLIC

CALIFORNIA JURAT WITH AFFIANT STATEMENT**GOVERNMENT CODE § 8202**

- ☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1 _____
 2 _____
 3 _____
 4 _____
 5 _____
 6 _____

Signature of Document Signer No. 1 Signature of Document Signer No. 2 (if any)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of San Mateo

Subscribed and sworn to (or affirmed) before me

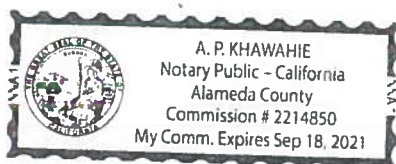
on this 26 day of February, 20 26
 by _____ Date _____ Month _____ Year _____

(1) Siddharth Viswanathan

(and (2) _____),
 Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence
 to be the person(s) who appeared before me.

Signature _____
 Signature of Notary Public



Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Ny out of State Pharmacy App. Document Date: 2/26/2026

Number of Pages: _____ Signer(s) Other Than Named Above: _____

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LA PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF JUNE, A.D. 2020.



7527289 8300

SR# 20205367738

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JB", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 203056142

Date: 06-05-20



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



July 10, 2020

TRUEPILL
ATTN: LOAN NGUYEN
3121 DIABLO AVE
HAYWARD CA 94545

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: LA PHARMACY LLC

License Type: PHARMACY

License Number: PHY 57474

Status: ACTIVE

Issue Date: 12/02/2019

Expiration Date: 12/01/2020

Address of Record: 1048 S GARFIELD AVE STE 101 ALHAMBRA CA 91801

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Barbera Schleicher
Public Inquiry Analyst
(916) 518-3081
Barbera.Schleicher@dca.ca.gov



Visit our website at www.pharmacy.ca.gov



Board of Pharmacy

ORIGINAL CERTIFICATE



Retail Pharmacy Permit

LICENSE NO. PHY 57474

ISSUE DATE DECEMBER 02, 2019

LA PHARMACY LLC

1048 S GARFIELD AVE STE 101
ALHAMBRA CA 91801

The above is licensed with the State Board of Pharmacy as a Limited Liability Company.

LIMITED LIABILITY COMPANY
THUY NGUYEN

PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL DECEMBER 01, 2020

RECEIPT NUMBER 00000000

This original license must be kept for the life of the license and posted in public view.

In accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

4K


RECEIVED
8/18/2020
NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,7

☒ Partnership – Pages 1,2,5,7

☐ Non Publicly Traded Corporation – Pages 1,2,4,7

☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

 Pharmacy Name: Magnolia Pharmacy

 Physical Address: 2620 Bethelview Dr. STE 100

 Mailing Address: SAME

 City: CUMMING State: GA Zip Code: 30040

 Telephone: 404 476 2273 Fax: 678-807-8812

 Toll Free Number: 800-361-2273 (Required per NAC 639.708)

 E-mail: _____ Website: MYMAGNOLIARX.COM

 Managing Pharmacist: LINDSEY TESSEYMAN License Number: RPH#27175
TYPE OF PHARMACY
AND
SERVICES PROVIDED

Yes/No

☒ ☐ Retail

☐ ☒ Hospital (# beds _____)

☐ ☒ Internet

☐ ☒ Nuclear

☐ ☒ Ambulatory Surgery Center

☒ ☐ Community

☒ ☐ Other: Mail Order

All boxes must be checked

For the application to be complete

Yes/No

☐ ☒ Off-site Cognitive Services

☐ ☒ Parenteral **

☐ ☒ Parenteral (outpatient)

☐ ☒ Outpatient/Discharge

☒ ☐ Mail Service

☐ ☐ Long Term Care

☐ ☒ Sterile Compounding **

☐ ☒ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding **

☐ ☐ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Sarah Roche

Print Name of Authorized Person

8/6/2020

Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP

General _____

Limited XPartnership Name: MAGNOLIA PHARMACY SERVICES, LLCMailing Address: 2620 Bethelview DR STE 100City: CUMMING State: GA Zip Code: 30040Telephone Number: 404 476 2273 Fax Number: 678 807 8812Contact Person: SARAH ROCHE

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
 Use separate sheet if necessary

Name	G or L	Percentage
LIST ATTACHED		
10 TOTAL PARTNERS		

List names of 4 largest partners and percentage of ownership:

Name: DOMENIC GATTO %: 36Name: SHEILA CHAPMAN %: 14Name: DAVID CHAPMAN %: 12Name: DAN CHAPMAN %: 12

List any physician shareholders and percentage of ownership.

Name: NONE %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 8:30 am 6 pmSaturday 9 am 12 pmSunday — am — pm24 Hours ON call

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Sarah Roche

Responsible Person of Magnolia Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

SBRoe

Original Signature of Person Authorized to Submit Application, no copies or stamps

Sarah Roche

Print Name of Authorized Person

8/6/2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Georgia)
Forsyth COUNTY) ss.)

I, Sarah Roche, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the VP operations for Magnolia Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

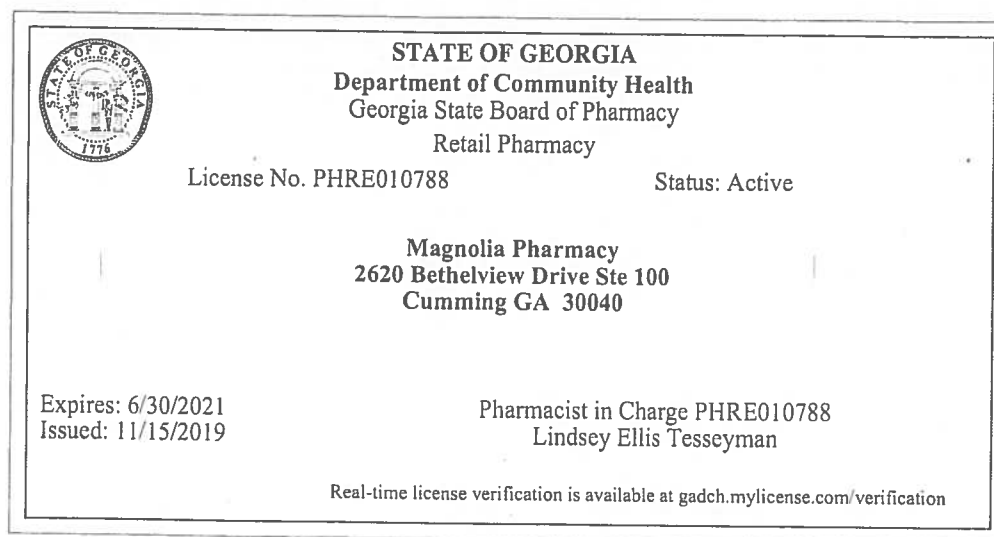
I, Sarah Roche, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
 before me, a notary public this

10th day of August, 2020.

Melody Ann Mattox
 NOTARY PUBLIC

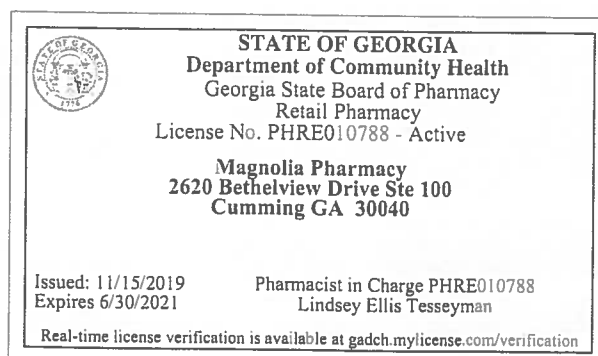
Melody Ann Mattox
 Name
Melody Ann Mattox
 Melody Ann Mattox
 NOTARY PUBLIC
 Forsyth County
 State of Georgia
 My Comm. Expires December 8, 2022



Above is your wall license to practice your profession. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.

Please notify the Board if you have a change of address or otherwise need to update your records.





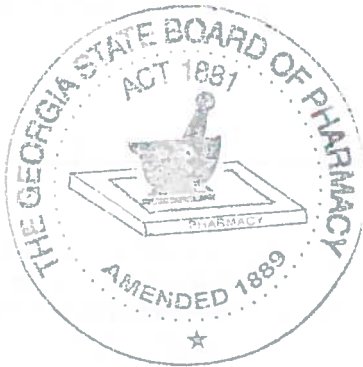
GEORGIA BOARD OF PHARMACY

Date Mailed: January 7, 2020

Full Name: Magnolia Pharmacy	Date Issued: 11/15/2019
Type of License: Retail Pharmacy	License #: PHRE010788
Obtained By: Application	Expiration Date: 06/30/2021
License Status: Active	Highest Degree:
Public Board Orders: none	Profession: Pharmacy
Schools:	

VERIFICATION OF LICENSURE

The information above is the only licensure certification information provided by this Division. If other information is needed, it must be obtained from the above-named individual or the agency or institution which initially generated the information. If this verification indicates that a board order exists, please visit our website at <https://gadch.mylicense.com/verification/Search.aspx?facility=N> to obtain a copy of the board order.



Tanja D. Battle

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Control Number : 18117447

STATE OF GEORGIA**Secretary of State**

Corporations Division

313 West Tower

2 Martin Luther King, Jr. Dr.

Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

Magnolia Pharmacy Services, LLC

a Domestic Limited Liability Company

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number : 19479917
Date Inc/Auth/Filed: 09/19/2018
Jurisdiction : Georgia
Print Date : 08/06/2020
Form Number : 211

*Brad Raffensperger*

Brad Raffensperger
Secretary of State

Control Number : 18117447

STATE OF GEORGIA

Secretary of State
Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFIED COPY

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that the attached documents are true and correct copies of documents filed with the Corporations Division of the Office of the Secretary of State of Georgia under the name of

Magnolia Pharmacy Services, LLC
a Domestic Limited Liability Company

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence of the existence or nonexistence of the facts stated herein.

Docket Number : 19479963
Date Inc/Auth/Filed: 09/19/2018
Jurisdiction : Georgia
Print Date : 08/06/2020
Form Number : 215



A handwritten signature in cursive script that reads 'Brad Raffensperger'.

Brad Raffensperger
Secretary of State

Control Number : 18117447

STATE OF GEORGIA**Secretary of State****Corporations Division****313 West Tower****2 Martin Luther King, Jr. Dr.****Atlanta, Georgia 30334-1530****CERTIFICATE OF ORGANIZATION**

I, **Brian P. Kemp**, the Secretary of State and the Corporation Commissioner of the State of Georgia, hereby certify under the seal of my office that

Magnolia Pharmacy Services, LLC**a Domestic Limited Liability Company**

has been duly organized under the laws of the State of Georgia on **09/19/2018** by the filing of articles of organization in the Office of the Secretary of State and by the paying of fees as provided by Title 14 of the Official Code of Georgia Annotated.

WITNESS my hand and official seal in the City of Atlanta
and the State of Georgia on **10/01/2018**.



A handwritten signature in black ink, appearing to read 'B: P. Kemp', written in a cursive style.

Brian P. Kemp
Secretary of State

ARTICLES OF ORGANIZATION

Electronically Filed
 Secretary of State
 Filing Date: 9/19/2018 10:57:39 AM

BUSINESS INFORMATION

CONTROL NUMBER 18117447
BUSINESS NAME Magnolia Pharmacy Services, LLC
BUSINESS TYPE Domestic Limited Liability Company
EFFECTIVE DATE 09/19/2018

PRINCIPAL OFFICE ADDRESS

ADDRESS Peachtree Parkway, E St Cumming, GA, , USA

REGISTERED AGENT

NAME	ADDRESS	COUNTY
David Chapman	Peachtree Parkwa USA	Cumming, GA, , Forsyth

ORGANIZER(S)

NAME	TITLE	ADDRESS
Robert J Kaufman	ORGANIZER	Roswell Road Atlanta, GA, USA

OPTIONAL PROVISIONS

N/A

AUTHORIZER INFORMATION

AUTHORIZER SIGNATURE Robert J. Kaufman
AUTHORIZER TITLE Organizer

STATE OF GEORGIA

Secretary of State

Corporations Division

313 West Tower

2 Martin Luther King, Jr. Dr.

Atlanta, Georgia 30334-1530

Annual Registration

Electronically Filed

Secretary of State

Filing Date: 05/06/2019 14:05:24

BUSINESS INFORMATION

BUSINESS NAME : Magnolia Pharmacy Services, LLC
 CONTROL NUMBER : 18117447
 BUSINESS TYPE : Domestic Limited Liability Company

BUSINESS INFORMATION CURRENTLY ON FILE

PRINCIPAL OFFICE ADDRESS : Peachtree Parkway, Bu , Suit Cumming, GA, , USA
 REGISTERED AGENT NAME : David Chapman
 REGISTERED OFFICE ADDRESS : Peachtree Parkway T Cumming, GA, I, USA
 REGISTERED OFFICE COUNTY : Forsyth

UPDATES TO ABOVE BUSINESS INFORMATION

PRINCIPAL OFFICE ADDRESS : Peachtree Parkway, B , Su , Cumming, GA. USA
 REGISTERED AGENT NAME : David Chapman
 REGISTERED OFFICE ADDRESS : Peachtree Parkwa 3T Cumming, GA. I, USA
 REGISTERED OFFICE COUNTY : Forsyth

AUTHORIZER INFORMATION

AUTHORIZER SIGNATURE : David Chapman
 AUTHORIZER TITLE : Organizer

STATE OF GEORGIA

Secretary of State

Corporations Division

313 West Tower

2 Martin Luther King, Jr. Dr.

Atlanta, Georgia 30334-1530

Annual Registration

Electronically Filed

Secretary of State

Filing Date: 01/09/2020 13:48:17

BUSINESS INFORMATION

BUSINESS NAME : Magnolia Pharmacy Services, LLC
 CONTROL NUMBER : 18117447
 BUSINESS TYPE : Domestic Limited Liability Company
 ANNUAL REGISTRATION PERIOD : 2020

BUSINESS INFORMATION CURRENTLY ON FILE

PRINCIPAL OFFICE ADDRESS Peachtree Parkway, l Su Cumming, G/ USA
 REGISTERED AGENT NAME : David Chapman
 REGISTERED OFFICE ADDRESS Peachtree Parkway l S Cumming, GA USA
 REGISTERED OFFICE COUNTY : Forsyth

UPDATES TO ABOVE BUSINESS INFORMATION

PRINCIPAL OFFICE ADDRESS Bethelview l , Cumming, GA , USA
 REGISTERED AGENT NAME : David Chapman
 REGISTERED OFFICE ADDRESS Peachtree Parkway l ST umming, GA, , USA
 REGISTERED OFFICE COUNTY : Forsyth

AUTHORIZER INFORMATION

AUTHORIZER SIGNATURE : sheila chapman
 AUTHORIZER TITLE : Organizer

4L

RECEIVED7/30/2020**NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8☐ Partnership - Pages 1,2,6,8☒ Non Publicly Traded Corporation – Pages 1,2,4,8☐ Sole Owner – Pages 1,2,7,8**GENERAL INFORMATION to be completed by all types of ownership**Pharmacy Name: MedWiseRxPhysical Address: 2202 N Forbes Blvd, Suite 252Mailing Address: 2202 N Forbes Blvd, Suite 252City: Tucson State: AZ Zip Code: 85745Telephone: (520) 526-7822 Fax: (520) 372-7881Toll Free Number: (844) 866-3735 (Required per NAC 639.708)E-mail: mwr-tuc@trhc.com Website: sinfoniarx.comManaging Pharmacist: Kwyn Morales License Number: S017224**TYPE OF PHARMACY AND****SERVICES PROVIDED**

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☒ ☐ Other: Consulting/non-dispensing

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☐ ☒ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☒ ☐ Other Services: Medication Therapy Mgmt

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

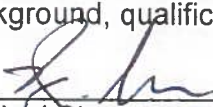
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Brian W. Adams

Print Name of Authorized Person

Date

2/14/20

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: Tabula Rasa HealthCare, Inc.Mailing Address: 228 Strawbridge Dr., Suite 100City: Moorestown State: NJ Zip: 08057Telephone: 866-648-2767 Fax: (856) 273-0254Contact Person: Richard Greene, VP Regulatory Affairs

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

Tabula Rasa HealthCare Group, Inc. owns 100% of the pharmacy called MedWiseRx

a) 228 Strawbridge Dr, Suite 100; Moorestown, NJ 08057

Name

Address

b)

Name

Address

c)

Name

Address

d)

Name

Address

- 2) Provide the number of shares issued by the corporation.
- 100

- 3) What was the price paid per share?
- \$0.0001 per value per share

- 4) What date did the corporation actually receive the cash assets?
- 6/30/2014

- 5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: Name: %: **Hours of Operation for the pharmacy:**Monday thru Friday 8:00 am 5:30 pmSaturday 9:00 am 12:00 pmSunday Closed am pm24 Hours A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA


I, Brian W. Adams

Responsible Person of TRHC OpCo, Inc. dba MedWiseRx

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Brian W. Adams

Print Name of Authorized Person

7/14/20
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF New Jersey)
) ss.
Burlington COUNTY)

I, Brian W. Adams, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary/CFO for MedWiseRx (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

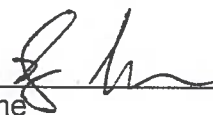
3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

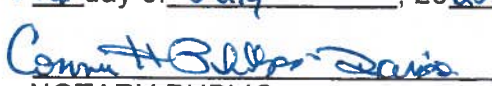
4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Brian W. Adams, do hereby swear under penalty of perjury that the assertions of this affidavit are true.


 Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
14th day of July, 2020.

 NOTARY PUBLIC

CONNIE H. PHILLIPS-DAVIS
 NOTARY PUBLIC NEW JERSEY
 Comm # 218667
 My Commission Expires Feb. 27, 2021

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TABULA RASA HEALTHCARE GROUP, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF JULY, A.D. 2020.



4674249 8300

SR# 20206379304

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature of Jeffrey W. Bullock in black ink, written over a horizontal line.

Jeffrey W. Bullock, Secretary of State

Authentication: 203339011

Date: 07-23-20



ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
<http://www.azpharmacy.gov>

Receipt Date: 01/24/2020
Receipt Number: 202081168
Receipt Amount \$: 480.00

Pharmacy - Limited Service

PERMIT NO
Y008306

EXPIRES
10/31/2021

Issued to : MedWiseRx
TRHC OpCo, Inc.
228 STRAWBRIDGE DRIVE SUITE 100
MOORESTOWN, NJ 08057

MedWiseRx
2202 N. FORBES BLVD SUITE 252
TUCSON, AZ 85745


EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749



WALLET CARD

NAME : TRHC OpCo, Inc.
LICENSE NUMBER : Y008306
EXPIRES : 10/31/2021

<http://www.azpharmacy.gov>

- Your license must be available for inspections during business hours.
- Permit holder(s) must display permit in the location to which it is issued.
- Please note it is your responsibility to keep this license/permit current.

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C. R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.



Arizona State Board of Pharmacy

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007

Mailing Address: P.O. Box 18520, Phoenix, AZ 85005

(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/permit but serves as the primary source of verification.

Name :	MedWiseRx
Address :	2202 N. Forbes Blvd Suite 252 Tucson AZ 85745
License No :	Y008306
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	03/16/2020
Expiration Date :	10/31/2021
Status :	OPEN
Discipline :	No

A handwritten signature in cursive script, reading "Kam Gandhi".

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 03/16/2020

AZCensus2020 (<https://azcensus2020.gov/>)

Visit OpenBooks (<https://openbooks.az.gov>)

Ombudsman-Citizens Aide (<https://www.azoca.gov>)

Get the facts on COVID-19 (<https://azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-home>)

AZ.Gov (<https://az.gov/search/>)



(<https://az.gov>)



(/)

Arizona State Board of Pharmacy (/)

Protects the health, safety and welfare of the citizens of Arizona

Search



Online Verification

The Arizona State Board of Pharmacy no longer provides hardcopy verifications of licensure, however we are still able to offer this service via our website. Please choose from the following links to verify applications, licenses, and permits:

[Click here to verify the status of an application \(https://azbop.igovsolution.net/online/Lookups/Application_StatusCheck.aspx\)](https://azbop.igovsolution.net/online/Lookups/Application_StatusCheck.aspx)

[Click here to verify a license \(https://azbop.igovsolution.net/online/Lookups/AZIndividual_Lookup.aspx\)](https://azbop.igovsolution.net/online/Lookups/AZIndividual_Lookup.aspx)

[Click here to verify a permit \(https://azbop.igovsolution.net/online/Lookups/AZBusiness_Lookup.aspx\)](https://azbop.igovsolution.net/online/Lookups/AZBusiness_Lookup.aspx)

Pursuant to A.R.S. § 32-3214(C), a person may obtain additional public records related to any licensee or certificate holder, including dismissed complaints and nondisciplinary actions and orders, by contacting the Board directly.

[Click here to submit a public records request \(https://pharmacy.az.gov/public-records-request\)](https://pharmacy.az.gov/public-records-request)

Contact Us (node/5226)

Board of Pharmacy

1616 W. Adams St., Suite 120

Phoenix, AZ 85007

[Find in Google Maps](#)

(<https://www.google.com/maps/place/1616+W+Adams+St,+Phoenix,+AZ+85007/@33.4495549,-112.0960746,17z/data=!3m1!1e3!1s1616+W+Adams+St,+Phoenix,+AZ+85007>)

Phone: (602) 771-2727

Fax: (602) 771-2749





MedWiseRx Description of Services

Patients with chronic illness face a number of challenges managing their day-to-day and long-term health, in part because medications are complex, confusing, costly and potentially dangerous. MedWiseRx was founded to optimize medication use and improve the health of patients with chronic illness by providing through Medication Therapy Management (MTM).

We offer a comprehensive approach to patient care and population health, with our team of dedicated pharmacists solely focused on providing medication reviews and clinical interventions to improve health, wellness and the management of chronic health conditions

MedWiseRx operates a pharmacist-run call center that provides phone-based medication therapy management (MTM) services. This is not retail or mail order pharmacy. It does not purchase, stock, compound, or dispense medications of any kind. Thus, it is not required to have either a state or federal controlled substance license.

The pharmacists make and receive calls to and from patients and physicians Monday through Friday from 8:00 am to 5:30 pm and Saturday from 9:00 am to 12:00 pm EST. However, pharmacist and healthcare providers have access to a pharmacist 24 hours per day, 7 days a week, toll-free at 844-866-3735.

The pharmacy complies with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. All patient records are only available to personnel as needed to provide service to patients. Paper records are kept in a secure storage system within the pharmacy.



Corporate Officers:

Orsula V. Knowlton, PharmD President

Business Address: 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057

Home Address: Spyglass Circle, Fernandina Beach, FL 32034

Business Phone: 866-648-2767

Calvin H. Knowlton, BScPharm, MDiv, PhD CEO

Business Address: 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057

Home Address: Spyglass Circle, Fernandina Beach, FL 32034

Business Phone: 866-648-2767

Brian W. Adams Secretary

Business Address: 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057

Home Address: Station Avenue, Haddonfield, NJ 08033

Business Phone: 866-648-2767

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT
COPY OF THE CERTIFICATE OF AMENDMENT OF "TRHC OPCO, INC.",
CHANGING ITS NAME FROM "TRHC OPCO, INC." TO "TABULA RASA
HEALTHCARE GROUP, INC.", FILED IN THIS OFFICE ON THE TWENTY-
THIRD DAY OF JUNE, A.D. 2020, AT 10:33 O'CLOCK A.M.



4674249 8100
SR# 20205843172

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed in a small font.

Authentication: 203158771
Date: 06-23-20

**CERTIFICATE OF AMENDMENT
TO THE FOURTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TRHC OPCO, INC.**

TRHC OpCo, Inc., a corporation organized and existing under the laws of the State of Delaware (the “Corporation”), hereby certifies as follows:

1. Article First of the Fourth Amended and Restated Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety to read as follows:

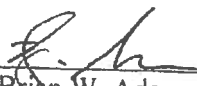
“The name of the Corporation is Tabula Rasa HealthCare Group, Inc. (the “Corporation”).”

2. The foregoing amendment was duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed
this 23rd day of June , 2020.

TRHC OPCI, INC.

By: 
Name: Brian W. Adams
Title: Chief Financial Officer and Secretary

F. ANN RODRIGUEZ, RECORDER
Recorded By: SMJ
DEPUTY RECORDER
5017



SEQUENCE: 20200290204
NO. PAGES: 2
01/29/2020
10:49:53

MAIL

CORPORATION SERVICE COMPANY
8825 N 23RD AVE 100
PHOENIX AZ 85021

Corporation Service Company
8825 N. 23rd Avenue
Suite 100
Phoenix, AZ 85021

(this area reserved for county recorder)

CAPTION HEADING:

CERTIFICATE OF DOING BUSINESS UNDER FICTITIOUS NAME

DO NOT REMOVE

This is part of the official document.

CERTIFICATE OF DOING BUSINESS UNDER FICTITIOUS NAME
GENERAL FORM
PURSUANT TO PROVISION OF A.R.S. SEC.44-1236

KNOWN ALL MEN BY THESE PRESENTS:

1. That TRHC OpCo, Inc. whose
(Name of Owner)
address is 228 Strawbridge Drive, Ste 100 Moorestown, NJ 08057
(Address of Owner)
are conducting a business in Arizona under the name and style of: MedWiseRx
(Name of Business)

The General nature of the business is: Provide and coordinate medication management services.
(Type of Business)

2. The business will be conducted at 2202 North Forbes Blvd, Suite 252
(Address of Business)
city of Tucson, county of Pima, State of Arizona

If corporation, show state of Incorporation: Delaware
(Article of Incorporation)

Signed: [Signature]
(Signature of Owner)

By: Brian W. Adams Its: Chief Financial Officer
(Printed name of Owner) (Title Owner wants to be known as)

Signed: _____
(Signature of Owner)

By: _____ Its: _____
(Printed name of Owner) (Title Owner wants to be known as)

State of NJ
County of Burlington

Subscribed and sworn before me on this 22nd day of January 2020

Notary Public signature Maureen E. Vurgason (seal)


MAUREEN E. VURGASON
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 3/25/2024

Certificate No. 1 For 150 Shares Issued to Tabula Rasa Healthcare, Inc Transferred from / 120
Dated , 20 Receipt acknowledged
No. Original Certificate No. Original Shares No. Of Shares Transferred

NUMBER 150

INCORPORATED UNDER THE LAWS OF

THE STATE OF DELAWARE



CAREKINESIS, INC.

Authorized Common Stock 100 Shares, \$0.0001 Par Value Per Share

This Certifies that *is the owner of* *fully paid*


and non-assessable Shares of the Capital Stock of the above named Corporation


transferable only on the books of the Corporation by the holder hereof in person or

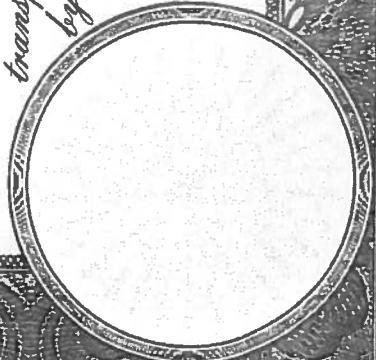
by duly authorized Attorney upon surrender of this Certificate properly endorsed.

In Witness Whereof, the said Corporation has caused this Certificate to be signed by its duly authorized officers

and its Corporate Seal to be hereunto affixed this 30th *day of* June 2014


TREASURER/SECRETARY


PRESIDENT



EXPLANATION OF ABBREVIATIONS

The following abbreviations, when used in the inscription of ownership on the face of this certificate, shall be construed as if they were written out in full according to applicable laws or regulations. Abbreviations, in addition to those appearing below, may be used.

JT TEN As joint tenants with right of survivorship and
not as tenants in common

TEN COM As tenants in common

TEN ENT

UNIF GIFT MIN ACT

CUST

UNIF TRANS MIN ACT

As tenants by the entireties

Uniform Gifts to Minors Act

Custodian for

Uniform Transfers to Minors Act

For Value Received, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER
IDENTIFYING NUMBER OF ASSIGNEE

_____ Shares represented by the within
Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney
to transfer the said Shares on the books of the within named Corporation with
full power of substitution in the premises.

Dated _____ 20____
In presence of _____

NOTICE: THE SIGNATURE OF THE ASSIGNEE MUST CORRESPOND WITH THE
NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE. IN EVENT OF DISCREPANCY
BETWEEN THE SIGNATURE OF THE ASSIGNEE AND THE NAME AS WRITTEN UPON THE
FACE OF THE CERTIFICATE, THE CERTIFICATE SHALL BE VOID.



THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE TRANSFERRED EXCEPT (A) PURSUANT TO AN EFFECTIVE REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS, OR (B) IN A TRANSACTION WHICH IS EXEMPT FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "CAREKINESIS, INC.", CHANGING ITS NAME FROM "CAREKINESIS, INC." TO "TRHC OPCO, INC.", FILED IN THIS OFFICE ON THE TWENTIETH DAY OF DECEMBER, A.D. 2019, AT 4:56 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE KENT COUNTY RECORDER OF DEEDS.



4674249 8100
SR# 20198800595

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JB", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 204276857
Date: 12-20-19

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:56 PM 12/20/2019
FILED 04:56 PM 12/20/2019
SR 20198800595 - File Number 4674249

**CERTIFICATE OF AMENDMENT
TO THE FOURTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
CAREKINESIS, INC.**

CareKinesis, Inc., a corporation organized and existing under the laws of the State of Delaware (the "**Corporation**"), hereby certifies as follows:

1. Article First of the Fourth Amended and Restated Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety to read as follows:

"The name of the Corporation is TRHC OpCo, Inc. (the "**Corporation**")."

2. The foregoing amendment was duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed
this 20th day of December, 2019.

CAREKINESIS, INC.

By: 

Name: Brian W. Adams

Title: Chief Financial Officer and Secretary

[Signature Page to Certificate of Amendment]



**Name Change to Tabula Rasa HealthCare Group, Inc. (formerly) TRHC OpCo, Inc.
dba MedWiseRx**

RE: Explanation of Name Change for Applicant Owner of the Pharmacy

On 1/1/2020 CareKinesis, Inc. changed its name to TRHC OpCo, Inc. (FEIN: 26-4642609) On June 23, 2020 TRHC OpCo, Inc. legally changed its name to Tabula Rasa HealthCare Group, Inc. Neither the parent company (Tabula Rasa Health Care, Inc.) nor the officers have changed. This was a name change of the owner of the pharmacy and not a change in ownership.

The name of the pharmacy is MedWiseRx. The physical location of the pharmacy is 2202 N. Forbes Blvd., Suite 252, Tucson, AZ 85745.

MedWiseRx is a non-dispensing pharmacy that provides medication therapy management services.

4M

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ **New Pharmacy** or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership – Pages 1,2,6,8

☒ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: MK PHARMACY

Physical Address: 18006 PARK ROW DR, STE 350, HOUSTON, TX 77084

Mailing Address: 18006 PARK ROW DR, STE 350

City: HOUSTON State: TX Zip Code: 77084

Telephone: (346) 322-4998 Fax: (346) 322-4995

Toll Free Number: (866) 507-9419 (Required per NAC 639.708)

E-mail: MKPHARMACYLLC@GMAIL.COM Website: N/A

Managing Pharmacist: MALAK KHOUDAY License Number: 40685

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

☒ ☐ Retail

☐ ☒ Hospital (# beds _____)

☐ ☒ Internet

☐ ☒ Nuclear

☐ ☒ Ambulatory Surgery Center

☐ ☒ Community

☒ ☐ Other: MAIL ORDER/NON-RESIDENT

All boxes must be checked

For the application to be complete

Yes/No

☐ ☒ Off-site Cognitive Services

☐ ☒ Parenteral **

☐ ☒ Parenteral (outpatient)

☐ ☒ Outpatient/Discharge

☒ ☐ Mail Service

☐ ☒ Long Term Care

☐ ☒ Sterile Compounding **

☐ ☒ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding **

☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

MALAK

Original Signature of Person Authorized to Submit Application, no copies or stamps

MALAK KHOUDAY

Print Name of Authorized Person

Date

8/25/2020

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

NV

Posted April 1, 2020

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: TEXASParent Company if any: MK PHARMACY LLCMailing Address: 18006 PARK ROW DR, STE 350City: HOUSTON State: TX Zip: 77084Telephone: (346) 322-4998 Fax: (346) 322-4995Contact Person: MANAL ELAMRAWY

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A

Name Address

b) _____

Name Address

c) _____

Name Address

d) _____

Name Address

2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 9:00 am 6:00 pmSaturday 10:00 am 6:00 pmSunday CLOSED am CLOSED pm24 Hours N/AA Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, MALAK KHOUDAY

Responsible Person of MK PHARMACY

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

MALAK KHOUDAY

Print Name of Authorized Person

8/25/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF TEXAS)
Harris) ss.)
COUNTY)

I, MALAK KHOUDAY, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST IN CHARGE for MK PHARMACY (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

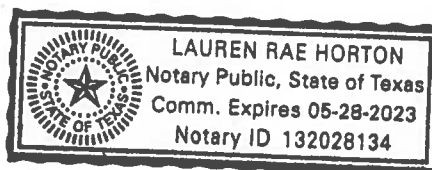
FURTHER AFFIANT SAYETH NOT.

I, MALAK KHOUDAY, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name MALAK

SUBSCRIBED AND SWORN TO
before me, a notary public this

25 day of August, 2020
Lauren Rae Horton
NOTARY PUBLIC



TEXAS STATE BOARD OF PHARMACY
333 GUADALUPE ST STE 3 500
AUSTIN TX 78701

MK PHARMACY
18006 PARK ROW DR STE 350
HOUSTON TX 77084



This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **32420**

Expiration Date: **1/31/2021**

Balances: 1

MK PHARMACY
18006 PARK ROW DR STE 350
HOUSTON TX 77084




Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW



TEXAS STATE BOARD OF PHARMACY

Re: MK Pharmacy

Address: 18006 Park Row Drive, Suite 350
Houston, Texas 77084

License No.: 32420

Date Issued: January 15, 2019

Licensure Status: Active

Expiration Date: January 31, 2021

Type of Pharmacy: Community – Class A

Prior Disciplinary Orders: No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. MK Pharmacy (Texas Pharmacy License #32420) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

A handwritten signature in black ink, reading "Megan G. Holloway".

Megan G. Holloway
Deputy General Counsel
Texas State Board of Pharmacy

June 11, 2020
Date



The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.



TEXAS STATE BOARD OF PHARMACY
333 Guadalupe St., Suite 3-500
Austin, TX 78701
(512) 305-8000

License Number: 40685

01/31/2022



(Date PDF Version Generated: 01/02/2020)

An up-to-date License Verification is always available on the Board's website:
<http://www.pharmacy.texas.gov/>

TEXAS STATE BOARD OF PHARMACY

License No.
40685

Expiration Date
01/31/2022

MALAK KHOUDAY
REGISTERED PHARMACIST

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

- Pharmacists are required to obtain CE as outlined in Rule 295.8, and are subject to random audits by TSBP.
- Update your address and/or employment through your online account at www.pharmacy.texas.gov.

TEXAS STATE BOARD OF PHARMACY

License No.
40685

Expiration Date
01/31/2022

MALAK KHOUDAY
REGISTERED PHARMACIST

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary



TEXAS STATE BOARD OF PHARMACY

Re: Malak Khouday, R.Ph.
License No.: 40685
Date Issued: May 2, 2002
Licensure Status: Active
Expiration Date: January 31, 2022
Granted by: Examination
Prior Disciplinary Orders: No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Malak Khouday, R.Ph. (Texas Pharmacist License #40685) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Megan G. Holloway
Deputy General Counsel
Texas State Board of Pharmacy

June 11, 2020
Date



Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697



Rolando B. Pablos
Secretary of State

Office of the Secretary of State

CERTIFICATE OF FILING OF

M K PHARMACY LLC
File Number: 802720539

The undersigned, as Secretary of State of Texas, hereby certifies that a Certificate of Formation for the above named Domestic Limited Liability Company (LLC) has been received in this office and has been found to conform to the applicable provisions of law.

ACCORDINGLY, the undersigned, as Secretary of State, and by virtue of the authority vested in the secretary by law, hereby issues this certificate evidencing filing effective on the date shown below.

The issuance of this certificate does not authorize the use of a name in this state in violation of the rights of another under the federal Trademark Act of 1946, the Texas trademark law, the Assumed Business or Professional Name Act, or the common law.

Dated: 05/12/2017

Effective: 05/12/2017



A handwritten signature in black ink, appearing to read "R. Pablos".

Rolando B. Pablos
Secretary of State

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 05-15-2017

Employer Identification Number:
82-1531169

Form: SS-4

Number of this notice: CP 575 G

For assistance you may call us at:
1-800-829-4933

M K PHARMACY LLC
18006 Park Row Dr. STE 350
Houston, TX 77084

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 82-1531169. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

When filing tax documents, payments, and related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear off stub and return it to us.

A limited liability company (LLC) may file Form 8832, *Entity Classification Election*, and elect to be classified as an association taxable as a corporation. If the LLC is eligible to be treated as a corporation that meets certain tests and it will be electing S corporation status, it must timely file Form 2553, *Election by a Small Business Corporation*. The LLC will be treated as a corporation as of the effective date of the S corporation election and does not need to file Form 8832.

To obtain tax forms and publications, including those referenced in this notice, visit our Web site at www.irs.gov. If you do not have access to the Internet, call 1-800-829-3676 (TTY/TDD 1-800-829-4059) or visit your local IRS office.

IMPORTANT REMINDERS:

- * Keep a copy of this notice in your permanent records. **This notice is issued only one time and the IRS will not be able to generate a duplicate copy for you.** You may give a copy of this document to anyone asking for proof of your EIN.
- * Use this EIN and your name exactly as they appear at the top of this notice on all your federal tax forms.
- * Refer to this EIN on your tax-related correspondence and documents.

If you have questions about your EIN, you can call us at the phone number or write to us at the address shown at the top of this notice. If you write, please tear off the stub at the bottom of this notice and send it along with your letter. If you do not need to write us, do not complete and return the stub.

Your name control associated with this EIN is MKPH. You will need to provide this information, along with your EIN, if you file your returns electronically.

Thank you for your cooperation.

MK PHARMACY

18006 PARK ROW DR, STE 350, HOUSTON, TX 77084

P: (346) 322-4998 | F: (346) 322-4995 | TF: (866) 507-9419

OWNER: MK PHARMACY LLC

ADDRESS: 18006 PARK ROW DR, STE 350, HOUSTON, TX 77084

PHONE: (866) 507-9419

FEIN: 82-1531169

OWNERSHIP: 100%

LLC MANAGER: MANAL ELAMRAWY

ADDRESS: WINDSOR LAKES DR, HOUSTON, TX 77094

PHONE: (866) 507-9419

DOB: 01/01/1980

SS: 123-45-6789

OWNERSHIP: 100%

PHARMACIST IN CHARGE: MALAK KHOUDAY

ADDRESS: TIVOLI DR, HOUSTON, TX 77077

PHONE: (866) 507-9419

DOB: 01/01/1980

SS: 123-45-6789

TX RPH LICENSE: 40685

MK PHARMACY

18006 PARK ROW DR, STE 350, HOUSTON, TX 77084

P: (346) 322-4998 | F: (346) 322-4995 | TF: (866) 507-9419

Pharmacy Description

MK Pharmacy is a retail, community, mail order pharmacy that dispenses retail medications. MK Pharmacy would like to broaden our services to patients who prefer to have their prescriptions delivered to their doorstep. New patients of MK Pharmacy will receive a Welcome Packet that includes the toll-free number, hours of operation and the phone number to the Texas State Board of Pharmacy. MK Pharmacy DOES NOT dispense any controlled substances or compounding. If they pharmacy operations change at any point in time, the board of pharmacy will be notified immediately.

For questions, please email: mkpharmacyllc@gmail.com



TEXAS STATE BOARD OF PHARMACY

Re: MK Pharmacy
Address: 18006 Park Row Drive, Suite 350
 Houston, Texas 77084
License No.: 32420
Date Issued: January 15, 2019
Licensure Status: Active
Expiration Date: January 31, 2021
Type of Pharmacy: Community – Class A
Prior Disciplinary Orders: No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. MK Pharmacy (Texas Pharmacy License #32420) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Megan G. Holloway
 Deputy General Counsel
 Texas State Board of Pharmacy

August 31, 2020
 Date



The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.



TEXAS STATE BOARD OF PHARMACY

Re: Malak Khouday, R.Ph.
License No.: 40685
Date Issued: May 2, 2002
Licensure Status: Active
Expiration Date: January 31, 2022
Granted by: Examination
Prior Disciplinary Orders: No

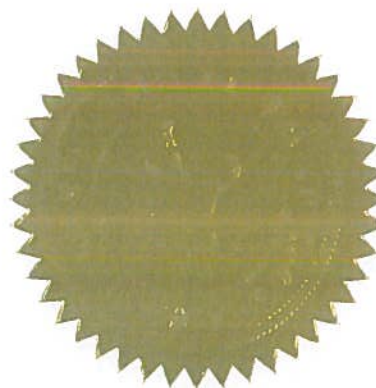
The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Malak Khouday, R.Ph. (Texas Pharmacist License #40685) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

A handwritten signature in black ink that reads "Megan G. Holloway".

Megan G. Holloway
Deputy General Counsel
Texas State Board of Pharmacy

August 31, 2020
Date



4N

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,8 ☒ Partnership – Pages 1,2,6,8
☐ Non Publicly Traded Corporation – Pages 1,2,4,8 ☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Morris Apothecary LLC

Physical Address: 69 New Road

Mailing Address: 69 New Road

City: Parsippany State: NJ Zip Code: 07054

Telephone: 973-870-0540 Fax: 973-870-0544

Toll Free Number: 866-588-7756 (Required per NAC 639.708)

E-mail: info@morrisapothecary.com Website: morrisapothecary.com

Managing Pharmacist: Rishi Desai License Number: 28RI03908100

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

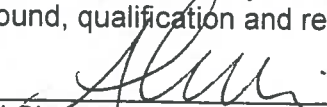
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Anush Amin

Print Name of Authorized Person

Date

8/20/20

Page 2

Board Use Only

Date Processed: _____

Amount:

500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIPGeneral _____ Limited ✓Partnership Name: Morris Apothecary LLCMailing Address: 69 New RoadCity: Parsippany State: NJ Zip Code: 07054Telephone Number: 973-870-0540 Fax Number: 973-870-0544Contact Person: Nikki BaniewiczList each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
<u>List of LLC officers attached</u>		

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday Closed am _____ pm

Sunday Closed am _____ pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

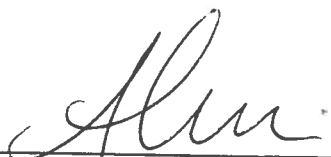
I, Anush Amin

Responsible Person of Morris Apothecary

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Anush Amin

Print Name of Authorized Person

8/20/20
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF New Jersey)
Essex COUNTY) ss.

I, Amish Amin, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OFFICER & PRESIDENT for MORRIS PHARMACY LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Amish Amin, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name Amish Amin

SUBSCRIBED AND SWORN TO
 before me, a notary public this
20 day of August, 2020.

Danielle L. Rocco
 NOTARY PUBLIC

DANIELLE L. ROCCO
 NOTARY PUBLIC OF NEW JERSEY
 Commission # 50118055
 My Commission Expires 12/4/2024

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY "MORRIS APOTHECARY LLC" IS DULY FORMED
UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND
HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS
OF THE TWENTY-NINTH DAY OF JUNE, A.D. 2020.



7363385 8300

SR# 20205956516

You may verify this certificate online at corp.delaware.gov/authver.shtmlA handwritten signature of Jeffrey W. Bullock in black ink, written over a horizontal line.

Jeffrey W. Bullock, Secretary of State

Authentication: 203195940

Date: 06-29-20



PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102



GURBIR S. GREWAL
Attorney General

PAUL R. RODRIGUEZ
Acting Director

June 4, 2020

Via email to rishi@apothecopharmacy.com

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by MORRIS APOTHECARY to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that MORRIS APOTHECARY was issued a New Jersey registration 28RS00758500 on or about 10/23/2017 and is currently Active and in good standing with an expiration date of 06/30/2021 . A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacy.

Very truly yours,

Anthony Rubinaccio, RPh
Executive Director
Board of Pharmacy

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

MORRIS APOTHECARY
RISHI DESAI
69 New Rd.
Parsippany NJ 07054

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

05/18/2020 TO 06/30/2021
VALID

28RS00758500
LICENSEE/REGISTRATION/CERTIFICATION #

Paul Rodriguez
ACTING DIRECTOR

Signature of Licensee/Registrant/Certificate Holder

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
MORRIS APOTHECARY
Pharmacy

05/18/2020 TO 06/30/2021
VALID

28RS00758500
License/Registration/Certificate #

SIGNATURE

ACTING DIRECTOR

PLEASE DETACH HERE
IF YOUR LICENSE/REGISTRATION/
CERTIFICATE ID CARD IS LOST

PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PLEASE DETACH HERE

Morris Apothecary LLC Officers

- 1) **Joel Saban – CEO** - 090
Address: Avalon Drive
Buffalo Grove, IL 60089-4685
- 2) **Anush Amin - President** - 090
Address Groff Court
Flemington, NJ 08822-6939
- 3) **James C. Luthin- CFO** - 090
Address Schiller Ave.
Wilmette, IL 60091-2329
- 4) **Nikki Baniewicz – Secretary and Treasurer** - 090
Address: Madison St., Ap
Hoboken, NJ 07030-6364

40



RECEIVED
7-29-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership – Pages 1,2,5,7
☒ Non Publicly Traded Corporation – Pages 1,2,4,7 *LLC ☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Pharmxpress Limited Liability Company (DBA) Pharmxpress Pharmacy

Physical Address: 507 E Dr. Martin Luther King JR. Blvd Ste #101

Mailing Address: Same as physical

City: Tampa State: Florida Zip Code: 33603

Telephone: 813-406-4491 Fax: 813-406-4493

Toll Free Number: 833-353-6693 (Required per NAC 639.708)

E-mail: mypharmxpress@gmail.com Website: N/A

Managing Pharmacist: Tyler King License Number: PS60436

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

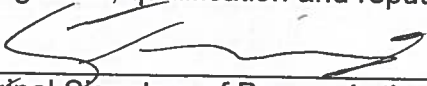
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Sam Knight

Print Name of Authorized Person

Date

06/15/2020

Page 2

Board Use Only

Date Processed: _____

Amount:

\$00.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

Ownership entity of Pharmacy is an LLC

State of Incorporation: FloridaParent Company if any: Viking Man IncMailing Address: 507 E Dr. Martin Luther King Jr. Blvd Ste #101City: TampaState: FloridaZip: 33603Telephone: 813-406-4491Fax: 813-406-4493Contact Person: Sam Knight

For any corporation non publicly traded, disclose the following: *LLC

- 1) List top 4 persons to whom the shares were issued by the corporation? Ownership % Not Shares

a) Andrew McCubbinsS Draper Woods Cove, Draper, U33%

Name

Address

b) Chad Altman14th St N, St Petersburg, F33%

Name

Address

c) Greg Warnock3 Mivv Cir, Sandy, U33%

Name

Address

d) _____

Name

Address

- 2) Provide the number of shares issued by the corporation.
- No Shares

- 3) What was the price paid per share?
- No Shares

- 4) What date did the corporation actually receive the cash assets? _____

- 5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: NA

%: _____

Name: N/A

%: _____

Hours of Operation for the pharmacy:Monday thru Friday 9:00 am 5:00 pmSaturday 11:00 am 5:00 pmSunday On-Call am On-Call pm

24 Hours _____

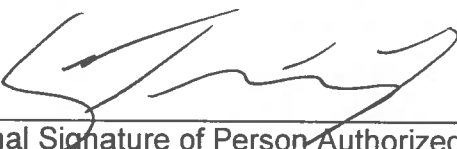
A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Sam Knight
Responsible Person of Pharmexpress Limited Liability Company
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Sam Knight
Print Name of Authorized Person

05/07/2020
Date

AC# 9662848

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
05/29/2020	PH 24350	116762

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

Expiration Date: FEBRUARY 28, 2021
PHARMXPRESS LIMITED LIABILITY COMPANY
Pharmxpress Pharmacy
507 E DR MARTIN LUTHER KING JR BLVD
STE 101
TAMPA, FL - 33603

QUALIFICATION(S):

Community Pharmacy
Schedule II & III
2:1 Pharmacy Technician Ratio Approved



R. DeSantis

Ron DeSantis
GOVERNOR

DISPLAY IF REQUIRED BY LAW

Scott A. Rivkees

Scott A. Rivkees, MD
State Surgeon General

9662848

AC#

STATE OF FLORIDA
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
05/29/2020	PH 24350	116762

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

Expiration Date: FEBRUARY 28, 2021
PHARMXPRESS LIMITED LIABILITY COMPANY
Pharmxpress Pharmacy

REGISTRANT SIGNATURE

QUALIFICATION(S):
Community Pharmacy
Schedule II & III
2:1 Pharmacy Technician Ratio
Approved

Actively Licensed States

State	License Date	License Expiration Date	License Number
Arizona	4/6/2020	10/31/2020	Y008350
Colorado	4/10/2020	10/31/2020	OSP.0007409
Illinois	5/14/2020	3/31/2022	54.021564
Iowa	6/5/2020	12/31/2020	5264
Missouri	6/26/2020	10/31/2021	2020018815
New York	6/8/2020	5/31/2023	038250
Ohio	4/30/2020	3/31/2021	0240000175
Pennsylvania	6/15/2020	8/31/2021	NP001617
Wyoming	6/23/2020	6/30/2021	NR-51849

State of Florida

Department of State

I certify from the records of this office that PHARMXPRESS LIMITED LIABILITY COMPANY is a limited liability company organized under the laws of the State of Florida, filed on September 15, 2009.

The document number of this limited liability company is L09000089004.

I further certify that said limited liability company has paid all fees due this office through December 31, 2020, that its most recent annual report was filed on January 24, 2020, and that its status is active.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Twenty-second day of April,
2020*



Ramón M. Bu
Secretary of State

Tracking Number: 9679483265CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>

Viking Man, Inc

Parent

(99% Owner of Pharmxpress Limited Liability Company)

Pharmxpress Limited Liability Company (DBA) Pharmxpress Pharmacy

Subsidiary

Viking Man, Inc

Name	Andrew McCubbins – President
Address	S Draper Woods Cove
City, State, Zip	Draper, UT 84020
DOB	
SS#	
Email	Andrew@vikingman.com
Name	Greg Warnock - Director
Address	Mivu Cir
City, State, Zip	Sandy, UT 84093
DOB	
SS#	
Email	greg@vikingman.com
Name	Chad Altman - Director
Address	St N
City, State, Zip	St Petersburg, FL 33703
DOB	
SS#	
Email	chad@vikingman.com

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Utah)
Salt Lake) ss.
COUNTY)

I, Sam Knight, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager for Pharmexpress Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

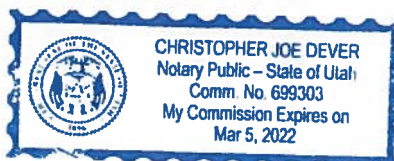
FURTHER AFFIANT SAYETH NOT.

I, Sam Knight, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

[Signature]
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
7 day of May, 2020.

[Signature]
NOTARY PUBLIC



Mission:

To protect, promote & improve the health
of all people in Florida through integrated
state, county & community efforts.

**Ron DeSantis**

Governor

Scott A. Rivkees, MD

State Surgeon General

Vision: To be the Healthiest State in the Nation

July 16, 2020

Pharmxpress Limited Liability Company
Jacqueline Phillips
507 E Dr Martin Luther King Jr Blvd, Ste 101
Tampa, FL 33603

RE: License Certification for Pharmxpress Limited Liability Company

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the
above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH24350
ORIGINAL CERTIFICATION:	11/18/2009
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No

To expedite the verification process, the above format is the standard format for all healthcare
practitioners. If you have questions regarding the status of this license, please call the Customer
Contact Center at (850) 488-0595, option 5.

Sincerely,

Gerisla K. Still
Regulatory Specialist II

/gs

**Florida Department of Health**

Division of Medical Quality Assurance • Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX: (850) 245-4791



Accredited Health Department
Public Health Accreditation Board

**APPLICATION FOR CERTIFICATION AS A PROVIDER OF
INTERNET PHARMACY SERVICES**

*Addendum to Pharmacy Application
(Only required if providing internet services)*

GENERAL INFORMATION

Name of Nevada license pharmacy: Pharmxpress Limited Liability Company (DBA) Pharmxpress Pharmacy

Nevada license number: PH24350

Websites in use or intended to be used: Parent company website is www.vikingman.com

Affiliated websites (websites that link to or otherwise direct users to your website):

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered by NABP) certified? Please provide a copy with application. Yes ☐ No ☒

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☒ No ☐

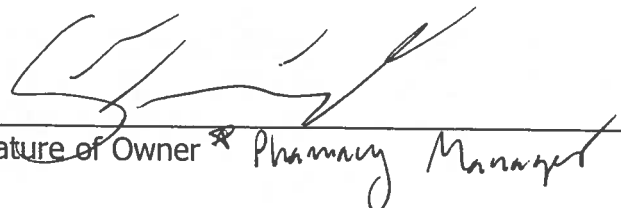
PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:
- A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☒ No ☐
 - B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☒ No ☐
 - C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☒ No ☐
 - D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☒ No ☐
 - E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☒ No ☐
 - F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☒ No ☐
 - G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☒ No ☐
 - H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☒ No ☐
 - I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☒ No ☐
 - J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☒ No ☐
3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☒ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☒ No ☐
5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☒ No ☐
6. Does the pharmacy comply with applicable federal and state laws regarding the following:
- A) To the dispensing of prescription drugs? Yes ☒ No ☐
- B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☒ No ☐
- C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs? Yes ☒ No ☐
7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☒ No ☐
8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia*, 25th edition, 2002, which is hereby adopted by reference? Yes ☒ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.


 Signature of Owner * Pharmacy Manager

05/07/2020
 Date

4P

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ **New Pharmacy** or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,8 ☒ Partnership – Pages 1,2,6,8
☐ Non Publicly Traded Corporation – Pages 1,2,4,8 ☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Princeton Medical Pharmacy LLC

Physical Address: 10 Forrestal Road South, Suite 102

Mailing Address: 10 Forrestal Road South, Suite 102

City: Princeton State: NJ Zip Code: 08540

Telephone: 609-503-7731 Fax: 609-503-7732

Toll Free Number: 866-588-7756 (Required per NAC 639.708)

E-mail: info@apothecoprinceton.com Website: apothecoprinceton.com

Managing Pharmacist: Sagar Shah License Number: 28RI03089800

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Anush Amin

Print Name of Authorized Person

Date

Page 2

Board Use Only

Date Processed: _____

Amount:

20.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP

General _____ Limited ✓

Partnership Name: Princeton Medical Pharmacy LLC

Mailing Address: 10 Forrestral Road South, Suite 102

City: Princeton State: NJ Zip Code: 08540

Telephone Number: 609-503-7731 Fax Number: 609-503-7732

Contact Person: Sagar Shah

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
List of LLC officers attached		

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday Closed am pm
Sunday Closed am pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

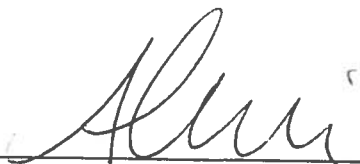
I, Anush Amin

Responsible Person of Princeton Medical Pharmacy LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Anush Amin

Print Name of Authorized Person

Date

8/20/20

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF New Jersey)
ESSOP COUNTY) ss.

I, Trish Ann, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Officer / President for West Coast Pharmacy LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Trish Ann, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Trish Ann
 Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
20 day of August, 2020.

Danielle L. Rocco
 NOTARY PUBLIC

DANIELLE L. ROCCO
 NOTARY PUBLIC OF NEW JERSEY
 Commission # 50118055
 My Commission Expires 12/4/2024

Officers of Princeton Medical Pharmacy LLC**1) Joel Saban – CEO – 090**

Address: Avalon Drive
Buffalo Grove, IL 60089-4685

2) Anush Amin - President – 090

Address: Groff Court
Flemington, NJ 08822-6939

3) James C. Luthin- CFO – 090

Address: Schiller Ave.
Wilmette, IL 60091-2329

4) Nikki Baniewicz – Secretary and Treasurer – 090

Address: Madison St., Apt
Hoboken, NJ 07030-6364

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY "PRINCETON MEDICAL PHARMACY LLC" IS
DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD
STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS
OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF JUNE, A.D. 2020.



7363407 8300

SR# 20205956430

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed in a small font.

Authentication: 203195925

Date: 06-29-20



PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102



GURBIR S. GREWAL
Attorney General

PAUL R. RODRIGUEZ
Acting Director

June 4, 2020

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by APOTHECO PHARMACY PRINCETON to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that APOTHECO PHARMACY PRINCETON was issued a New Jersey registration 28RS00735600 on or about 09/15/2014 and is currently Active and in good standing with an expiration date of 06/30/2021 . A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacy.

Very truly yours,

Anthony Rubinaccio, R.Ph.
Executive Director
Board of Pharmacy

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

APOTHECO PHARMACY PRINCETON
SAGAR S SHAH
10 Forrestal Rd. S
Princeton NJ 08540

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

05/18/2020 TO 06/30/2021

VALID

28RS00735600
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

Paul Rodriguez
ACTING DIRECTOR

New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
APOTHECO PHARMACY PRINCETON
Pharmacy

05/18/2020 TO 06/30/2021

VALID

SIGNATURE

28RS00735600

License/Registration/Certificate #

Paul Rodriguez
ACTING DIRECTOR

PLEASE DETACH HERE
IF YOUR LICENSE/REGISTRATION
CERTIFICATE ID CARD IS LOST
PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PLEASE DETACH HERE

4Q



RECEIVED
8-11-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☒ Partnership - Pages 1,2,6,8

☐ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Spring Creek Pharmacy, LLC

Physical Address: 1218 E. 9th Street, Suite 1, Edmond, OK 73034

Mailing Address: 1218 E. 9th Street, Suite 1, Edmond, OK 73034

City: _____ State: _____ Zip Code: _____

Telephone: 405-285-9082 Fax: 405-471-6256

Toll Free Number: 833-9761843 (Required per NAC 639.708)

E-mail: scpharmrx@gmail.com Website: _____

Managing Pharmacist: Macvictor Nguyen License Number: 17206

TYPE OF PHARMACY **AND**

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☒ ☐ Outpatient/Discharge
☐ ☒ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Kimberly Stuart

Print Name of Authorized Person

7/30/2020
Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Dianna Gutierrez

Kimberly Stuart

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP

General _____

Limited ☒Partnership Name: Spring Creek Pharmacy, LLCMailing Address: 1218 E. 9th Street, Suite 1, Edmond, OK 73034

City: _____ State: _____ Zip Code: _____

Telephone Number: 405-285-9082 Fax Number: 405-471-6256

Contact Person: _____

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
<u>Dianna Gutierrez</u>	<u>L</u>	<u>90</u>
<u>Kimberly Stuart</u>	<u>L</u>	<u>10</u>

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday	<u>9</u> am	<u>1</u> pm	Saturday	<u>Closed</u> am	_____ pm
Sunday	<u>Closed</u> am	_____ pm	24 Hours	<u>N/A</u>	

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Kimberly Stuart

Responsible Person of Spring Creek Pharmacy, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Kimberly Stuart

Print Name of Authorized Person

7/30/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Texas)
Jarris) ss.
COUNTY)

I, Kimberly Stuart, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Officer for Spring Creek Pharmacy, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

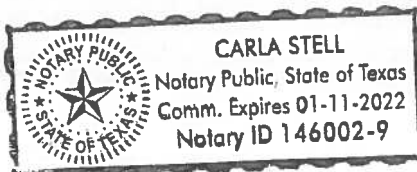
FURTHER AFFIANT SAYETH NOT.

I, Kimberly Stuart, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
before me, a notary public this
3 day of August, 2020.

Carla Stell
NOTARY PUBLIC

Name [Signature]



Posted April 1, 2020


OKLAHOMA

405-521-3815 • Fax 405-521-3758

State Board of Pharmacy

2920 N Lincoln Blvd Ste A, Oklahoma City, OK 73105

PHARMACY
#1-8736
RETAIL
EXPIRES JUL 31, 2021

SPRING CREEK PHARMACY LLC
 1218 E 9TH STREET STE 1
 EDMOND, OK 73034

2021

Amount: \$350.00

Receipt: 2021-0054

Date: 7/10/2020

This License is not transferable.
License must be conspicuously displayed in the location to which it is issued.

Important Information

- **Change of Location:** This license is not transferable for a change of location. A new license is required.
- **Change of Name:** This license is not transferable for a change of name. A new license is required.
- **Change of Owner:** This license is not transferable for a change of owner. A new license is required when the ownership changes by 20% or more.
- **Forms & Applications, Current Announcements and Laws & Rules** are available at the Board's website: www.pharmacy.ok.gov
- **Board Contact:**

 Email: pharmacy@pharmacy.ok.gov

Phone: 405-521-3815

Fax: 405-531-3758

All changes in any information required for the licensure must be reported to the Board within ten (10) days.

It is your responsibility to keep this license current.

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,8 ☐ Partnership – Pages 1,2,6,8
☐ Non Publicly Traded Corporation – Pages 1,2,4,8 ☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Lucile Packard Children's Hospital Outpatient Pharmacy

Physical Address: 725 Welch Road, Palo Alto, CA 94304

Mailing Address: 725 Welch Road #166

City: Palo Alto State: CA Zip Code: 94304

Telephone: 650-497-8289 Fax: 650-497-8974

Toll Free Number: _____ (Required per NAC 639.708)

Toll free #
in process

E-mail: CHong@stanfordchildrens.org Website: <https://www.stanfordchildrens.org/en/service/pharmacy-services/outpatient-pharmacy>

Managing Pharmacist: Carolyn M. Hong License Number: RPH 52573

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☒ ☐ Parenteral (outpatient)
☒ ☐ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☒ ☐ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☐ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting.**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

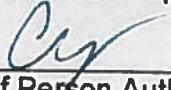
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Carolyn M. Hong

Print Name of Authorized Person

Date

Sept 3, 2020

Page 2

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Lucile Packard Children's Hospital Stanford (100% ownership)

Business Name: Lucile Packard Children's Hospital Outpatient Pharmacy

Current Business Address: 725 Welch Road #166

City: Palo Alto State: CA Zip Code: 94304

Telephone: 650-497-8289

Fax: 650-497-8974

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 08:00 am 7:00 pm

Saturday 9:00 am 4:00 pm

Sunday 9:00 am 4:00 pm

24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

**STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA**

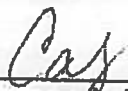
I, Carolyn M. Hong

Responsible Person of Lucile Packard Children's Hospital Outpatient Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Carolyn Hong
Print Name of Authorized Person

Sept 3, 2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF CA)
) ss.
Santa Clara COUNTY)

I, Carolyn M Hong, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the phamacist in charge for Lucile Packard Children's Hospital Outpatient Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of- State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Carolyn M. Hong, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
 before me, a notary public this
 ___ day of ___, 20__.

 Name

 NOTARY PUBLIC



CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Retail Pharmacy Permit

LICENSE NO. PHY 52051
RECEIPT NO. 00166057

VALID UNTIL JUNE 01, 2021

LUCILE PACKARD CHILDRENS HOSPITAL OUTPATIENT PHARMACY
725 WELCH ROAD #166
PALO ALTO CA 94304

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge. This permit is valid only at the address shown.

/30/20

/30/20 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19)

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership - Pages 1,2,6,8

☒ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Saveway Market Pharmacy

Physical Address: 1200 Shoup Street

Mailing Address: 1200 Shoup Street

City: Salmon State: ID Zip Code: 83467

Telephone: 208.756.1940 Fax: 208.756.1790

Toll Free Number: 1.844.812.2551 (Required per NAC 639.708)

E-mail: pharmacy@savewaymarket.com Website: savewaymarket.com

Managing Pharmacist: Allison Cardona License Number: P7027

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☒ ☐ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Nathan Bills

Print Name of Authorized Person

8.18.2020
Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: Idaho

Parent Company if any: _____

Mailing Address: 1200 Shoup StreetCity: SalmonState: IDZip: 83467Telephone: 208.756.2822Fax: 208.756.6129Contact Person: Nathan Bills

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

33.3% a) Richard J. Bills N. Fairmont Road, Salmon, ID 83467

Name

Address

33.3% b) Nathan J. Bills Island Farm Road, Salmon, ID 83467

Name

Address

33.3% c) Patrick M. Bills Meadow Lane, Salmon, ID 83467

Name

Address

d) _____

Name

Address

2) Provide the number of shares issued by the corporation. Small, long standing family owned corporation...three3) What was the price paid per share? _____ partners (father and twosons), each own 33.3%.

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 9 am 7 pmSaturday 9 am 6 pm

Sunday _____ am _____ pm

24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Idaho)
) ss.
Lemhi COUNTY)

I, Allison Cardona, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PIC for Saveway Market Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Allison Cardona, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
 before me, a notary public this

18 day of August, 2020

[Signature]
 NOTARY PUBLIC



STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Allison Cardona

Responsible Person of Saveway Market Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Allison Cardona

Original Signature of Person Authorized to Submit Application, no copies or stamps

Allison Cardona

Print Name of Authorized Person

08.18.2020

Date

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

See State of Idaho Certificate of Corporate Status

Richard J Bills, President
Nathan J Bills, Vice President
Patrick M Bills, Vice President
Sandra L Bills, Secretary



317

0003905747

**STATE OF IDAHO***Office of the secretary of state, Lawrence Denney***ANNUAL REPORT**

Idaho Secretary of State

PO Box 83720

Boise, ID 83720-0080

(208) 334-2301

Filing Fee: \$0.00

For Office Use Only

-FILED-

File #: 0003905747

Date Filed: 6/10/2020 10:02:03 AM

Entity Name and Mailing Address:

Entity Name:

SAVEWAY MARKET, INC.

The file number of this entity on the records of the Idaho Secretary of State is: 0000160182

Address

RICHARD JIM BILLS
1200 SHOUP ST
SALMON, ID 83467-4300

Entity Details:

Entity Status

Active - Good Standing

This entity is organized under the laws of:

IDAHO

If applicable, the old file number of this entity on the records of the Idaho Secretary of State was: C49489

The registered agent on record is:

Registered Agent

RICHARD J BILLS
Registered Agent
Physical Address
1200 SHOUP STREET
SALMON, ID 83467
Mailing Address

The name and street address of the new registered agent and office in Idaho is:

Registered Agent

NATHAN BILLS
Registered Agent
Physical Address
1200 SHOUP STREET
SALMON, ID 83467
Mailing Address☒ I affirm that the registered agent appointed has consented to serve as registered agent for this entity.

Corporate Officers and Directors:

Name	Title	Business Address
+ Richard J Bills	President	1200 SHOUP STREET SALMON, ID 83467
+ Nathan J Bills	Vice President	1200 SHOUP STREET SALMON, ID 83467
+ Patrick M Bills	Vice President	1200 SHOUP STREET SALMON, ID 83467
+ Sandra L Bills	Secretary	1200 SHOUP STREET SALMON, ID 83467

The annual report must be signed by an authorized signer of the entity.

Nathan J Bills

Sign Here

06/10/2020

Date

Job Title: Vice President

0516-8111 U6/10/2020 10:02 AM Received by ID Secretary of State Lawrence Denney

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

RECEIVED
AUG 10 2020
IDAHO BOARD
OF PHARMACY

LICENSE VERIFICATION

Name: Saveway Market Pharmacy

Address: 1200 Shoup Street

City: Salmon State: ID Zip: 83467

I hereby authorize the Idaho State Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [Signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE
LICENSING AGENCY FOR COMPLETION. DO NOT WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
39073RP	Active	6/18/2015	12/31/2020

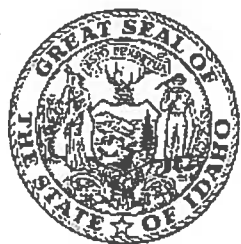
Has this license been encumbered in any way? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Type of Encumbrance: (if any)
	<input type="checkbox"/> Revoked <input type="checkbox"/> Surrendered <input type="checkbox"/> Limited <input type="checkbox"/> Suspended <input type="checkbox"/> Restricted <input type="checkbox"/> Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has applicant met all licensing requirements of your state? (If no, please explain)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Signature of State Official	Title	State	Date	State Seal
<u>[Signature]</u>	Licensing Specialist	Idaho	8/12/2020	




IDAHO STATE BOARD OF PHARMACY

P.O. Box 83720 Boise, Idaho 83720-0067

Telephone: (208) 334-2356 FAX: (208) 334-3536

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Idaho State Board of Pharmacy statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below.

SAVEWAY MARKET PHARMACY
Community Pharmacy Registration
Registration No: 39073RP
Automated Dispensing & Storage System(s)/(ADS)
ISSUED: 06/18/2015 EXPIRES: 12/31/2020

The official status and business address of this license must be verified at Idaho Board of Pharmacy License Verification.

<http://bop.idaho.gov>

A handwritten signature in cursive script that reads "Nicki Chopski".

597877

Printed: 12/24/2019

**NICKI CHOPSKI PHARM.D.
EXECUTIVE DIRECTOR**

4T



RECEIVED
8/16/2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change
(Please provide current license number if making changes: MP or MW _____)	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input checked="" type="checkbox"/> Partnership - Pages 1,2,3,6
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: Bonds Therapeutics LLC

Physical Address: 126 Nulfer Columbiana, OH 44408
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 126 Nulfer

City: Columbiana State: OH Zip Code: 44408

Telephone: 937-478-0469 Fax: _____

E-mail: Sales@BondsTherapeutics.com Website: TrocarSupplies.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9 to 5 Tue: 9 to 5 Wed: 9 to 5 Thu: 9 to 5 Fri: 9 to 5
Sat: 0 to 0 Sun: 0 to 0 Holidays: 0 to 0

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Max Peppel

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|---|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: <u>Medical procedure kit</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

<u>N/A</u>	_____	_____
_____	_____	_____
_____	_____	_____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- ☐ Practitioner
- ☐ Advanced Practitioner of Nursing
- ☐ Physician's Assistant
- ☐ Physical Therapist
- ☐ Occupational Therapist
- ☐ Registered Nurse
- ☐ Respiratory Therapist

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

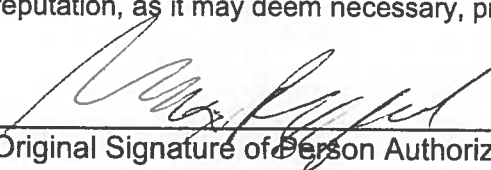
This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Max Peppel
Print Name of Authorized Person

8-4-20
Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP

General _____

Limited XPartnership Name: Bonds Therapeutics LLCMailing Address: 126 Nulf DrCity: Columbiana State: OH Zip: 44408Telephone: 937-478-0469 Fax: _____Contact Person: max peppel

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
 Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
<u>See attcheed</u>	_____	_____
_____	_____	_____

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

BONDS THERAPEUTICS 126 NULF DRIVE COLUMBIANA OH 44408
SALES@BONDSTHERAPEUTICS.COM
 937-478-0469

Name and Title	Business Address	Home Address	Business Phone number	Home Phone number	SSN	DOB
Maxwell Victor Peppel Owner/Officer 37.50%	126 Nulf Dr, Columbiana OH 44408	Butcher Rd. Leetonia, OH	(330)-892-0318			
Michael Edward Peppel Jr. Owner/Officer 20.83%	126 Nulf Dr, Columbiana OH 44408	Butcher Rd. Leetonia, OH	(330)-892-0318			
Montgomery Duncan Peppel 20.83%	126 Nulf Dr, Columbiana OH 44408	Butcher Rd. Leetonia, OH	(330)-892-0318			
Michaela Fiona Peppel 20.83%	126 Nulf Dr, Columbiana OH 44408	Butcher Rd. Leetonia, OH	(330)-892-0318			



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

7/29/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Hub International Northeast 100 Sunnyside Blvd Woodbury NY 11797	CONTACT NAME: PHONE (A/C, No, Ext): 516-677-4700		FAX (A/C, No): 516-496-4040
	E-MAIL ADDRESS:		
INSURED Robert Busse & Co., Inc. 75 Arkay Drive Hauppauge NY 11788	INSURER(S) AFFORDING COVERAGE		NAIC #
	INSURER A: Hanover Insurance Company		22292
	INSURER B: Mitsui Sumitomo Insurance USA		22551
	INSURER C: Hartford Insurance Group		914
	INSURER D:		
	INSURER E:		
INSURER F:			

COVERAGES

CERTIFICATE NUMBER: 115368747

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR <input checked="" type="checkbox"/> Primary & Non <input type="checkbox"/> Contributory GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input checked="" type="checkbox"/> LOC OTHER:			RHYA64791504	5/27/2020	5/27/2021	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 100,000 MED EXP (Any one person) \$ 10,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 3,000,000 PRODUCTS - COMP/OP AGG \$ 3,000,000 \$
B	<input checked="" type="checkbox"/> AUTOMOBILE LIABILITY <input checked="" type="checkbox"/> ANY AUTO <input type="checkbox"/> OWNED AUTOS ONLY <input checked="" type="checkbox"/> HIRED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input checked="" type="checkbox"/> NON-OWNED AUTOS ONLY			BVR8406796	5/27/2020	5/27/2021	COMBINED SINGLE LIMIT (Ea accident) \$ 1,000,000 BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$ \$
A	<input type="checkbox"/> UMBRELLA LIAB <input checked="" type="checkbox"/> OCCUR <input checked="" type="checkbox"/> EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE <input type="checkbox"/> DED <input checked="" type="checkbox"/> RETENTION \$ 0			UHY-H213474-00	5/27/2020	5/27/2021	EACH OCCURRENCE \$ 10,000,000 AGGREGATE \$ 10,000,000 \$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N	N/A	31WBA1Z80	4/1/2020	4/1/2021	<input type="checkbox"/> PER STATUTE <input type="checkbox"/> OTH-ER E.L. EACH ACCIDENT \$ 1,000,000 E.L. DISEASE - EA EMPLOYEE \$ 1,000,000 E.L. DISEASE - POLICY LIMIT \$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Location: 75 Arkay Drive Hauppauge, NY 11788 & 175 Wireless Blvd, Hauppauge, NY 11788

The insurance coverages referred to on this certificate are in force for the protection of the above Named Insured only. This certificate has been issued as a matter of information only.

CERTIFICATE HOLDER

CANCELLATION

Bonds Therapeutics
 126 Nulf Drive
 Columbiana OH 44408

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

STATE LICENSES FOR BONDS THERAPEUTICS

ARIZONA	W003386.	1/17/2020	10/31/2021
ARKANSAS	WD05387.	6/10/2020	12/31/20
CONNETICUT	CSW.0004695	6/19/2020	6/30/2021
MISSISSIPPI	18121/11.	7/7/2020	6/30/2021
OHIO	0130000151	6/30/2019	6/30/2021
PENNSYLVANIA	3000010170		
SOUTH CAROLINA	19516	07/21/2020	6/30/2021
WEST VIRGINIA	WD0560273	6/30/2020	6/30/2021

Ship to:

AZ, AR, CT, FL, IO, MA, MN, MS, NC, OH, PA, SC,
TX, WV, WI



**STATE OF
OHIO**
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2021.

Bonds Therapeutics LLC

Bonds Therapeutics LLC

126 Nulf Dr

Columbiana, OH 44408

License Number: 0130000151

Wholesaler - Category 2

Expiration Date: June 30, 2021

CLASS: Wholesaler - Category 2
BUSINESS TYPE: FS - Full Service

Responsible Person - Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print) MICHAEL PEPPEL JR.	Signature of Responsible Person
--	---------------------------------

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change (Please provide current license number if making changes: MP or MW _____)
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: Capital Medical Corporation
 Physical Address: 1324 Thomaswood Dr. Tallahassee, FL 32308
 (This must be a business address, we cannot issue a license to a home address)

Mailing Address: PO Box 15013
 City: Tallahassee State: FL Zip Code: 32317
 Telephone: 850 386 1978 Fax: 850 386 3151
 E-mail: john@capital-medical.com Website: www.capital-medical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

EST Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5 Fri: 8 to 5
 Sat: 8 to 5 to Sun: 8 to 5 to Holidays: 8 to 5 to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Lauren Gidus

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|--|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input checked="" type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: <u>compression therapy</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

MCR 0923240001

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

- Practitioner
- Advanced Practitioner of Nursing
- Physician's Assistant
- Physical Therapist
- Occupational Therapist
- Registered Nurse
- Respiratory Therapist

Name:

N/A

Name:

N/A

Name:

N/A

Name:

N/A

Name:

N/A

Name:

N/A

Name:

N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

John H. Wood
Original Signature of Person Authorized to Submit Application, no copies or stamps

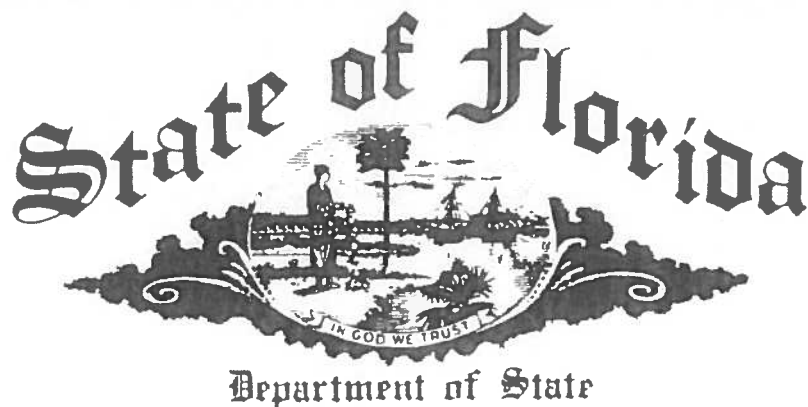
John H. Wood
Print Name of Authorized Person

8/26/2020
Date

Board Use Only

Received: _____

Amount: 500.00



I certify the attached is a true and correct copy of the Articles of Incorporation of CAPITAL MEDICAL CORPORATION, a Florida corporation, filed on November 29, 1994, as shown by the records of this office.

The document number of this corporation is P94000086284.

Given under my hand and the
Great Seal of the State of Florida,
at Tallahassee, the Capital, this the
Twenty-ninth day of November, 1994



CR2EO22 (2-91)

A handwritten signature in cursive script, reading "Jim Smith".

Jim Smith
Secretary of State



FLORIDA DEPARTMENT OF STATE

Jim Smith
Secretary of State

November 29, 1994

JOHN WOOD
919 SHADOWLAWN DRIVE
TALLAHASSEE, FL 32312

The Articles of Incorporation for CAPITAL MEDICAL CORPORATION were filed on November 29, 1994 and assigned document number P94000086284. Please refer to this number whenever corresponding with this office regarding the above corporation. The certification you requested is enclosed.

PLEASE NOTE: COMPLIANCE WITH THE FOLLOWING PROCEDURES IS ESSENTIAL TO MAINTAINING YOUR CORPORATE STATUS. FAILURE TO DO SO MAY RESULT IN DISSOLUTION OF YOUR CORPORATION.

A CORPORATION ANNUAL REPORT MUST BE FILED WITH THIS OFFICE BETWEEN JANUARY 1 AND MAY 1 OF EACH YEAR BEGINNING WITH THE CALENDAR YEAR FOLLOWING THE YEAR OF THE FILING DATE NOTED ABOVE AND EACH YEAR THEREAFTER. FAILURE TO FILE THE ANNUAL REPORT ON TIME MAY RESULT IN ADMINISTRATIVE DISSOLUTION OF YOUR CORPORATION.

A FEDERAL EMPLOYER IDENTIFICATION (FEI) NUMBER MUST BE SHOWN ON THE ANNUAL REPORT FORM PRIOR TO ITS FILING WITH THIS OFFICE. CONTACT THE INTERNAL REVENUE SERVICE TO RECEIVE THE FEI NUMBER IN TIME TO FILE THE ANNUAL REPORT AT 1-800-829-3676 AND REQUEST FORM SS-4.

SHOULD YOUR CORPORATE MAILING ADDRESS CHANGE, YOU MUST NOTIFY THIS OFFICE IN WRITING, TO INSURE IMPORTANT MAILINGS SUCH AS THE ANNUAL REPORT NOTICES REACH YOU.

Should you have any questions regarding corporations, please contact this office at the address given below.

Sharon Tala, Document Specialist Supervisor
New Filings Section

Letter Number: 994A00051131

Division of Corporations - P.O. BOX 6327 -Tallahassee, Florida 32314

ARTICLES OF INCORPORATION
OF
CAPITAL MEDICAL CORPORATION

The undersigned subscriber to these Articles of Incorporation, a natural person competent to do so, hereby forms a corporation for profit under the laws of the State of Florida.

ARTICLE I

NAME

The name of the corporation is Capital Medical Corporation.

ARTICLE II

NATURE OF BUSINESS

The general character or nature of the business to be transacted by this Corporation is to engage in any and all lawful business, trades, occupations, and professions, including the transaction of any and all lawful business for which corporations may be incorporated under Chapter 607, Florida Statutes.

ARTICLE III

CAPITAL STOCK

The maximum number of shares of stock that this Corporation is authorized to have outstanding at any time is one hundred (100) shares of common stock, each share having the par value of Five (\$5.00) dollars.

ARTICLE IV

INITIAL CAPITAL

The amount of capital with which this Corporation shall begin business is not less than Five Hundred (\$500.00) Dollars.

ARTICLE V

TERM OF EXISTENCE

This corporation shall have perpetual existence.

94 NOV 29 P.M. 1994
TALLAHASSEE, FLORIDA
SECRETARY OF STATE

ARTICLE VI

ADDRESS AND REGISTERED AGENT

The initial street address of the principal office of this Corporation is to be at 919 Shadowlawn Drive, Tallahassee, Florida, 32312. The Board of Directors may from time to time designate such other address and place for the principal office of this Corporation as it may see fit. The registered address for the Corporation shall be 919 Shadowlawn Drive, Tallahassee, Florida, 32312, and the registered agent at such address is John H. Wood.

ARTICLE VII

DIRECTORS - INITIAL DIRECTORS

The corporation shall have no more than one (1) director initially, but the number of directors may be increased from time to time by the Bylaws. The name and street address of the initial director, who shall hold office until his successors are elected and have qualified, is as follows:

JOHN H. WOOD
919 Shadowlawn Drive
Tallahassee, Florida 32312

ARTICLE VIII

SUBSCRIBERS

The name and street address of each subscriber of these Articles of Incorporation and the number of shares of stock each agrees to take are as follows:

JOHN H. WOOD, 919 Shadowlawn Drive, Tallahassee, Florida, 32312, one hundred (100) shares.

ARTICLE IX

EFFECTIVE DATE

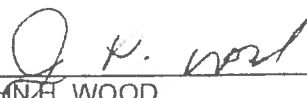
These Articles of Incorporation shall be effective upon filing with the Secretary of State of Florida.

ARTICLE X

AMENDMENT

These Articles of Incorporation may be amended in the manner provided by law. Every amendment shall be approved by the Board of Directors, proposed by them to the Stockholders meeting by a majority of the Stockholders entitled to vote thereon, unless all the Directors and all the Stockholders sign a written statement manifesting their intention that a certain amendment of these Articles of Incorporation be made.

IN WITNESS WHEREOF, I have hereunto set my hand and seal, acknowledged and filed the foregoing Articles of Incorporation under the laws of the State of Florida, this 29th day of November, 1994.



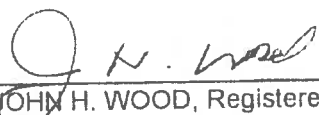
JOHN H. WOOD

REGISTERED AGENT

In pursuance of and in compliance with the Florida Statutes, the following is submitted:

That CAPITAL MEDICAL CORPORATION, desiring to organize under the laws of the State of Florida with its principal office, as indicated in the Articles of Incorporation, in the City of Tallahassee, County of Leon, has named JOHN H. WOOD, located at 919 Shadowlawn Drive, City of Tallahassee, County of Leon, State of Florida, as its agent to accept service of process within this State.

Having been named to accept service of process for the above named Corporation, at the place designated in this Certificate, I hereby accept to act in this capacity, and agree to comply with the provisions of law relative to keeping open said office.



JOHN H. WOOD, Registered Agent

94 NOV 29 5:15 PM
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

FILED

State of Florida

Department of State

I certify from the records of this office that CAPITAL MEDICAL CORPORATION is a corporation organized under the laws of the State of Florida, filed on November 29, 1994.

The document number of this corporation is P94000086284.

I further certify that said corporation has paid all fees due this office through December 31, 2020, that its most recent annual report/uniform business report was filed on January 20, 2020, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Twenty-sixth day of August,
2020*



Randy Bue
Secretary of State

Tracking Number: 8219536032CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>



CAPIMED-02

SVOLZ

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

8/25/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER License # L000563 Demont Insurance Agency, Inc. 2400 Mahan Dr Tallahassee, FL 32308	CONTACT Graham Demont NAME: PHONE (A/C, No, Ext): (850) 942-7760 FAX (A/C, No): (850) 942-7758 E-MAIL ADDRESS: documents@demontinsurance.com
INSURER(S) AFFORDING COVERAGE	
INSURER A : Philadelphia Indemnity Insurance Company	
INSURER B : Travelers Indemnity of America	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

COVERAGES

CERTIFICATE NUMBER:

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL SUBR INSD WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PROJECT <input type="checkbox"/> LOC OTHER:		PHPK2079820	1/1/2020	1/1/2021	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea. occurrence) \$ 100,000 MED EXP (Any one person) \$ 5,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 3,000,000 PRODUCTS - COMP/OP AGG \$ 3,000,000
A	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO OWNED AUTOS ONLY <input type="checkbox"/> HIRED AUTOS ONLY <input checked="" type="checkbox"/> SCHEDULED AUTOS <input checked="" type="checkbox"/> NON-OWNED AUTOS ONLY		PHPK2079820	1/1/2020	1/1/2021	COMBINED SINGLE LIMIT (Ea. accident) \$ 1,000,000 BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$
	UMBRELLA LIAB <input type="checkbox"/> OCCUR EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE DED <input type="checkbox"/> RETENTION \$					EACH OCCURRENCE \$ AGGREGATE \$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N N/A	UB2J871694	3/31/2020	3/31/2021	<input checked="" type="checkbox"/> PER STATUTE <input type="checkbox"/> OTH-ER E.L. EACH ACCIDENT \$ 100,000 E.L. DISEASE - EA EMPLOYEE \$ 100,000 E.L. DISEASE - POLICY LIMIT \$ 500,000
A	Professional		PHPK2079820	1/1/2020	1/1/2021	Per Occurrence \$ 1,000,000
B	Crime		106654203	1/1/2020	1/1/2021	Limit of Liability \$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
 Certificate Holder is listed as an additional insured with respect to the general liability policy when required by written contract.

CERTIFICATE HOLDER

CANCELLATION

National Supplier Clearinghouse
 Po Box 100142
 Columbia, SC 29202-3143

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG <input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4 <input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Ownership Change (Please provide current license number if making changes: MP or MW _____) <input type="checkbox"/> Partnership - Pages 1,2,3,6 <input type="checkbox"/> Sole Owner – Pages 1,2,3,7
---	---

Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: DJO, LLC

Physical Address: 5919 Sea Otter Place, Ste. 200, Carlsbad CA 92008

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 7000 Cardinal Place - QRA Facility Licensing

City: Dublin State: OH Zip Code: 43017

Telephone: 614-553-3076 Fax: 614-652-0674

E-mail: licensure@cardinalhealth.com Website: www.djoglobal.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8am to 5pm Tue: 8am to 5pm Wed: 8am to 5pm Thu: 8am to 5pm Fri: 8am to 5pm
 Sat: Closed Sun: Closed Holidays: Closed

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Joseph G. Martinez

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|---|---|
| <input type="checkbox"/> Medical Gases**
<input type="checkbox"/> Respiratory Equipment**
<input type="checkbox"/> Life-sustaining equipment**
<input checked="" type="checkbox"/> Diabetic Supplies | <input type="checkbox"/> Assistive Equipment
<input type="checkbox"/> Parenteral and Enteral Equipment**
<input checked="" type="checkbox"/> Orthotics and Prosthesis
Other: _____ |
|---|---|

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: N/A

Telephone: N/A

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

N/A		

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

<input checked="" type="checkbox"/> Practitioner	Name: N/A
<input checked="" type="checkbox"/> Advanced Practitioner of Nursing	Name: _____
<input checked="" type="checkbox"/> Physician's Assistant	Name: _____
<input checked="" type="checkbox"/> Physical Therapist	Name: _____
<input checked="" type="checkbox"/> Occupational Therapist	Name: _____
<input checked="" type="checkbox"/> Registered Nurse	Name: _____
<input checked="" type="checkbox"/> Respiratory Therapist	Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Keegan Chamberlain

Original Signature of Person Authorized to Submit Application, no copies or stamps

Keegan Chamberlain

Print Name of Authorized Person

08/27/2020

Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: DJO Finance, LLCCorporation Name: DJO, LLCMailing Address: 7000 Cardinal Place - QRA Facility LicensingCity: Dublin State: OH Zip: 43017Telephone: 614-553-3076Fax: 614-652-0674Contact Person: Cynthia Rhodes

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) <u>DJO Finance, LLC</u>	<u>Sea Otter Place, !</u>	<u>Carlsbad CA 92008</u>
Name	Address	

b) _____	_____
Name	Address

c) _____	_____
Name	Address

d) _____	_____
Name	Address

- 2) Provide the number of shares issued by the corporation.
- 100% interest

- 3) What was the price paid per share?
- N/A

- 4) What date did the corporation actually receive the cash assets?
- N/A

- 5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.



DJO LLC / 9801 Metcalf Blvd. / Austin, TX 78758 / 512.832.9500 / djoglobal.com

July 28, 2020

Subject: Delegation of Authorization for DJO, LLC

To Whom It May Concern,

The undersigned, Joseph G. Martinez, Senior Vice President and General Counsel, an Authorized Employee of DJO, LLC, hereby delegates to Keegan Chamberlain, Director of Quality Management and Cynthia Rhodes, Manager of Quality Management, employees of Cardinal Health 200, LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the licensing and legally required permits filed on behalf of DJO, LLC and that this delegation of authority is subject to revocation by any officer of DJO, LLC at any time and shall occur automatically when Keegan Chamberlain or Cynthia Rhodes ceases to be an employee of Cardinal Health 200, LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain or Cynthia Rhodes prior to this date, in connection with the execution of the above-referenced matters.

Respectfully,

Joseph G. Martinez
Senior Vice President and General Counsel

5919 Sea Otter Place, Ste. 200
Carlsbad, California 92008

Officer Name	Title	Company
Michael C. Eklund	Chief Operating Officer/Chief Financial Officer	DJO, LLC
Joseph G. Martinez	Senior Vice President & Assistant General Counsel	DJO, LLC
Brady Rodgers Shirley	President and CEO	DJO, LLC
Bradley J. Tandy	Executive Vice President, General Counsel & Secretary	DJO, LLC

The above information is confidential and to be used for licensing purposes only. Any other use is strictly prohibited without prior consent of Cardinal Health.



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
07/27/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, INC.
445 SOUTH STREET
MORRISTOWN, NJ 07960-6454
Attn: morristown.certrequest@marsh.com Fax 212-948-0979

CONTACT
NAME:
PHONE
(A/C, No, Ext): FAX
E-MAIL (A/C, No):
ADDRESS:

CN102317258-DJO-GAWU-20-21

INSURED
DJO Global, Inc.
1430 Decision Street
Vista, CA 92081

INSURER(S) AFFORDING COVERAGE

NAIC #

INSURER A : ACE American Insurance Company

22667

INSURER B : Federal Insurance Company

20281

INSURER C : N/A

N/A

INSURER D : Pacific Indemnity Company

20346

INSURER E : N/A

N/A

INSURER F :

COVERAGES

CERTIFICATE NUMBER:

NYC-010815058-05

REVISION NUMBER: 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL SUBR INSD WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	X COMMERCIAL GENERAL LIABILITY		OGL G2570132A	05/31/2020	05/31/2021	
	CLAIMS-MADE X OCCUR					EACH OCCURRENCE \$ 5,000,000
						DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 100,000
						MED EXP (Any one person) \$
						PERSONAL & ADV INJURY \$ 5,000,000
						GENERAL AGGREGATE \$ 10,000,000
						PRODUCTS - COMP/OP AGG \$ EXCLUDED
	GEN'L AGGREGATE LIMIT APPLIES PER:					
	X POLICY PRO-JECT LOC					
	OTHER:					
B	AUTOMOBILE LIABILITY		73551172	05/31/2020	05/31/2021	
	X ANY AUTO					COMBINED SINGLE LIMIT (Ea accident) \$ 1,000,000
	OWNED AUTOS ONLY	SCHEDULED AUTOS				BODILY INJURY (Per person) \$
	HIRED AUTOS ONLY	NON-OWNED AUTOS ONLY				BODILY INJURY (Per accident) \$
						PROPERTY DAMAGE (Per accident) \$
	UMBRELLA LIAB	OCCUR				EACH OCCURRENCE \$
	EXCESS LIAB	CLAIMS-MADE				AGGREGATE \$
	DED RETENTION \$					
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY		71737407	05/31/2020	05/31/2021	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	Y/N N	N/A			X PER STATUTE OTH-ER
	If yes, describe under DESCRIPTION OF OPERATIONS below					E.L. EACH ACCIDENT \$ 1,000,000
						E.L. DISEASE - EA EMPLOYEE \$ 1,000,000
						E.L. DISEASE - POLICY LIMIT \$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

DJO, LLC
5919 Sea Otter Place, Ste 200
Carlsbad, CA 92008

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA Inc.

Manashi Mukherjee

AGENCY CUSTOMER ID: CN102317258

LOC #: New York



ADDITIONAL REMARKS SCHEDULE

Page 2 of 2

AGENCY MARSH USA, INC.		NAMED INSURED DJO Global, Inc. 1430 Decision Street Vista, CA 92081
POLICY NUMBER		
CARRIER	NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Name Insured Schedule:

DJO Global, Inc.
 DJO Incorporated
 DJO Surgical
 DJO, LLC
 Chaitanooga Group, Inc.
 Compex Technologies
 Empi, Inc.
 Empicare, Inc.
 Encore Medical Corporation
 ReAble Therapeutics, Inc.
 Rehabicare
 Saunders Group, Inc.
 Osteoimplant Technology, Inc.
 EMPI Canada, Inc.
 DJ Ortho Canada, Inc.
 dj Orthopaedics, Pty Ltd (Australia)
 DJO Australasia Pty Ltd
 DJO France
 Dr. Comfort
 Elastic Therapy Inc.
 Elastic Therapy LLC
 Speetec Implantate GmbH
 Speetec Implantate AG
 DJO Consumer, LLC
 Exos, LLC
 DJ Orthopedics LLC
 DJO Surgical Services, LLC
 Surgi-Care, Inc.
 Ortho Pros Express
 DJO UK, LTD

EXCESS AUTO LIABILITY:

CARRIER: TRAVELERS PROPERTY CASUALTY COMPANY OF AMERICA
 POLICY NO: ZUP-71M20824-20-NF
 EFFECTIVE: 01/01/2020 - 01/01/2021
 COMBINED SINGLE LIMIT: \$4,000,000

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DJO, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF AUGUST, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



3019890 8300

SR# 20206576358

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature of Jeffrey W. Bullock in black ink, written over a horizontal line. Below the line, the text "Jeffrey W. Bullock Secretary of State" is printed.

Authentication: 203406139

Date: 08-04-20

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

DJO, LLC
5919 Sea Otter Place Suite 200
Carlsbad, CA 92008

LICENSE NUMBER: 104927
EXPIRATION DATE: 1/30/2021

Instate Retail Firm

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

4W



RECEIVED
7-30-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input type="checkbox"/> New MDEG	<input checked="" type="checkbox"/> Ownership Change
(Please provide current license number if making changes: MP or MW <u>MP 00792</u>)	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: GORDIAN MEDICAL, INC.

Physical Address: 17595 CARTWRIGHT ROAD, IRVINE, CA 92614

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip Code: 92614

Telephone: 714-556-0200 Fax: 877-232-9366

E-mail: licensure@amtwoundcare.com Website: www.amtwoundcare.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 am to 5 pm Tue: 8 am to 5 pm Wed: 8 am to 5 pm Thu: 8 am to 5 pm Fri: 8 am to 5 pm
Sat: Closed to Closed Sun: Closed to Closed Holidays: Closed to Closed

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: GLORIA KARNES

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- ☐ Medical Gases**
- ☐ Respiratory Equipment**
- ☐ Life-sustaining equipment**
- ☐ Diabetic Supplies

- ☐ Assistive Equipment
- ☐ Parenteral and Enteral Equipment**
- ☐ Orthotics and Prosthesis

Other: Ostomy, Urological, Tracheostomy and Surgical Dressings

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____

Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

See attached.

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☒ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner
- Advanced Practitioner of Nursing
- Physician's Assistant
- Physical Therapist
- Occupational Therapist
- Registered Nurse
- Respiratory Therapist

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

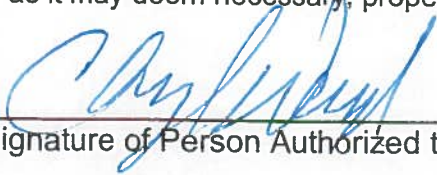
This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

CHERYL WARD

Print Name of Authorized Person

7/25/20
Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION

State of Incorporation: NEVADA

Parent Company if any: AMT BUYER CORP

Corporation Name: GORDIAN MEDICAL, INC.

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip: 92614

Telephone: 714-556-0200 Fax: 877-232-9268

Contact Person: STONEY HARVILLE

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?
 - a) AMT BUYER CORP, 17595 CARTWRIGHT ROAD, IRVINE, CA 92614

Name	Address
------	---------
 - b) _____

Name	Address
------	---------
 - c) _____

Name	Address
------	---------
 - d) _____

Name	Address
------	---------
- 2) Provide the number of shares issued by the corporation. 103,000,000
- 3) What was the price paid per share? N/A (stock transferred to AMT Buyer Corp. through a stock transfer transaction)
- 4) What date did the corporation actually receive the cash assets? N/A
- 5) Provide a copy of the corporation's stock register evidencing the above information N/A

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Gordian Medical, Inc.
dba American Medical Technologies

17595 Cartwright Road Irvine, CA 92614
PHONE: (714) 556-0200 FAX (877) 232-9268

Gordian Medical II, Inc.

5834 Louetta Road, Suite D
Spring, TX 77379

Gordian Medical IV, Inc.

1430 3rd Street #6
Riverside, CA 92507

Gordian Medical V, Inc.

9894 Bissonnet St., Suite 420
Houston, TX 77036

Gordian Medical VI, Inc.

17901 Von Karman Ave., Suite 600
Irvine, CA 92614

Gordian Medical VIII, Inc.

7226 Taft St.
Hollywood, FL 33024

Gordian Medical X, Inc.

1097 Weston Drive, Suite B
Mount Juliet, TN 37122

Gordian Medical, Inc.
dba American Medical Technologies

17595 Cartwright Road Irvine, CA 92614
PHONE: (714) 556-0200 FAX (877) 232-9268

Directors and Officers

Director/Officer: Suresh Muppalla, *Chief Executive Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

Director/Officer: Cheryl L. Ward, *Chief Operating Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational documents on file in this office for
GORDIAN MEDICAL, INC.

Organizational Documents on File	Filing Date
----------------------------------	-------------

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, GORDIAN MEDICAL, INC., as a corporation duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 03/16/2007, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my
hand and affixed the Great Seal of State, at my
office on 07/23/2020

Barbara K. Cegavske

Certificate Number: B20200723945491
You may verify this certificate
online at <http://www.nvsos.gov>

BARBARA K. CEGAVSKE
Secretary of State

GORDIAN MEDICAL, INC.**MEDICARE PTAN**

6112960001

MEDICAID STATE**MEDICAID PROVIDER NO.**

Alabama	104474
Alaska	1021467
Arizona	375389
Arkansas	173356741
California	1013124213
Colorado	36420859
Connecticut	8002173
Florida	009429200
Georgia	583748890A
Hawaii	1013124213
Hawaii -MedQuest	630922
Idaho	1013124213
Illinois	320198007-001
Indiana	200914330A
Iowa	1013124213
Kansas	200570340A
Kansas	200570340B
Kentucky	7100072610
Louisiana	1886211
Maine	1013124213
Maryland	8420400
Massachusetts	110087981A
Michigan	1013124213 FAO
Minnesota	1013124213
Mississippi	06336001
Missouri	626489801
Montana	1013124213
Nebraska	1013124213
New Jersey	0239631
New Mexico	28123387
New York	3156521
North Carolina	2449249
Ohio	2876311
Oklahoma	200211020A
Oregon	500621516
Pennsylvania	102324539-0001
Rhode Island	GM72832
South Carolina	DM1312
South Dakota	9164030
Tennessee	1508028
Texas	196219302
Utah	1013124213
Vermont	1030817
Virginia	1013124213
Washington	9063322
West Virginia	1013124213
Wisconsin	1013124213
Wyoming	1013124213



CERTIFICATE OF LIABILITY INSURANCE

361
DATE (MM/DD/YYYY)
4/1/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ARCON' Insurance Brokers 4533 MacArthur Blvd. #5126 Newport Beach CA 92660		CONTACT NAME: Arcon Service PHONE (A/C, No, Ext): (866) 661-2345 E-MAIL ADDRESS: contact@arconinsurance.com FAX (A/C, No):	
INSURED Gordian Medical, Inc. DBA: American Medical Technologies 17595 Cartwright Road Irvine CA 92614		INSURER(S) AFFORDING COVERAGE INSURER A: Pharmacist Mutual Insurance Company NAIC # 13714 INSURER B: Landmark American Insurance Company 33138 INSURER C: INSURER D: INSURER E: INSURER F:	

COVERAGES CERTIFICATE NUMBER: 2020 Master Certificate REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:			BOP 0165706 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 50,000 MED EXP (Any one person) \$ 10,000 PERSONAL & ADV INJURY \$ INCLUDED GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$ EXCLUDED Employee Benefits \$ 1,000,000
	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) \$ BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$ \$
	<input checked="" type="checkbox"/> UMBRELLA LIAB <input type="checkbox"/> EXCESS LIAB DED <input checked="" type="checkbox"/> RETENTION \$ 10,000			DCL 0162880 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 4,000,000 AGGREGATE \$ 4,000,000 \$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N <input type="checkbox"/> N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT \$ E.L. DISEASE - EA EMPLOYEE \$ E.L. DISEASE - POLICY LIMIT \$
B	PROFESSIONAL LIABILITY			LHM839929	4/1/2020	4/1/2021	PER OCCURRENCE \$2,000,000 AGGREGATE \$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
COMMERCIAL CRIME POLICY - HISCOX INSURANCE COMPANY NAIC# 10200 - 04/01/2020 TO 04/01/2021 - \$1,000,000
LIMIT - POLICY NUMBER UC24090420.20.

CERTIFICATE HOLDER IS INCLUDED AS ADDITIONAL INSURED.

CERTIFICATE HOLDER

CANCELLATION

NATIONAL SUPPLIER CLEARING HOUSE-AG-
495PALMETTO GBA
P.O. BOX 100142
COLUMBIA, SC 29202-3142

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Graham Harvey/H001

© 1988-2014 ACORD CORPORATION. All rights reserved.

Gordian Medical, Inc.

17595 CARTWRIGHT ROAD, IRVINE, CA 92614-5847

PHONE: (714) 556-0200 FAX: (714) 556-0300

July 25, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Via U.S. Priority Mail
With Delivery Confirmation
Tracking No. 9470103699300051497274

**RE: Application for Transfer of Ownership for DME Permit
Gordian Medical, Inc. dba American Medical Technologies
EIN: 32-0198007**

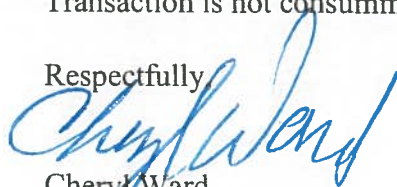
To Whom it May Concern:

On behalf of Gordian Medical Inc. dba American Medical Technologies, I submit the enclosed Application for Transfer of Ownership for DME Permit along with payment in the amount of \$500.00 with required documentation.

The purpose of this letter is to notify the Nevada Board of Pharmacy of a proposed transaction (the "Transaction") with respect to the ownership of Licensee (as defined above). As part of the Transaction, which is expected to occur on or around July 31, 2020, AMT Buyer Corp. plans to purchase 100% of the common stock of Gordian Medical, Inc. (Licensee). The Transaction is not expected to result in any changes to Licensee's name, tax identification number, locations, National Provider Identifier ("NPI") or policies and procedures. While Licensee believes that no other action is necessary with respect to its licensure, please promptly notify us if the Board of Pharmacy requires any additional information or forms to be filed.

If you have any questions or concerns regarding the Transaction, please do not hesitate to contact Stoney Harville at 951-398-5910 or stoney.harville@amtwoundcare.com. If for any reason the Transaction is not consummated, this letter will have no force or effect.

Respectfully,



Cheryl Ward
Chief Operating Officer

Attachments:

- Proof of Insurance
- Certificate of Corporate Status
- List of Officers and Directors
- List of Medicare & Medicaid Provider Numbers

4X

RECEIVED
8-3-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change
(Please provide current license number if making changes: MP or MW <u>MP 02980</u>)	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: GORDIAN MEDICAL II, INC.

Physical Address: 5834 LOUETTA ROAD, SUITE D, SPRING, TX 77379-7884

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip Code: 92614

Telephone: 714-556-0200

Fax: 877-232-9268

E-mail: licensure@amtoundcare.com

Website: www.amtwoundcare.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9 am to 3 pm Tue: 9 am to 3 pm Wed: 9 am to 3 pm Thu: 9 am to 3 pm Fri:

9 am to 3 pm Sat: to Sun: to Holidays: to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: APRIL CHURCH

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**

☐ Respiratory Equipment**

☐ Life-sustaining equipment**

☐ Diabetic Supplies

☐ Assistive Equipment

☐ Parenteral and Enteral Equipment**

☐ Orthotics and Prosthesis

Other: Ostomy, Urological, Tracheostomy, Surgical Dressings

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____

Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

See Attached		

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☒ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

<input type="checkbox"/> Practitioner	Name: <u>N/A</u>
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: <u>N/A</u>
<input type="checkbox"/> Physician's Assistant	Name: <u>N/A</u>
<input type="checkbox"/> Physical Therapist	Name: <u>N/A</u>
<input type="checkbox"/> Occupational Therapist	Name: <u>N/A</u>
<input type="checkbox"/> Registered Nurse	Name: <u>N/A</u>
<input type="checkbox"/> Respiratory Therapist	Name: <u>N/A</u>

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

CHERYL WARD

Print Name of Authorized Person

7/28/20
Date

Board Use Only

Received: _____

Amount: 500.00

State of Incorporation: TEXAS

Parent Company if any: GORDIAN MEDICAL, INC

Corporation Name: GORDIAN MEDICAL II, INC.

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip: 92614

Telephone: 714-556-0200 Fax: 877-232-9268

Contact Person: STONEY HARVILLE

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) GORDIAN MEDICAL, INC., 17595 CARTWRIGHT ROAD, IRVINE, CA 92614

Name	Address
GORDIAN MEDICAL, INC.	17595 CARTWRIGHT ROAD, IRVINE, CA 92614

b) _____

Name	Address
------	---------

c) _____

Name	Address
------	---------

[illegible]

- 2) Provide the number of shares issued by the corporation. 1,000
- 3) What was the price paid per share? N/A
- 4) What date did the corporation actually receive the cash assets? N/A
- 5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Gordian Medical II, Inc.

Louetta RD.

Spring TX 77379

PHONE: (

FAX: (281) 205-7093

Directors and Officers

Director/Officer: Suresh Muppalla, *Chief Executive Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

Director/Officer: Cheryl L. Ward, *Chief Operating Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200



Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Gordian Medical II, Inc. (file number 801536663), a Domestic For-Profit Corporation, was filed in this office on January 19, 2012.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on July 23, 2020.



A handwritten signature in black ink, appearing to read "Ruth R. Hughs".

Ruth R. Hughs
Secretary of State

GORDIAN MEDICAL II, INC.**MEDICARE PTAN**

7565280001

MEDICAID STATE**MEDICAID PROVIDER NO.**

Alabama	1063771798
Alaska	1703530
Arizona	228661
California Crossover	1063771798
Colorado	9000143125
Connecticut	1063771798
Idaho	1063771798
Illinois	1063771798
Indiana	300003799
Iowa	1063771798
Kansas	201149250A
Kentucky	7100477670
Maryland	4244362 00
Michigan	1063771798
Minnesota	1063771798
Mississippi	9722542
Montana	1063771798
Nebraska	10026638400
New Hampshire	3108874
New Mexico	58080708
North Carolina	1063771798
Oklahoma	200699500A
Oregon	1063771798
Pennsylvania	103234178 0001
South Carolina	DM1648
Tennessee	Q030405
Texas	149338
Utah	3001875
Vermont	1029386
Washington	2149270
West Virginia	1063771798
Wyoming	1063771798



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

5/8/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ARCON Insurance Brokers 4533 MacArthur Blvd. #5126 Newport Beach CA 92660	CONTACT NAME: Arcon Service PHONE (A/C, No, Ext): (866) 661-2345 FAX (A/C, No): E-MAIL ADDRESS: contact@arconinsurance.com
INSURED Gordian Medical II, Inc. Better Balance Pharmacy 5834 Louetta Road, Suite D Spring TX 77379	INSURER(S) AFFORDING COVERAGE INSURER A: Pharmacist Mutual Insurance Company INSURER B: Landmark American Insurance Company INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** Gordian Medical II BBP **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PROJECT <input type="checkbox"/> LOC <input type="checkbox"/> OTHER:			BOP 0165706 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 100,000 MED EXP (Any one person) \$ 5,000 PERSONAL & ADV INJURY \$ INCLUDED GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$ EXCLUDED Employee Benefits \$ 1,000,000
	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) \$ BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$ \$
	<input checked="" type="checkbox"/> UMBRELLA LIAB <input type="checkbox"/> EXCESS LIAB <input type="checkbox"/> DED <input checked="" type="checkbox"/> RETENTION \$ 10,000			UCL 0162880 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 4,000,000 AGGREGATE \$ 4,000,000 \$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N <input type="checkbox"/> N/A					PER STATUTE <input type="checkbox"/> OTH-ER <input type="checkbox"/> E.I. EACH ACCIDENT \$ E.I. DISEASE - EA EMPLOYEE \$ E.I. DISEASE - POLICY LIMIT \$
B	PROFESSIONAL LIABILITY			LHM039929	4/1/2020	4/1/2021	EACH OCCURRENCE \$2,000,000 AGGREGATE \$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
COMMERCIAL CRIME POLICY - HISCOX INSURANCE COMPANY NAIC# 10200 - 04/01/2020 TO 04/01/2021 - \$1,000,000
LIMIT - POLICY NUMBER UC24090420.20.

CERTIFICATE HOLDER**CANCELLATION**

NATIONAL SUPPLIER CLEARING HOUSE-AG-
495 PALMETTO GBA
P.O. BOX 100142
COLUMBIA, SC 29202-3142

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Graham Harvey/H001

© 1988-2014 ACORD CORPORATION. All rights reserved.

Gordian Medical II, Inc.

5834 Louetta RD. Suite D, Spring TX 77379
PHONE: (281) 205-7091 FAX: (281) 205-7093

July 25, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Via U.S. Priority Mail
With Delivery Confirmation
Tracking No. 9470103699300051497274

**RE: Application for Transfer of Ownership for DME Permit
Gordian Medical, Inc. dba American Medical Technologies
EIN: 32-0198007**

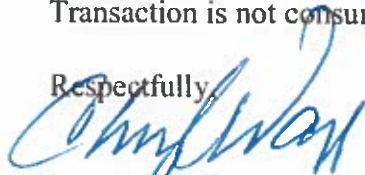
To Whom it May Concern:

On behalf of Gordian Medical II, Inc. dba American Medical Technologies, I submit the enclosed Application for Transfer of Ownership for DME Permit along with payment in the amount of \$500.00 with required documentation.

The purpose of this letter is to notify the Nevada Board of Pharmacy of a proposed transaction (the "Transaction") with respect to the ownership of Licensee (as defined above). As part of the Transaction, which is expected to occur on or around July 31, 2020, AMT Buyer Corp. plans to purchase 100% of the common stock of Gordian Medical, Inc., which is the 100% direct owner of Licensee. The Transaction is not expected to result in any changes to Licensee's name, tax identification number, locations, National Provider Identifier ("NPI") or policies and procedures. While Licensee believes that no other action is necessary with respect to its licensure, please promptly notify us if the Board of Pharmacy requires any additional information or forms to be filed.

If you have any questions or concerns regarding the Transaction, please do not hesitate to contact Stoney Harville at 951-398-5910 or stoney.harville@amtboundcare.com. If for any reason the Transaction is not consummated, this letter will have no force or effect.

Respectfully,



Cheryl Ward
Chief Operating Officer

Attachments:

- Proof of Insurance
- Certificate of Corporate Status
- List of Officers and Directors
- List of Medicare & Medicaid Provider Numbers

4Y



RECEIVED
7-30-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input type="checkbox"/> New MDEG	<input checked="" type="checkbox"/> Ownership Change
(Please provide current license number if making changes: MP or MW <u>MP 01403</u>)	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: GORDIAN MEDICAL IV, INC.

Physical Address: 1430 3RD STREET, SUITE #6, RIVERSIDE, CA 92507-3498

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip Code: 92614

Telephone: 714-556-0200 Fax: 877-232-9268

E-mail: licensure@amtoundcare.com Website: www.amtwoundcare.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 am to 2 pm Tue: 8 am to 2 pm Wed: 8 am to 2 pm Thu: 8 am to 2 pm Fri: 8 am to 2 pm

Sat: 8 am to 2 pm Sun: 8 am to 2 pm Holidays: 8 am to 2 pm

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: JANET SOLORZANO

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|--|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: <u>Ostomy, Urological, Tracheostomy, and Surgical Dressings</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

See Attached

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☒ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner
- Advanced Practitioner of Nursing
- Physician's Assistant
- Physical Therapist
- Occupational Therapist
- Registered Nurse
- Respiratory Therapist

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Name: N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

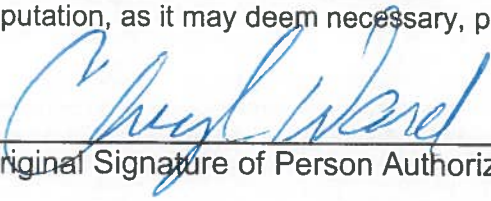
This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

CHERYL WARD

Print Name of Authorized Person

Date



Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION

State of Incorporation: NEVADA

Parent Company if any: GORDIAN MEDICAL, INC

Corporation Name: GORDIAN MEDICAL IV, INC.

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip: 92614

Telephone: 714-556-0200 Fax: 877-232-9268

Contact Person: STONEY HARVILLE

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?
 - a) GORDIAN MEDICAL, INC, 17595 CARTWRIGHT ROAD, IRVINE, CA 92614

Name	Address
------	---------
 - b) _____

Name	Address
------	---------
 - c) _____

Name	Address
------	---------
 - d) _____

Name	Address
------	---------
- 2) Provide the number of shares issued by the corporation. 1,500
- 3) What was the price paid per share? N/A
- 4) What date did the corporation actually receive the cash assets? N/A
- 5) Provide a copy of the corporation's stock register evidencing the above information N/A

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Gordian Medical IV, Inc.

Street Ste Riverside, CA 92507

Phone: FAX (951) 934-0106

Directors and Officers

Director/Officer: Suresh Muppalla, *Chief Executive Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

Director/Officer: Cheryl L. Ward, *Chief Operating Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE
WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly elected and qualified Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **GORDIAN MEDICAL IV, INC.**, as a corporation duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since December 28, 2015, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on July 3, 2017.

A handwritten signature in cursive script that reads "Barbara K. Cegavske".

Barbara K. Cegavske
Secretary of State

Electronic Certificate
Certificate Number: C20170703-1335
You may verify this electronic certificate
online at <http://www.nvsos.gov/>

GORDIAN MEDICAL IV, INC.**MEDICARE PTAN**

7599760001

MEDICAID STATE

Alabama

California

Colorado

Idaho

Kansas

Louisiana

Maryland

Michigan

Mississippi

Montana

Nebraska

New York

North Carolina

Ohio

Oklahoma

Oregon

Pennsylvania

South Carolina

Vermont

Washington

Wyoming

MEDICAID PROVIDER NO.

1992162911

1992162911

1992162911

1992162911

201159940A

2449249

300286100

1992162911

8724809

1992162911

10026672800

3156521

1992162911

228912

200711680A

500775991

103356288 0001

DM1587

1030817

2083657

146619400



CERTIFICATE OF LIABILITY INSURANCE

381
DATE (MM/DD/YYYY)
4/1/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ARCON Insurance Brokers 4533 MacArthur Blvd. #5126 Newport Beach CA 92660	CONTACT NAME: Arcon Service PHONE (A/C, No, Ext): (866) 661-2345 E-MAIL ADDRESS: contact@arconinsurance.com FAX (A/C, No):														
INSURED Gordian Medical IV, Inc. DBA: American Medical Technologies 17595 Cartwright Road Irvine CA 92614	<table border="1"><thead><tr><th>INSURER(S) AFFORDING COVERAGE</th><th>NAIC #</th></tr></thead><tbody><tr><td>INSURER A: Pharmacist Mutual Insurance Company</td><td>13714</td></tr><tr><td>INSURER B: Landmark American Insurance Company</td><td>33138</td></tr><tr><td>INSURER C:</td><td></td></tr><tr><td>INSURER D:</td><td></td></tr><tr><td>INSURER E:</td><td></td></tr><tr><td>INSURER F:</td><td></td></tr></tbody></table>	INSURER(S) AFFORDING COVERAGE	NAIC #	INSURER A: Pharmacist Mutual Insurance Company	13714	INSURER B: Landmark American Insurance Company	33138	INSURER C:		INSURER D:		INSURER E:		INSURER F:	
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INSURER C:															
INSURER D:															
INSURER E:															
INSURER F:															

COVERAGES

CERTIFICATE NUMBER: 2020 Cert for Gordian IV

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS														
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:			BOP 0165706 00	4/1/2020	4/1/2021	<table border="1"><tr><td>EACH OCCURRENCE</td><td>\$ 1,000,000</td></tr><tr><td>DAMAGE TO RENTED PREMISES (Ea occurrence)</td><td>\$ 100,000</td></tr><tr><td>MED EXP (Any one person)</td><td>\$ 5,000</td></tr><tr><td>PERSONAL & ADV INJURY</td><td>\$ INCLUDED</td></tr><tr><td>GENERAL AGGREGATE</td><td>\$ 2,000,000</td></tr><tr><td>PRODUCTS - COMPI/OP AGG</td><td>\$ EXCLUDED</td></tr><tr><td>Employee Benefits</td><td>\$ 1,000,000</td></tr></table>	EACH OCCURRENCE	\$ 1,000,000	DAMAGE TO RENTED PREMISES (Ea occurrence)	\$ 100,000	MED EXP (Any one person)	\$ 5,000	PERSONAL & ADV INJURY	\$ INCLUDED	GENERAL AGGREGATE	\$ 2,000,000	PRODUCTS - COMPI/OP AGG	\$ EXCLUDED	Employee Benefits	\$ 1,000,000
EACH OCCURRENCE	\$ 1,000,000																				
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PRODUCTS - COMPI/OP AGG	\$ EXCLUDED																				
Employee Benefits	\$ 1,000,000																				
	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> NON-OWNED AUTOS						<table border="1"><tr><td>COMBINED SINGLE LIMIT (Ea accident)</td><td>\$</td></tr><tr><td>BODILY INJURY (Per person)</td><td>\$</td></tr><tr><td>BODILY INJURY (Per accident)</td><td>\$</td></tr><tr><td>PROPERTY DAMAGE (Per accident)</td><td>\$</td></tr></table>	COMBINED SINGLE LIMIT (Ea accident)	\$	BODILY INJURY (Per person)	\$	BODILY INJURY (Per accident)	\$	PROPERTY DAMAGE (Per accident)	\$						
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BODILY INJURY (Per accident)	\$																				
PROPERTY DAMAGE (Per accident)	\$																				
A	<input checked="" type="checkbox"/> UMBRELLA LIAB <input type="checkbox"/> EXCESS LIAB DED <input checked="" type="checkbox"/> RETENTION \$ 10,000 OCCUR CLAIMS-MADE			UCL 0162880 00	4/1/2020	4/1/2021	<table border="1"><tr><td>EACH OCCURRENCE</td><td>\$ 4,000,000</td></tr><tr><td>AGGREGATE</td><td>\$ 4,000,000</td></tr></table>	EACH OCCURRENCE	\$ 4,000,000	AGGREGATE	\$ 4,000,000										
EACH OCCURRENCE	\$ 4,000,000																				
AGGREGATE	\$ 4,000,000																				
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N <input type="checkbox"/>	N/A				<table border="1"><tr><td>PER STATUTE</td><td>OTH-ER</td></tr><tr><td>E.L. EACH ACCIDENT</td><td>\$</td></tr><tr><td>E.L. DISEASE - EA EMPLOYEE</td><td>\$</td></tr><tr><td>E.L. DISEASE - POLICY LIMIT</td><td>\$</td></tr></table>	PER STATUTE	OTH-ER	E.L. EACH ACCIDENT	\$	E.L. DISEASE - EA EMPLOYEE	\$	E.L. DISEASE - POLICY LIMIT	\$						
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E.L. DISEASE - EA EMPLOYEE	\$																				
E.L. DISEASE - POLICY LIMIT	\$																				
B	PROFESSIONAL LIABILITY			LHM839929	4/1/2020	4/1/2021	<table border="1"><tr><td>EACH OCCURRENCE</td><td>\$2,000,000</td></tr><tr><td>AGGREGATE</td><td>\$5,000,000</td></tr></table>	EACH OCCURRENCE	\$2,000,000	AGGREGATE	\$5,000,000										
EACH OCCURRENCE	\$2,000,000																				
AGGREGATE	\$5,000,000																				

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

COMMERCIAL CRIME POLICY - HISCOX INSURANCE COMPANY NAIC# 10200 - 04/01/2020 TO 04/01/2021 - \$1,000,000
LIMIT - POLICY NUMBER TBD.

LOCATION: 1430 3RD STREET, SUITE #6, RIVERSIDE, CA 92507

CERTIFICATE HOLDER

CANCELLATION

NATIONAL SUPPLIER CLEARING HOUSE-AG-
495PALMETTO GBA
P.O. BOX 100142
COLUMBIA, SC 29202-3142

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Graham Harvey/H001

Gordian Medical IV, Inc.

1430 3rd Street Ste. 6 Riverside, CA 92507

Phone (951) 736-9000 FAX (951) 934-0106

July 24, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Via U.S. Priority Mail
With Delivery Confirmation
Tracking No. 9470103699300051497366

**RE: Application for Transfer of Ownership for DME Permit
Gordian Medical IV, Inc. dba American Medical Technologies
EIN: 81-0934780**

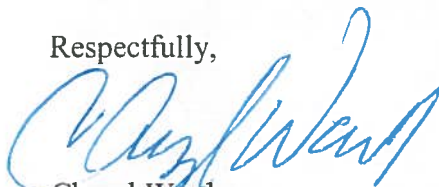
To Whom it May Concern:

On behalf of Gordian Medical IV, Inc. dba American Medical Technologies, I submit the enclosed *Application for Transfer of Ownership for DME Permit* along with payment in the amount of \$500.00 with required documentation.

The purpose of this letter is to notify the Nevada Board of Pharmacy of a proposed transaction (the "Transaction") with respect to the ownership of Licensee (as defined above). As part of the Transaction, which is expected to occur on or around July 31, 2020, AMT Buyer Corp. plans to purchase 100% of the common stock of Gordian Medical, Inc., which is the 100% direct owner of Licensee. The Transaction is not expected to result in any changes to Licensee's name, tax identification number, locations, National Provider Identifier ("NPI") or policies and procedures. While Licensee believes that no other action is necessary with respect to its licensure, please promptly notify us if the Board of Pharmacy requires any additional information or forms to be filed.

If you have any questions or concerns regarding the Transaction, please do not hesitate to contact Stoney Harville at 951-398-5910 or stoney.harville@amtwoundcare.com. If for any reason the Transaction is not consummated, this letter will have no force or effect.

Respectfully,



Cheryl Ward
Chief Operating Officer

Attachments:

- Proof of Insurance
- Certificate of Corporate Status
- List of Officers and Directors
- List of Medicare & Medicaid Provider Numbers

4Z



RECEIVED
7-30-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input type="checkbox"/> New MDEG	<input checked="" type="checkbox"/> Ownership Change
(Please provide current license number if making changes: MP or MW <u>MP 01520</u>)	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: GORDIAN MEDICAL V, INC.

Physical Address: 9894 BISSONNET STREET, SUITE 420, HOUSTON, TX 77036-8242

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip Code: 92614

Telephone: 714-556-0200 Fax: 877-232-9268

E-mail: licensure@amtoundcare.com Website: www.amtwoundcare.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9 am to 5 pm Tue: 9 am to 5 pm Wed: 9 am to 5 pm Thu: 9 am to 5 pm Fri: 9 am to 5 pm
Sat: 9 am to 5 pm Sun: 9 am to 5 pm Holidays: 9 am to 5 pm

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: TYRONE LAGRIA

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|---|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: <u>Ostomy, Urological, Tracheostomy and Surgical Dressings</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

_____	_____	_____
_____	_____	_____
_____	_____	_____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☒ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

<input type="checkbox"/> Practitioner	Name: <u>N/A</u>
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: <u>N/A</u>
<input type="checkbox"/> Physician's Assistant	Name: <u>N/A</u>
<input type="checkbox"/> Physical Therapist	Name: <u>N/A</u>
<input type="checkbox"/> Occupational Therapist	Name: <u>N/A</u>
<input type="checkbox"/> Registered Nurse	Name: <u>N/A</u>
<input type="checkbox"/> Respiratory Therapist	Name: <u>N/A</u>

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Cheryl Ward

Original Signature of Person Authorized to Submit Application, no copies or stamps

CHERYL WARD

Print Name of Authorized Person

Date

1/26/20

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATIONState of Incorporation: TEXASParent Company if any: GORDIAN MEDICAL, INC.Corporation Name: GORDIAN MEDICAL V, INC.Mailing Address: 17595 CARTWRIGHT ROADCity: IRVINE State: CA Zip: 92614Telephone: 714-556-0200 Fax: 877-232-9268Contact Person: STONEY HARVILLE

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) GORDIAN MEDICAL, INC., 17595 CARTWRIGHT ROAD, IRVINE, CA 92614

Name

Address

b)

Name

Address

c)

Name

Address

d)

Name

Address

2) Provide the number of shares issued by the corporation. 1,0003) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A5) Provide a copy of the corporation's stock register evidencing the above information N/A**Include with the application for a non-publicly traded corporation**

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Gordian Medical V, Inc.
dba Agra Health Medical Supply
9894 Bissonnet Street Ste. 420 Houston, TX 77036
Phone (832) 365-5117

Directors and Officers

Director/Officer: Suresh Muppalla, *Chief Executive Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

Director/Officer: Cheryl L. Ward, *Chief Operating Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200



Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Gordian Medical V, Inc. (file number 802160156), a Domestic For-Profit Corporation, was filed in this office on February 17, 2015.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on July 23, 2020.



A handwritten signature in black ink, appearing to read "Ruth R. Hughs".

Ruth R. Hughs
Secretary of State

GORDIAN MEDICAL V, INC.**MEDICARE PTAN**

7543020001

MEDICAID STATE

Alabama

California

Michigan

New Mexico

North Carolina

South Carolina

Texas

Utah

Washington

Wyoming

MEDICAID PROVIDER NO.

10247322

1225413743

1225413743

1331701

1225413743

DM1650

362093201

1225413743

2155882

155146900



CERTIFICATE OF LIABILITY INSURANCE

391
DATE (MM/DD/YYYY)
4/13/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

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PRODUCER ARCON Insurance Brokers 4533 MacArthur Blvd. #5126 Newport Beach CA 92660		CONTACT NAME: Arcon Service PHONE (A/C, No, Ext): (866) 661-2345 E-MAIL ADDRESS: contact@arconinsurance.com FAX (A/C, No):	
INSURED Gordian Medical V, Inc. DBA: Agra Health Medical Supply 9894 Bissonnet Street, Suite 420 Houston TX 77036		INSURER(S) AFFORDING COVERAGE INSURER A: Pharmacist Mutual Insurance Company INSURER B: Landmark American Insurance Company INSURER C: INSURER D: INSURER E: INSURER F:	
		NAIC # 13714 33138	

COVERAGES

CERTIFICATE NUMBER: Gordian V Cert

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY			BOP 0165706 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 1,000,000
	<input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR		DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 100,000				
			MED EXP (Any one person) \$ 5,000				
			PERSONAL & ADV INJURY \$ INCLUDED				
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE \$ 2,000,000
	<input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC						PRODUCTS - COMP/OP AGG \$ EXCLUDED
	OTHER:						Employee Benefits \$ 1,000,000
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident) \$
	<input type="checkbox"/> ANY AUTO		<input type="checkbox"/> SCHEDULED AUTOS				BODILY INJURY (Per person) \$
	<input type="checkbox"/> ALL OWNED AUTOS		<input type="checkbox"/> NON-OWNED AUTOS				BODILY INJURY (Per accident) \$
	<input type="checkbox"/> HIRED AUTOS		<input type="checkbox"/> AUTOS				PROPERTY DAMAGE (Per accident) \$
A	<input checked="" type="checkbox"/> UMBRELLA LIAB			UCL 0162880 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 4,000,000
	<input type="checkbox"/> EXCESS LIAB		<input type="checkbox"/> CLAIMS-MADE				AGGREGATE \$ 4,000,000
	<input type="checkbox"/> DED <input checked="" type="checkbox"/> RETENTION \$ 10,000						
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)						E.L. EACH ACCIDENT \$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE \$
B	PROFESSIONAL LIABILITY			LHM839929	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 2,000,000
							AGGREGATE \$ 5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

COMMERCIAL CRIME POLICY - HISCOX INSURANCE COMPANY NAIC# 10200 - 04/01/2020 TO 04/01/2021 - \$1,000,000
LIMIT - POLICY NUMBER UC24090420.20.

CERTIFICATE HOLDER

CANCELLATION

NSC P.O. BOX 100142 COLUMBIA, SC 29202-3142	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.
	AUTHORIZED REPRESENTATIVE Graham Harvey/H001

© 1988-2014 ACORD CORPORATION. All rights reserved.

Gordian Medical V, Inc.
dba Agra Health Medical Supply
9894 Bissonnet Street Ste. 420 Houston, TX 77036
Phone (832) 365-5117

July 24, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Via U.S. Priority Mail
With Delivery Confirmation
Tracking No. 9470103699300051497410

RE: Application for Transfer of Ownership for DME Permit
Gordian Medical V, Inc. dba Agra Health Medical Supply
EIN: 47-3146745

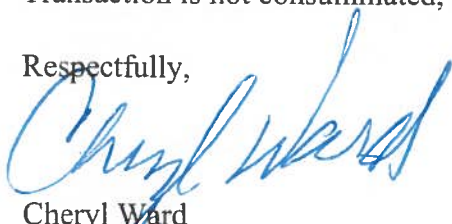
To Whom it May Concern:

On behalf of Gordian Medical V, Inc. dba Agra Health Medical Supply, I submit the enclosed *Application for Transfer of Ownership for DME Permit* along with payment in the amount of \$500.00 with required documentation.

The purpose of this letter is to notify the Nevada Board of Pharmacy of a proposed transaction (the "Transaction") with respect to the ownership of Licensee (as defined above). As part of the Transaction, which is expected to occur on or around July 31, 2020, AMT Buyer Corp. plans to purchase 100% of the common stock of Gordian Medical, Inc., which is the 100% direct owner of Licensee. The Transaction is not expected to result in any changes to Licensee's name, tax identification number, locations, National Provider Identifier ("NPI") or policies and procedures. While Licensee believes that no other action is necessary with respect to its licensure, please promptly notify us if the Board of Pharmacy requires any additional information or forms to be filed.

If you have any questions or concerns regarding the Transaction, please do not hesitate to contact Stoney Harville at 951-398-5910 or stoney.harville@amtboundcare.com. If for any reason the Transaction is not consummated, this letter will have no force or effect.

Respectfully,



Cheryl Ward
Chief Operating Officer

Attachments:

- Proof of Insurance
- Certificate of Corporate Status
- List of Officers and Directors
- List of Medicare & Medicaid Provider Numbers

4AA

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

☐ New MDEG ☒ Ownership Change
(Please provide current license number if making changes: MP or MW MP 01418)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☐ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7

Please check box for type of ownership and complete correct part of the application.

Facility Name: GORDIAN MEDICAL VI, INC.

Physical Address: 17901 VON KARMAN AVENUE, SUITE #600, IRVINE, CA 92614

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip Code: 3:30

Telephone: 714-556-0200 Fax: 877-232-9268

E-mail: licensure@amtwoundcare.com Website: www.amtwoundcare.com

Mon: 9 am to 3:30 Tue: 9 am to 3:30 pm Wed: 9 am to 3:30pm Thu: 9 am to 3:30pm Fri: 9 am to 3:30 pm
Sat: 9 am to 3:30 pm Sun: 9 am to 3:30 pm Holidays: 9 am to 3:30 pm

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: ANGELICA VILLA

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- ☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
- ☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosthesis
 Other: Ostomy, Urological, Tracheostomy and Surgical Dressings

****If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.**

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

_____	_____	_____
_____	_____	_____
_____	_____	_____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☒ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

<input type="checkbox"/> Practitioner	Name: <u>N/A</u>
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: <u>N/A</u>
<input type="checkbox"/> Physician's Assistant	Name: <u>N/A</u>
<input type="checkbox"/> Physical Therapist	Name: <u>N/A</u>
<input type="checkbox"/> Occupational Therapist	Name: <u>N/A</u>
<input type="checkbox"/> Registered Nurse	Name: <u>N/A</u>
<input type="checkbox"/> Respiratory Therapist	Name: <u>N/A</u>

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

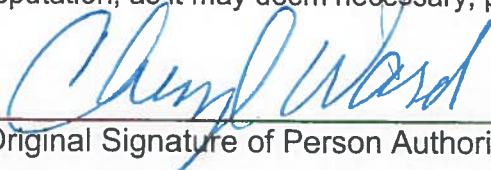
This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

CHERYL WARD

Print Name of Authorized Person

Date



Board Use Only

Received: _____

Amount: 500.00

State of Incorporation: CALIFORNIA

Parent Company if any: GORDIAN MEDICAL, INC.

Corporation Name: GORDIAN MEDICAL VI, INC.

Mailing Address: 17595 CARTWRIGHT ROAD

City: IRVINE State: CA Zip: 92614

Telephone: 714-556-0200 Fax: 877-232-9268

Contact Person: STONEY HARVILLE

1) List top 4 persons to whom the shares were issued by the corporation?

a) GORDIAN MEDICAL, INC., 17595 CARTWRIGHT ROAD, IRVINE, CA 92614

Address

b).

Address

c)

Address

d)

Address

2) Provide the number of shares issued by the corporation. 10,000

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information N/A

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

GORDIAN MEDICAL VI, INC.**MEDICARE PTAN**

6471690001

MEDICAID STATE

Arizona
CA Crossover
Colorado
Idaho
Iowa
Kansas
Michigan
Nebraska
New Mexico
North Carolina
Ohio
Oklahoma
Oregon
South Carolina
Utah
Vermont
Washington
Wisconsin

MEDICAID PROVIDER NO.

262317
1033436746
1033436746
1033436746
1033436746
201155740A
1033436746
10026664300
66276322
1033436746
024281
200703340A
1033436746
DM1586
1033436746
1031033
2082372
1033436746

Gordian Medical VI, Inc.
dba Quality Medical Equipment & Supply

Von Karman Ave, Irvine CA 92614

Phone

ax

Directors and Officers

Director/Officer: Suresh Muppalla, *Chief Executive Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

Director/Officer: Cheryl L. Ward, *Chief Operating Officer*
Ownership: 0%
DOB:
Mailing Address: 17595 Cartwright Road Irvine, CA 92614
SSN:
Telephone: (714) 556-0200

State of California

Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME:

GORDIAN MEDICAL VI, INC.

FILE NUMBER: C3282412
FORMATION DATE: 03/03/2010
TYPE: DOMESTIC CORPORATION
JURISDICTION: CALIFORNIA
STATUS: ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

The records of this office indicate the entity is authorized to exercise all of its powers, rights and privileges in the State of California.

No information is available from this office regarding the financial condition, business activities or practices of the entity.



IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of September 16, 2016.

ALEX PADILLA
Secretary of State



CERTIFICATE OF LIABILITY INSURANCE

401
DATE (MM/DD/YYYY)
4/1/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an **ADDITIONAL INSURED**, the policy(ies) must be endorsed. If **SUBROGATION IS WAIVED**, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ARCON Insurance Brokers 4533 MacArthur Blvd. #5126 Newport Beach CA 92660		CONTACT NAME: Arcon Service PHONE (A/C, No, Ext): (866) 661-2345 FAX (A/C, No): E-MAIL ADDRESS: contact@arconinsurance.com	
INSURED Gordian Medical VI, Inc. DBA: Quality Medical Equipment & Supply 17901 Von Karman Ave, Suite #600 Irvine CA 92614		INSURER(S) AFFORDING COVERAGE INSURER A: Pharmacist Mutual Insurance Company INSURER B: Landmark American Insurance Company INSURER C: INSURER D: INSURER E: INSURER F:	
		NAIC # 33138	

COVERAGES **CERTIFICATE NUMBER:** 2020 Cert for Quality Med **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY			BOP 0165706 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 1,000,000
	<input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 50,000
							MED EXP (Any one person) \$ 10,000
	GEN'L AGGREGATE LIMIT APPLIES PER: <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:						PERSONAL & ADV INJURY \$ INCLUDED GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$ EXCLUDED Employee Benefits \$ 1,000,000
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident) \$
	<input type="checkbox"/> ANY AUTO						BODILY INJURY (Per person) \$
	<input type="checkbox"/> ALL OWNED AUTOS						BODILY INJURY (Per accident) \$
	<input type="checkbox"/> HIRED AUTOS						PROPERTY DAMAGE (Per accident) \$
A	<input checked="" type="checkbox"/> UMBRELLA LIAB			UCL 0162880 00	4/1/2020	4/1/2021	EACH OCCURRENCE \$ 4,000,000
	<input type="checkbox"/> EXCESS LIAB						AGGREGATE \$ 4,000,000
	<input type="checkbox"/> DED <input checked="" type="checkbox"/> RETENTION \$ 10,000						
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE <input type="checkbox"/> OTH-ER <input type="checkbox"/> E.L. EACH ACCIDENT \$ E.L. DISEASE - EA EMPLOYEE \$ E.L. DISEASE - POLICY LIMIT \$
B	PROFESSIONAL LIABILITY			LHM839929	4/1/2020	4/1/2021	EACH OCCURRENCE \$2,000,000 AGGREGATE \$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

COMMERCIAL CRIME POLICY - HISCOX INSURANCE COMPANY NAIC# 10200 - 04/01/2020 TO 04/01/2021 - \$1,000,000
LIMIT - POLICY NUMBER UC24090420.20.

CERTIFICATE HOLDER

NATIONAL SUPPLIER CLEARING HOUSE-AG-
495PALMETTO GBA
P.O. BOX 100142
COLUMBIA, SC 29202-3142

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Graham Harvey/H001

Gordian Medical VI, Inc.
dba Quality Medical Equipment & Supply

17901 Von Karman Ave, Suite 600, Irvine, CA 92614

Phone (949) 287-8022 Fax (949) 874-3088

July 25, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Via U.S. Priority Mail
With Delivery Confirmation
Tracking No. 9470103699300051497465

RE: Application for Transfer of Ownership for DME Permit
Gordian Medical VI, Inc. dba Quality Medical Equipment & Supplies
EIN: 80-0554481

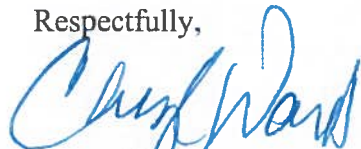
To Whom it May Concern:

On behalf of Gordian Medical VI, Inc. dba Quality Medical Equipment & Supplies, I submit the enclosed Application for Transfer of Ownership for DME Permit along with payment in the amount of \$500.00 with required documentation.

The purpose of this letter is to notify the Nevada Board of Pharmacy of a proposed transaction (the "Transaction") with respect to the ownership of Licensee (as defined above). As part of the Transaction, which is expected to occur on or around July 31, 2020, AMT Buyer Corp. plans to purchase 100% of the common stock of Gordian Medical, Inc., which is the 100% direct owner of Licensee. The Transaction is not expected to result in any changes to Licensee's name, tax identification number, locations, National Provider Identifier ("NPI") or policies and procedures. While Licensee believes that no other action is necessary with respect to its licensure, please promptly notify us if the Board of Pharmacy requires any additional information or forms to be filed.

If you have any questions or concerns regarding the Transaction, please do not hesitate to contact Stoney Harville at 951-398-5910 or stoney.harville@amtwoundcare.com. If for any reason the Transaction is not consummated, this letter will have no force or effect.

Respectfully,



Cheryl Ward
Chief Operating Officer

Attachments:

- Proof of Insurance
- Certificate of Corporate Status
- List of Officers and Directors
- List of Medicare & Medicaid Provider Numbers

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG <input type="checkbox"/> Ownership Change (Please provide current license number if making changes: MP or MW _____)	
<input checked="" type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4 <input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Partnership - Pages 1,2,3,6 <input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: Hanger Prosthetics & Orthotics, Inc. dba Hanger Clinic

Physical Address: 5316 South Woodrow Street, Suite 101, Salt Lake City, UT. 84107-5838
 (This must be a business address, we cannot issue a license to a home address)

Mailing Address: PO Box 82308

City: Austin State: TX Zip Code: 78708-2308

Telephone: 512-777-3654 Fax: 303-395-1310

E-mail: shscott@hanger.com Website: www.hangerclinic.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5 Fri: 8 to 5
 Sat: to Sun: to Holidays: to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Wendy J. Remington

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|---|
| <input type="checkbox"/> Medical Gases**
<input type="checkbox"/> Respiratory Equipment**
<input type="checkbox"/> Life-sustaining equipment**
<input type="checkbox"/> Diabetic Supplies | <input checked="" type="checkbox"/> Assistive Equipment
<input type="checkbox"/> Parenteral and Enteral Equipment**
<input checked="" type="checkbox"/> Orthotics and Prosthetics
Other: _____ |
|--|---|

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

Medicare: 414330358	_____	_____
UT Medicaid: 870524023000	_____	_____
WY Medicaid: 154355500	_____	_____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

<input type="checkbox"/> Practitioner	Name: _____
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: _____
<input type="checkbox"/> Physician's Assistant	Name: _____
<input type="checkbox"/> Physical Therapist	Name: _____
<input type="checkbox"/> Occupational Therapist	Name: _____
<input type="checkbox"/> Registered Nurse	Name: _____
<input type="checkbox"/> Respiratory Therapist	Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Shanie Scott

Original Signature of Person Authorized to Submit Application, no copies or stamps

Shanie Scott

Print Name of Authorized Person

8/31/2020

Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Hanger, Inc

Corporation Name: Hanger Prosthetics & Orthotics, Inc.

Mailing Address: _____

City: Austin State: TX Zip: 78708-2308

Telephone: 512-777-3654 Fax: 303-395-1310

License Contact Person: Shanie Scott

Ownership Information – Complete Section 1 or 2

Do not use N/A in this section – Section 1 or 2 must be completed.

Section 1: List the corporations four largest shareholders:
(Name and percentage of ownership)

1. <u>The Vanguard Group, Inc.</u>	%: <u>5.56 %</u>
2. <u>William Blair Investment</u>	%: <u>4.93%</u>
3. <u>Hotchkis & Wiley Capital</u>	%: <u>4.57 %</u>
4. <u>SCW Capital Management LP</u>	%: <u>3.71 %</u>

Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 03/03/1988

Registration number issued: 001-10670

Stock Exchange: NYSE

Include with the application for a publicly traded corporation**List of officers and directors.**

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from

to

Commission File Number 1-10670

HANGER, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

84-0904275

(I.R.S. Employer
Identification No.)

10910 Domain Drive, Suite 300, Austin, TX

(Address of principal executive offices)

78758

(Zip Code)

Registrant's phone number, including area code (512) 777-3800

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.01 per share	HNGR	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of common stock held by non-affiliates on June 30, 2019, was approximately \$629.1 million.

As of February 29, 2020 the registrant had 37,429,065 shares of its Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference from the registrant's definitive proxy statement or amendment hereto to be filed within 120 days after the close of the fiscal year covered by this annual report.

State Of Delaware

Entity Details

8/31/2020 3:36:41PM

File Number: 2153738

Incorporation Date / Formation Date: 3/3/1988

Entity Name: HANGER, INC.

Entity Kind: Corporation

Entity Type: General

Residency: Domestic

State: DELAWARE

Status: Good Standing

Status Date: 4/17/2019

Registered Agent Information

Name: CORPORATION SERVICE COMPANY

Address: 251 LITTLE FALLS DRIVE

City: WILMINGTON

Country:

State: DE

Postal Code: 19808

Phone: 302-636-5401

HANGER, INC				
BOARD OF DIRECTORS 2020				
NAME	ADDRESS	Phone Number	SOCIAL SECURITY	BIRTHDATE
Vinit K. Asar	Dawn River Cove Austin, TX 78732			5/21/2012
Asif Ahmad	Bridle Oak Court Spring, TX 77380			8/13/2014
Christopher Bruce Begley	Ashbury Lane Libertyville, IL 60048			11/21/2013
Tom Freyman	Lake Street, Libertyville, IL 60048			11/1/2017
John Fox	One Pine Road, Bloomfield Hills, MI 48304			11/1/2017
Kathryn Sullivan	N. Lake Shore Drive, #2309, Chicago IL 60611			12/18/2015
Stephen Edward Hare	3601 Palm Drive Boca Raton, FL 33432			2/5/2010
Cynthia L. Lucchesse	Statesmen Drive Indianapolis, IN 46250			5/14/2015
Richard R. Pettingill	Las Casas Drive San Rafael, CA 94901			2/6/2014



Hanger, Inc.
Managing Officers/Employees
2020

Managing Officers

<u>Title</u>	<u>Name</u>	<u>Home Address</u>	<u>Date of Birth</u>	<u>EIN</u> <u>SS Number</u>	<u>Phone #</u>
Owner	Hanger, Inc	Domain Drive Ste 300, Austin, TX. 78758	NA		512-777-3800
Chief Executive Officer	Vinit Asar	1000 Dawn River Cove, Austin, TX 78732-1987			512-777-3800
President/COO	Sam Liang	Domain Drive Austin, TX. 78758			512-777-3800
SVP & Chief Compliance Officer	Mitchell Dobson	E. Stony Point School Rd Grain Valley, MO 64029			512-777-3800
Executive Vice President/ CFO/Secretary	Thomas Kiraly	North Capitol of Texas Highway, Apt. E240 Austin, TX. 78746			512-777-3800
Vice President - HR	Keri Jolly	Fairway Cove, Austin, TX 78732-1713			512-777-3800
Vice President/General Counsel/Asst Sec	Thomas E. Hartman	Calistoga Ct Austin, TX 78732-2449			512-777-3800
Assistant Secretary	Scott Rowe	Grand Oaks Loop, Cedar Park, TX. 78613-4368			512-777-3800
<u>Managing Employee</u>					
Director State Compliance	Shanie Scott	MacDonough St Brooklyn, NY. 11216-5395			512-777-3654

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

 DATE (MM/DD/YYYY)
12/29/2008

PRODUCER

 Aon Risk Services, Inc. of Washington, D.C. / Hunti
1120 20th Street NW
Washington DC 20036 USA

 THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY
AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS
CERTIFICATE DOES NOT AMEND, EXTEND OR ALTER THE
COVERAGE AFFORDED BY THE POLICIES BELOW.

PHONE: (866) 283-7122

FAX: (847) 953-5390

INSURERS AFFORDING COVERAGE

NAIC #

INSURED

 Hanger Orthopedic Group, Inc.
& all its wholly owned subsidiaries
Two Bethesda Metro Center
Suite 1200
Bethesda MD 20814 USA

INSURER A:	Noetic Specialty Insurance Co	17400
INSURER B:	American Guarantee & Liability Ins Co	26247
INSURER C:	Travelers Property Cas Co of America	25674
INSURER D:	Hartford Fire Insurance Co.	19682
INSURER E:		

COVERAGES

SIR applies per terms and conditions of the policy

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. AGGREGATE LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

LIMITS SHOWN ARE AS REQUESTED

INSR LTR	ADD'L INSRD	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YY)	POLICY EXPIRATION DATE (MM/DD/YY)	LIMITS	
D		GENERAL LIABILITY <input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY CLAIMS MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER <input checked="" type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC	39UENAC9992 General Liability	01/01/09	01/01/10	EACH OCCURRENCE	\$1,000,000
						DAMAGE TO RENTED PREMISES (Ea occurrence)	\$300,000
						MED EXP (Any one person)	\$10,000
						PERSONAL AUTO	\$1,000,000
						GENERAL A & M	\$2,000,000
						PRODUCTS - COMP OP AGG	
D		AUTOMOBILE LIABILITY <input checked="" type="checkbox"/> ANY AUTO <input type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> HIRED AUTOS <input type="checkbox"/> NON OWNED AUTOS <input checked="" type="checkbox"/> Comp Deductible \$1,000 <input checked="" type="checkbox"/> Collision Deductible \$1,000	39UENAC9992 Auto Liability	01/01/09	01/01/10	COMBINED SINGLE LIMIT (Ea accident)	\$1,000,000
						BODILY INJURY (Per person)	
						BODILY INJURY (Per accident)	
						PROPERTY DAMAGE (Per accident)	
		GARAGE LIABILITY <input type="checkbox"/> ANY AUTO				AUTO ONLY - EA ACCIDENT	
						OTHER THAN AUTO ONLY: EA ACC AGG	
B		EXCESS UMBRELLA LIABILITY <input type="checkbox"/> OCCUR <input type="checkbox"/> CLAIMS MADE <input type="checkbox"/> DEDUCTIBLE <input type="checkbox"/> RETENTION	AUC591799003 Umbrella Liability	01/01/09	01/01/10	EACH OCCURRENCE	\$5,000,000
						AGGREGATE	\$5,000,000
C		WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR PARTNER EXECUTIVE OFFICER MEMBER EXCLUDED? If yes, describe under SPECIAL PROVISIONS below	TC2JUB823K600409TIL WC - All Other States TRJUB823K602809TIL WC - MA, OR, WI	01/01/09 01/01/09	01/01/10 01/01/10	<input checked="" type="checkbox"/> WC STATUTORY LIMITS <input type="checkbox"/> OTHER	
						E.L. EACH ACCIDENT	\$1,000,000
						E.L. DISEASE-EA EMPLOYEE	\$1,000,000
						E.L. DISEASE-POLICY LIMIT	\$1,000,000
A		OTHER Misc Med Prof	N09MD380001 Professional & Products	01/01/09	01/01/10	Per Occurrence	\$10,000,000
						Policy Aggregate	\$10,000,000

DESCRIPTION OF OPERATIONS LOCATIONS VEHICLES EXCLUSIONS ADDED BY ENDORSEMENT SPECIAL PROVISIONS

Products/Completed Ops coverage is included in the Professional/Products referenced above.

CERTIFICATE HOLDER

 Evidence of Insurance
MD, USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, THE ISSUING INSURER WILL ENDEAVOR TO MAIL 30 DAYS WRITTEN NOTICE TO THE CERTIFICATE HOLDER NAMED TO THE LEFT. BUT FAILURE TO DO SO SHALL IMPOSE NO OBLIGATION OR LIABILITY OF ANY KIND UPON THE INSURER, ITS AGENTS OR REPRESENTATIVES.

AUTHORIZED REPRESENTATIVE

Aon Risk Services, Inc. of Washington, D.C. / Hunti

ACORD 25 (2001/08)

ACORD CORPORATION 1988

Holder Identifier :

Certificate #: 5700

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE → EFFECTIVE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

OCT. 1, 2020
(NOT BEFORE)

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change (Please provide current license number if making changes: MP or MW _____)
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7

Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: MENDTRONIX INC. (3PL)

Physical Address: 12250 IAVELLI WAY, POWAY CA 92064
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 12250 IAVELLI WAY

City: POWAY State: CA Zip Code: 92064

Telephone: 858.726.0200 X202 Fax: 858.386.4218

E-mail: STEVE.STARR@MENDTRONIX.COM Website: MENDTRONIX.COM
C: 858.449.4929

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5 Fri: 8 to 5
Sat: NA to _____ Sun: NA to _____ Holidays: NA to _____

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: ANGELA TAYLOR 858.726.0200 X219, EMAIL: ANGELA.TAYLOR@MENDTRONIX.COM

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|--|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | <input checked="" type="checkbox"/> Other: <u>GENERAL PHARMA SUPPLIES (NO DRUGS)</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

NA

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? WOLF MEDICAL SUPPLY - SEE NEVADA LIC. ENCLOSED

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

NO.

- ☐ Practitioner
- ☐ Advanced Practitioner of Nursing
- ☐ Physician's Assistant
- ☐ Physical Therapist
- ☐ Occupational Therapist
- ☐ Registered Nurse
- ☐ Respiratory Therapist

Name: NA

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

STEPHEN STORR
Print Name of Authorized Person

SEPTEMBER 3, 2020
Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION

State of Incorporation: CALIFORNIA
 Parent Company if any: NA
 Corporation Name: MENDTRONIX INC.
 Mailing Address: 13880 STOWE DRIVE
 City: POWAY State: CA Zip: 92064
 Telephone: 858.726.0200 X202 Fax: 858.386.4218
 Contact Person: STEPHEN STORR

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) STEPHEN F. STORR HICKORY MILL LANE, MILTON GA 30004
 Name Address

b) REGINA M. STORR HICKORY MILL LANE, MILTON GA 30004
 Name Address

c) _____
 Name Address

d) _____
 Name Address

2) Provide the number of shares issued by the corporation. 10,000

3) What was the price paid per share? \$1.00

4) What date did the corporation actually receive the cash assets? FEB. 4, 2005

5) Provide a copy of the corporation's stock register evidencing the above information
NOTE: NAME CHANGE TO MENDTRONIX INC. FEB 28, 2012.

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. ENCLOSED.

List of officers and directors.

STEPHEN F. STORR - PRESIDENT/CEO
REGINA M. STORR - SECRETARY



Secretary of State Certificate of Status

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

Entity Name: MENDTRONIX, INC.
File Number: C2669283
Registration Date: 08/04/2004
Entity Type: DOMESTIC STOCK CORPORATION
Jurisdiction: CALIFORNIA
Status: ACTIVE (GOOD STANDING)

As of September 2, 2020 (Certification Date), the entity is authorized to exercise all of its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.



IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of September 3, 2020.

ALEX PADILLA
Secretary of State

Certificate Verification Number: RM3DA3Z

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at behizfile.sos.ca.gov/certification/index.

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Wolf Medical Supply
13951 Northwest 8th St
Sunrise FL 33325

Date: 01/24/2019

Amount:

License #: WH02499

(ID Card)

NEVADA STATE BOARD OF PHARMACY		Wholesaler Expires: 10/31/2020 Wolf Medical Supply 13951 Northwest 8th St Sunrise FL 33325
License # WH02499 Active		
IDENTIFICATION ONLY DOES NOT MEET POSTING REQUIREMENTS		

Trim ID Card to fit your wallet

NEVADA STATE BOARD OF PHARMACY

Wholesaler

Expires: 10/31/2020

STATUS: Active

License Type: Wholesaler

License #: WH02499

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Wolf Medical Supply

13951 Northwest 8th St
Sunrise FL 33325

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

Reprinted: 01/24/2019.

A0725597

CERTIFICATE OF AMENDMENT OF ARTICLES OF INCORPORATION
OF

PROJECTOR DOCTOR, INC.
a California Corporation

ENDORSED - FILED
In the office of the Secretary of State
of the State of California

TO THE SECRETARY OF STATE
STATE OF CALIFORNIA:

FEB 29 2012

Pursuant to the provisions of the General Corporation Law of the State of California, the undersigned Officers of the Corporation hereinafter named do hereby certify as follows:

1. Article I of the Corporation's Articles of Incorporation, which relates to the name of the Corporation, is hereby amended to read as follows:

The name of the corporation is MENDTRONIX, INC.

3. The Amendment herein provided for has been approved by the Corporation's Board of Directors.

4. The Amendment has been approved by the required vote of the Shareholders in accordance with Section 902 of the California Corporation Code. The Corporation has only one class of shares, each outstanding share is entitled to one vote. The Corporation has 10,000 shares outstanding, hence 10,000 shares are entitled to vote. The number of shares voting in favor of the Amendment was 10,000 or 100% of the outstanding shares.

Signed: February 28, 2012


Stephen F. Storr, President


Regina M. Storr, Secretary

Each of the undersigned declares under penalty of perjury that the matters set forth in the foregoing Certificate are true and correct of both their own knowledge and that this Declaration was executed on February 28, 2012 at San Diego, California.


Stephen F. Storr, President


Regina M. Storr, Secretary



PROJE-1

OP# KA

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

07/01/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Rubin Insurance Agency Inc.
CA Lic 0645355
5075 Shoreham Place, Suite 100
San Diego, CA 92122
Stuart Rubin

858-457-5720

CONTACT NAME: Kathy Kelly

PHONE (A/C, No, Ext): 858-457-5720

FAX (A/C, No): 858-457-5729

E-MAIL ADDRESS: kathy@rubininsurance.com

INSURER(S) AFFORDING COVERAGE

NAIC #

INSURER A: Great American E&S Ins Co

37532

INSURER B: Ohio Security Insurance Co

24082

INSURER C: Zenith Insurance Company

13269

INSURER D:

INSURER E:

INSURER F:

INSURED Mendtronix Inc
12250 Iavelli Way
Poway, CA 92064

COVERAGES

CERTIFICATE NUMBER:

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL SUBR INSD WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PROJECT <input type="checkbox"/> LOC OTHER:	Y	PL2258320-02	02/04/2020	02/04/2021	EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 500,000 MED EXP (Any one person) \$ 20,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 2,000,000 PRODUCTS - COMP/OP AGG \$ 2,000,000
B	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO OWNED AUTOS ONLY <input checked="" type="checkbox"/> HIRED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input checked="" type="checkbox"/> NON-OWNED AUTOS ONLY		BAS59306678	02/04/2020	02/04/2021	COMBINED SINGLE LIMIT (Ea accident) \$ 1,000,000 BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$
A	UMBRELLA LIAB <input checked="" type="checkbox"/> OCCUR <input checked="" type="checkbox"/> EXCESS LIAB CLAIMS-MADE DED <input checked="" type="checkbox"/> RETENTION \$ 0		XS2258321-02	02/04/2020	02/04/2021	EACH OCCURRENCE \$ 4,000,000 AGGREGATE \$ 4,000,000
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y / N N / A	M1030510	02/04/2020	02/04/2021	<input checked="" type="checkbox"/> PER STATUTE <input type="checkbox"/> OTHER E.L. EACH ACCIDENT \$ 1,000,000 E.L. DISEASE - EA EMPLOYEE \$ 1,000,000 E.L. DISEASE - POLICY LIMIT \$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Pomerado Leasing No 2 LP and its respective officers, directors, shareholders, agents, contractors and employees are named as additional insured with respects to general liability of the named insured. Re: 12131 Community Rd Ste A-2, Poway CA 92064. Blanket general liability additional insured and primary and non-contributory wording endorsement ESG3206(0116)

CERTIFICATE HOLDER

POMER65

Pomerado Leasing No 2 LP
Attn: Eric Dye
1320 Columbia St Ste 300
San Diego, CA 92101

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



Board of Pharmacy

ORIGINAL CERTIFICATE



Third-Party Logistics Provider

LICENSE NO. TPL 1249

ISSUE DATE JUNE 04, 2020

MENDTRONIX INC

12250 IAVELLI WY
 POWAY CA 92064

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL JUNE 01, 2021

RECEIPT NUMBER 00000000

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4160 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer(s), shareholder (more than 10 percent share change), responsible manager. If you are planning to change location or responsible manager, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
 2720 GATEWAY OAKS DRIVE, SUITE 100
 SACRAMENTO, CA 95833
 (916) 518-3100

----- POST IN PUBLIC VIEW -----

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG		<input type="checkbox"/> Ownership Change	
(Please provide current license number if making changes: MP or MW _____)			
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4		<input type="checkbox"/> Partnership - Pages 1,2,3,6	
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5		<input checked="" type="checkbox"/> Sole Owner – Pages 1,2,3,7	
Please check box for type of ownership and complete correct part of the application.			

FACILITY INFORMATION

Facility Name: Nexel Services LLC, DBA Nexel Health

Physical Address: 810 S Mason Road Suite 205

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: Same

City: Katy State: TX Zip Code: 77450

Telephone: 855-586-3935 Fax: 832-201-7548

E-mail: info@nexelhealth.com Website: www.nexelhealth.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9am to 5pm Tue: 9am to 5pm Wed: 9am to 5pm Thu: 9am to 5pm Fri:

Fri: 9am to 5pm Sat: Closed to Sun: Closed to Holidays: Closed to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Kashif Ijaz

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- ☐ Medical Gases**
- ☐ Respiratory Equipment**
- ☐ Life-sustaining equipment**
- ☒ Diabetic Supplies

- ☒ Assistive Equipment
- ☐ Parenteral and Enteral Equipment**
- ☒ Orthotics and Prosthesis

Other: Urology supplies, hot & cold applications, UV light devices and supplies

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: N/A

Telephone:

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

Medicare	7807110001	
TX Medicaid	Pending enrollment	

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

<input checked="" type="checkbox"/> Practitioner	Name: N/A
<input checked="" type="checkbox"/> Advanced Practitioner of Nursing	Name: N/A
<input checked="" type="checkbox"/> Physician's Assistant	Name: N/A
<input checked="" type="checkbox"/> Physical Therapist	Name: N/A
<input checked="" type="checkbox"/> Occupational Therapist	Name: N/A
<input checked="" type="checkbox"/> Registered Nurse	Name: N/A
<input checked="" type="checkbox"/> Respiratory Therapist	Name: N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?
- Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Kashif Ijaz

Print Name of Authorized Person

09/04/2020

Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Kashif Ijaz

List all previous names: _____

Social Security Number: _____

Date of Birth: _____

Place of Birth: City: Rawalpindi State: Punjab Country: Pakistan

Citizenship: USA X other _____

If applicable, list Naturalization Number: _____ Passport Number: _____

Current residence address Stilton Lake Lane City: Katy

State: TX Zip Code: 77494 Telephone Number: 6 Fax Number: N/A

Previous address (last 5 years):

Address: 9991 Willow Falls Land City: Brookshire State: TX Zip Code: 77423

Address: _____ City: _____ State: _____ Zip Code: _____

Address: _____ City: _____ State: _____ Zip Code: _____

Address: _____ City: _____ State: _____ Zip Code: _____

Business Name: Nexel Services LLC

Current Business Address: 810 S Mason Road Suite 205

City: Katy State: TX Zip Code: 77450

Telephone Number: 855-586-3935 Fax Number: 832-201-7548

Previous Employment (last 5 years):

Name: _____ Address: _____

City: _____ State: _____ Zip Code: _____

Name: _____ Address: _____

City: _____ State: _____ Zip Code: _____

Name: _____ Address: _____

City: _____ State: _____ Zip Code: _____



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

07/06/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Thumann Agency, Inc. 12770 Coit Road Suite 110, Suite 110 Dallas TX 75251	CONTACT NAME: CSR HOUSE PHONE (A/C, No, Ext): (972) 991-9100 FAX (A/C, No): (972) 890-1733 E-MAIL ADDRESS: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2">INSURER(S) AFFORDING COVERAGE</th> <th>NAIC #</th> </tr> <tr> <td>INSURER A:</td> <td>Ohio Security Insurance Co</td> <td>24082</td> </tr> <tr> <td>INSURER B:</td> <td></td> <td></td> </tr> <tr> <td>INSURER C:</td> <td></td> <td></td> </tr> <tr> <td>INSURER D:</td> <td></td> <td></td> </tr> <tr> <td>INSURER E:</td> <td></td> <td></td> </tr> <tr> <td>INSURER F:</td> <td></td> <td></td> </tr> </table>	INSURER(S) AFFORDING COVERAGE		NAIC #	INSURER A:	Ohio Security Insurance Co	24082	INSURER B:			INSURER C:			INSURER D:			INSURER E:			INSURER F:		
INSURER(S) AFFORDING COVERAGE		NAIC #																				
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INSURER B:																						
INSURER C:																						
INSURER D:																						
INSURER E:																						
INSURER F:																						
INSURED Nexel Services LLC 810 S Mason Rd Ste 210 Katy TX 77450																						

COVERAGES

CERTIFICATE NUMBER: GL

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY			BLS57359507	05/26/2020	05/26/2021	EACH OCCURRENCE \$ 1,000,000
	<input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 1,000,000
							MED EXP (Any one person) \$ 15,000
							PERSONAL & ADV INJURY \$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE \$ 2,000,000
	POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC						PRODUCTS - COMP/OP AGG \$ 2,000,000
	OTHER:						Package Modification \$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident) \$
	ANY AUTO						BODILY INJURY (Per person) \$
	OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident) \$
	HIRED AUTOS ONLY <input type="checkbox"/>						PROPERTY DAMAGE (Per accident) \$
	UMBRELLA LIAB <input type="checkbox"/> OCCUR						EACH OCCURRENCE \$
	EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE						AGGREGATE \$
	DED <input type="checkbox"/> RETENTION \$						\$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE <input type="checkbox"/> OTH-ER <input type="checkbox"/>
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) <input type="checkbox"/> Y/N N/A						E.L. EACH ACCIDENT \$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE \$
							E.L. DISEASE - POLICY LIMIT \$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

CANCELLATION

B.O.C. (Board of Certification/Accreditation) 10461 Mill Run Circle Suite 1250 Owingsmills MI 21117	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS. AUTHORIZED REPRESENTATIVE
--	---

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4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change (Please provide current license number if making changes: MP or MW _____)
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4 <input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input checked="" type="checkbox"/> Partnership - Pages 1,2,3,6 <input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: Next Level Medical Supply LLC

Physical Address: 2900 W Cypress Creek Road Suite 6
 (This must be a business address, we cannot issue a license to a home address)

Mailing Address: 2900 W Cypress Creek Road Suite 6

City: Ft. Lauderdale State: FL Zip Code: 33309

Telephone: 954-653-8313 Fax: 954-623-7700

E-mail: kdisorbo@nextlevelmedicalsupply.com Website: www.nextlevelmedicalsupply.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9am to 4:30pm Tue: 9am to 4:30pm Wed: 9am to 4:30pm Thu: 9am to 4:30pm Fri:
Closed to Sat: Closed to Sun: Closed to Holidays: Closed to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Kristopher DiSorbo

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|---|--|
| <input type="checkbox"/> Medical Gases**
<input type="checkbox"/> Respiratory Equipment**
<input type="checkbox"/> Life-sustaining equipment**
<input checked="" type="checkbox"/> Diabetic Supplies | <input checked="" type="checkbox"/> Assistive Equipment
<input type="checkbox"/> Parenteral and Enteral Equipment**
<input checked="" type="checkbox"/> Orthotics and Prosthesis
Other: <u>UV Lights, ostomy/urological supplies, Surgical dressing, breast prostheses, NMES, Pneumatic compression dev., TENS, diabetic shoe inserts</u> |
|---|--|

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: N/A Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

Medicare	7809960001	
FL Medicaid Pending	ATN#801990	

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

■ Practitioner	Name: N/A
■ Advanced Practitioner of Nursing	Name: N/A
■ Physician's Assistant	Name: N/A
■ Physical Therapist	Name: N/A
■ Occupational Therapist	Name: N/A
■ Registered Nurse	Name: N/A
■ Respiratory Therapist	Name: N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Kristopher DiSorbo

Print Name of Authorized Person

8/31/2020

Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIPGeneral X Limited Partnership Name: Next Level Medical Supply LLCMailing Address: 2900 W Cypress Creek Road Suite 6City: Ft. Lauderdale State: FL Zip: 33309-1715Telephone: 954-653-8313 Fax: 954-623-7700Contact Person: Kristopher DiSorbo

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
 Use separate sheet if necessary

<u>Name</u>	<u>G or L</u>	<u>Percentage</u>
<u>Mark Kokonas</u>	<u>G</u>	<u>50%</u>
<u>Kristopher DiSorbo</u>	<u>G</u>	<u>50%</u>

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)

1/27/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Provider Professional Insurance 4345 SW 72ND AVE STE A MIAMI, FLORIDA 33155	CONTACT NAME:	
	PHONE (A/C, No, Ext): (305)740-5319	FAX (A/C, No): (305)740-3459
	E-MAIL ADDRESS: gofarril01@gmail.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
INSURED NEXT LEVEL MEDICAL SUPPLY, LLC 2900 W CYPRESS CREEK ROAD STE 6 FORT LAUDERDALE, FL 33309	INSURER A: UNDERWRITERS AT LLOYDS	
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES

CERTIFICATE NUMBER:

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
<input checked="" type="checkbox"/>	COMMERCIAL GENERAL LIABILITY			NPP8657088	01/24/2020	01/24/2021	EACH OCCURRENCE \$ 1,000,000
<input type="checkbox"/>	CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 50,000
<input checked="" type="checkbox"/>	PROFESSIONAL LIABILITY						MED EXP (Any one person) \$ 5,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY \$ 1,000,000
<input type="checkbox"/>	POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC						GENERAL AGGREGATE \$ 3,000,000
	OTHER:						PRODUCTS - COMP/OP AGG \$ INCLUDED
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident) \$
<input type="checkbox"/>	ANY AUTO						BODILY INJURY (Per person) \$
<input type="checkbox"/>	OWNED AUTOS ONLY	<input type="checkbox"/>	SCHEDULED AUTOS				BODILY INJURY (Per accident) \$
<input type="checkbox"/>	HIRED AUTOS ONLY	<input type="checkbox"/>	NON-OWNED AUTOS ONLY				PROPERTY DAMAGE (Per accident) \$
	UMBRELLA LIAB						\$
	EXCESS LIAB						EACH OCCURRENCE \$
	DEFD						AGGREGATE \$
	RETENTION \$						\$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE <input type="checkbox"/> OTH-ER <input type="checkbox"/>
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	<input type="checkbox"/>	N/A				E.L. EACH ACCIDENT \$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE \$
							E.L. DISEASE - POLICY LIMIT \$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

CANCELLATION

AGENCY FOR HEALTHCARE ADMINISTRATION
2727 MAHAN DRIVE
TALLAHASSEE, FLORIDA 32308

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

MARIO O'FARRILL

4FF



RECEIVED
8/18/2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change
(Please provide current license number if making changes: MP or MW _____)	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

FACILITY INFORMATION

Facility Name: Permobil, Inc.

Physical Address: 300 Duke Drive
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 300 Duke Drive

City: Lebanon State: TN Zip Code: 37090

Telephone: 800-736-0925 Fax: 800-231-3256

E-mail: Ivan.Fernandez@permobil.com Website: www.permobilus.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 6am to 6pm Tue: 6am to 6pm Wed: 6am to 6pm Thu: 6am to 6pm Fri: 6am to 6pm
Sat: - to - Sun: - to - Holidays: - to -

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Chuck Witkowski

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|---|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: <u>Powered Wheelchairs</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: Ivan Fernandez Telephone: 800-736-0925

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

N/A

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? There are no shareholders.

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

<input checked="" type="checkbox"/> Practitioner	Name: <u>N/A</u>
<input checked="" type="checkbox"/> Advanced Practitioner of Nursing	Name: <u>N/A</u>
<input checked="" type="checkbox"/> Physician's Assistant	Name: <u>N/A</u>
<input checked="" type="checkbox"/> Physical Therapist	Name: <u>N/A</u>
<input checked="" type="checkbox"/> Occupational Therapist	Name: <u>N/A</u>
<input checked="" type="checkbox"/> Registered Nurse	Name: <u>N/A</u>
<input checked="" type="checkbox"/> Respiratory Therapist	Name: <u>N/A</u>

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Christopher C. Javillonar
Print Name of Authorized Person

8/14/2020
Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATIONState of Incorporation: TennesseeParent Company if any: Permobil Holding ABCorporation Name: Permobil, Inc.Mailing Address: 300 Duke DriveCity: Lebanon State: TN Zip: 37090Telephone: 800-736-0925 Fax: 800-231-3256Contact Person: Ivan Fernandez

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

- a) N/A
- | Name | Address |
|----------|---------|
| b) _____ | |
| Name | Address |
| c) _____ | |
| Name | Address |
| d) _____ | |
| Name | Address |

2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A5) Provide a copy of the corporation's stock register evidencing the above information N/A**Include with the application for a non-publicly traded corporation**

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

**COMMERCIAL GENERAL LIABILITY DECLARATIONS
OCCURRENCE**


Issued By Liberty Mutual Fire Insurance Co.

Policy Number TB2-691-468704-010
Renewal Of TB2-691-468704-019
Account Number 9-468704

Issuing Office BOSTON, MA-157
Issue Date 2020-04-27
Sub Account 0002

Named Insured and Mailing Address
Permobil Inc.
300 Duke Drive
Lebanon TN 37090-8115

Form of Business: Corporation

Policy Period: The policy period is from 04/01/2020 to 04/01/2021 12:01 A.M. standard time at the Insured's mailing address.

In return for the payment of the premium, and subject to all the terms of this policy, we agree with you to provide the insurance as stated in this policy.

LIMITS OF INSURANCE

Each Occurrence Limit	\$	3,000,000	
Damage to Premises Rented to You Limit	\$	100,000	Any one premises
Medical Expense Limit	\$	5,000	Any one person
Personal & Advertising Injury Limit	\$	3,000,000	
General Aggregate Limit	\$	3,000,000	
Products-Completed Operations Aggregate Limit	\$	3,000,000	

SCHEDULE

The declarations are completed on the accompanying "Declarations Extension Schedule(s)".

Commercial General Liability Coverage Part Premium	\$	322,857
Total Estimated Premium Policywriting minimum premium is charged	\$	322,857
Other Charge(s)	\$	

Policywriting Minimum Premium \$ 1,000

Forms Applicable: See Attached Inventory

IMA INC 0002013464
IMA INC
6200 LYNDON B JOHNSON FWY
STE 200
DALLAS TX 752406331

Permobil, Inc. Officers

Name: Chuck Witkowski
Title: President
D/O/
SSN
Address Duke Dr.
City, State, Zip: Lebanon, TN
Phone Number
Email Address: permobil.com

Name: Todd Walling
Title: Vice President
D/O/
SSN
Address Duke Dr.
City, State, Zip: Lebanon, TN
Phone Number
Email Address: permobil.com

Name: Christopher Javillonar
Title: Secretary
D/O/B
SSN:
Address Duke Dr.
City, State, Zip: Lebanon, TN
Phone Number:
Email Address: permobil.com

Name: Aron Hjertberg
Title: Treasurer
D/O/B
SSN: 1
Address Duke Dr.
City, State, Zip: Lebanon, TN
Phone Number
Email Address: permobil.com

FDA Home³ Medical Devices⁴ Databases⁵**Establishment Registration & Device Listing**
New Search[Back To Search Results](#)

Establishment:
PERMOBIL, INC.
300 Duke Dr
LEBANON, TN 37090
Registration Number: 1221084
FEI Number: 1221084
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information
Date Of Registration Status: 2019

Owner/Operator:
PERMOBIL AB⁶
300 Duke Drive
Lebanon, TN 37090
Owner/Operator Number: 8030931⁷

Official Correspondent:
Ivan Fernandez
300 Duke Drive
Lebanon, TN 37090
Phone: 1-615-5853169

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/MedicalDevices/default.htm>
5. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8030931&OwnerOperatorNa
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8030931&OwnerOperatorNa

Page Last Updated: 10/07/2019

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyol Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No FEAR Act](#) [Nondiscrimination Website Policies](#)

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA



For Government For Press

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U.S. Department of Health & Human Services

Links on this page:



47438

444

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000005855

EXPIRATION DATE: 12/31/2021

*This is to certify that all requirements of the State of Tennessee have been met.*PHARMACY BOARD
MANUFACTURER
PERMOBIL, INC.
COMMISSIONER OF HEALTHIVAN FERNANDEZ
PERMOBIL, INC.
300 DUKE DRIVE
LEBANON TN 37090-8115State of Tennessee
Department of Health11944802
27458TENNESSEE BOARD OF PHARMACY
MANUFACTURER
PERMOBIL, INC.
300 DUKE DRIVE
LEBANON TN 37090*This is to certify that all requirements of the State of Tennessee
have been met.*

ID NUMBER: 0000005855

EXPIRATION DATE: 12/31/2021

DIRECTOR, HEALTH RELATED BOARDS

COMMISSIONER



Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE. 6th FL
Nashville, TN 37243-1102

ADAM LATONDRESS
816 GENERAL WESTMORELAND CT
MURFREESBORO, TN 37129-1350

April 30, 2020

Request Type: Certificate of Existence/Authorization
Request # 0363143

Issuance Date: 04/30/2020
Copies Requested: 1

Document Receipt

Receipt #: 005522627

Filing Fee: \$20 00

Payment-Check/MO - ADAM LATONDRESS, MURFREESBORO, TN

\$20.00

Regarding: PERMOBIL, INC.

Filing Type: For-profit Corporation - Domestic

Formation/Qualification Date: 08/22/2000

Status: Active

Duration Term: Perpetual

Business County: WILSON COUNTY

Control #: 394528

Date Formed: 08/22/2000

Formation Locale: TENNESSEE

Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

PERMOBIL, INC.

* is a Corporation duly incorporated under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Deborah Chaney

Verification #: 039428234

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521 (775) 850-1440

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG		<input type="checkbox"/> Ownership Change	
(Please provide current license number if making changes: MP or MW _____)			
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4		<input type="checkbox"/> Partnership - Pages 1,2,3,6	
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5		<input type="checkbox"/> Sole Owner – Pages 1,2,3,7	
Please check box for type of ownership and complete correct part of the application.			

FACILITY INFORMATION

Facility Name: SourceMark, LLC

Physical Address: 1605 Worldwide Blvd. Hebron, KY 41048

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 302 Innovation Drive Ste 410

City: Franklin State: TN Zip Code: 37067

Telephone: 615-269-6010 Fax: 615-324-8426

E-mail: rmanson@sourcemarkusa.com Website: sourcemarkusa.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5 Fri: 8 to 5
 Sat: NA to Sun: NA to Holidays: NA to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Richard Manson

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|---|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: <u>Medical Devices</u> |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

NA		

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed?

Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

<input checked="" type="checkbox"/> Practitioner	Name: <u>No</u>
<input checked="" type="checkbox"/> Advanced Practitioner of Nursing	Name: <u>No</u>
<input checked="" type="checkbox"/> Physician's Assistant	Name: <u>No</u>
<input checked="" type="checkbox"/> Physical Therapist	Name: <u>No</u>
<input checked="" type="checkbox"/> Occupational Therapist	Name: <u>No</u>
<input checked="" type="checkbox"/> Registered Nurse	Name: <u>No</u>
<input checked="" type="checkbox"/> Respiratory Therapist	Name: <u>No</u>

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

- 1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

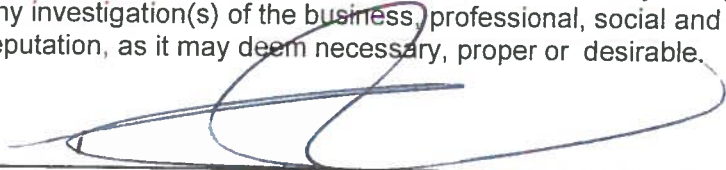
This page must be submitted for all types of ownership.

- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Richard Manson

Print Name of Authorized Person

8/25/2020

Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATIONState of Incorporation: Tennessee

Parent Company if any: _____

Corporation Name: SourceMark, LLCMailing Address: 302 Innovation Drive Ste 410City: Franklin State: TN Zip: 37067Telephone: 615-269-6010 Fax: 615-324-8426Contact Person: Richard Manson

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) <u>Lawrence Jackson</u>	<u>Elliston Place #451 Nashville, TN 37203</u>
Name	Address

b) <u>Heritage Group Holdings, GP</u>	<u>Burton Hills Blvd., Nashville, TN 37215</u>
Name	Address

c) <u>WBR Family Ltd Partnership</u>	<u>Ellendale Avenue Nashville, TN 37205-3402</u>
Name	Address

d) <u>Richard Manson</u>	<u>Close Circle Nashville, TN 37205</u>
Name	Address

2) Provide the number of shares issued by the corporation. NA3) What was the price paid per share? NA4) What date did the corporation actually receive the cash assets? NA

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

SourceMark, LLC**1. Certificate of Good Standing**

- a. Control # 000427733

2. Officers

- a. Dan Blucher – CEO
- b. Richard Manson – President
- c. Michelle Anderson – CFO

3. Board of Directors

- a. Lawrence Jackson – Chairman
- b. David Anderson
- c. Brian Reames
- d. Richard Manson
- e. Michelle Anderson



Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

RICHARD MANSON

410
302 INNOVATION DRIVE
FRANKLIN, TENNESSEE, 37067, TN 37067

July 14, 2020

Request Type: Certificate of Existence/Authorization

Request #: 0372881

Issuance Date: 07/14/2020

Copies Requested: 1

Document Receipt

Receipt #: 005664179

Filing Fee: \$20.00

Payment-Credit Card - State Payment Center - CC #: 3785486788

\$20.00

Regarding: SOURCEMARK, LLC.

Filing Type: Limited Liability Company - Domestic

Formation/Qualification Date: 05/30/2002

Status: Active

Duration Term: Perpetual

Business County: WILLIAMSON COUNTY

Control #: 427733

Date Formed: 05/30/2002

Formation Locale: TENNESSEE

Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

SOURCEMARK, LLC.

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 040623322

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
05/14/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an **ADDITIONAL INSURED**, the policy(ies) must have **ADDITIONAL INSURED** provisions or be endorsed. If **SUBROGATION IS WAIVED**, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C No. Ext): 1-877-945-7378 FAX (A/C No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com														
INSURED SourceMark LLC 302 Innovation Drive Suite 41 Franklin, TN 37067 USA	<table border="1"> <thead> <tr> <th data-bbox="786 371 1382 382">INSURER(S) AFFORDING COVERAGE</th> <th data-bbox="1382 371 1513 382">NAIC #</th> </tr> </thead> <tbody> <tr> <td data-bbox="786 382 1382 390">INSURER A: Travelers Property Casualty Company of Ame</td> <td data-bbox="1382 382 1513 390">25674</td> </tr> <tr> <td data-bbox="786 390 1382 401">INSURER B:</td> <td data-bbox="1382 390 1513 401"></td> </tr> <tr> <td data-bbox="786 401 1382 409">INSURER C:</td> <td data-bbox="1382 401 1513 409"></td> </tr> <tr> <td data-bbox="786 409 1382 420">INSURER D:</td> <td data-bbox="1382 409 1513 420"></td> </tr> <tr> <td data-bbox="786 420 1382 428">INSURER E:</td> <td data-bbox="1382 420 1513 428"></td> </tr> <tr> <td data-bbox="786 428 1382 434">INSURER F:</td> <td data-bbox="1382 428 1513 434"></td> </tr> </tbody> </table>	INSURER(S) AFFORDING COVERAGE	NAIC #	INSURER A: Travelers Property Casualty Company of Ame	25674	INSURER B:		INSURER C:		INSURER D:		INSURER E:		INSURER F:	
INSURER(S) AFFORDING COVERAGE	NAIC #														
INSURER A: Travelers Property Casualty Company of Ame	25674														
INSURER B:															
INSURER C:															
INSURER D:															
INSURER E:															
INSURER F:															

COVERAGES

CERTIFICATE NUMBER: W16464996

REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

GENERAL AND SPECIAL CONDITIONS OF SURETY POLICIES - LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS													
INSR LTR	TYPE OF INSURANCE			ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS				
A	<input checked="" type="checkbox"/>	COMMERCIAL GENERAL LIABILITY				ZLP-14R47612-19-I6	05/17/2020	05/17/2021	EACH OCCURRENCE		\$	1,000,000	
	<input type="checkbox"/>	CLAIMS-MADE	<input checked="" type="checkbox"/>	OCCUR	DAMAGE TO RENTED PREMISES (Ea occurrence)				\$	300,000			
	<input type="checkbox"/>				MED EXP (Any one person)				\$	10,000			
	GEN'L AGGREGATE LIMIT APPLIES PER:				PERSONAL & ADV INJURY				\$	1,000,000			
	<input checked="" type="checkbox"/>	POLICY	<input type="checkbox"/>	PRO-JECT	<input type="checkbox"/>				LOC	GENERAL AGGREGATE		\$	2,000,000
	<input type="checkbox"/>	OTHER:							PRODUCTS - COMP/OP AGG		\$	0	
	AUTOMOBILE LIABILITY								COMBINED SINGLE LIMIT (Ea accident)		\$		
	<input type="checkbox"/>	ANY AUTO							BODILY INJURY (Per person)		\$		
	<input type="checkbox"/>	OWNED AUTOS ONLY	<input type="checkbox"/>	SCHEDULED AUTOS					BODILY INJURY (Per accident)		\$		
	<input type="checkbox"/>	HIRED AUTOS ONLY	<input type="checkbox"/>	NON-OWNED AUTOS ONLY					PROPERTY DAMAGE (Per accident)		\$		
	<input type="checkbox"/>										\$		
A	<input checked="" type="checkbox"/>	UMBRELLA LIAB		<input checked="" type="checkbox"/>	OCCUR	CUP-1N75197A-19-I6	05/17/2020	05/17/2021	EACH OCCURRENCE		\$	9,000,000	
	<input type="checkbox"/>	EXCESS LIAB		<input type="checkbox"/>	CLAIMS-MADE				AGGREGATE		\$	9,000,000	
	<input type="checkbox"/>	DED	<input checked="" type="checkbox"/>	RETENTION \$	10,000						\$		
											\$		
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY								<input type="checkbox"/>	PER STATUTE	<input type="checkbox"/>	OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)			<input type="checkbox"/>	N/A				E.L. EACH ACCIDENT		\$		
	If yes, describe under DESCRIPTION OF OPERATIONS below								E.L. DISEASE - EA EMPLOYEE		\$		
									E.L. DISEASE - POLICY LIMIT		\$		
A	Product Liability					ZPP-14R47624-19-I6	05/17/2020	05/17/2021	Each Occurrence		\$	5,000,000	
									Aggregate		\$	5,000,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Umbrella Liability Policy is excess over the General Liability only.

CERTIFICATE HOLDER

CANCELLATION

<div data-bbox="71 1684 774 1791" data-label="Text"> <p>Evidence of Insurance</p> </div>	<div data-bbox="774 1684 1505 1791" data-label="Text"> <p>CANCELLATION</p> <p>SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.</p> </div>
	<div data-bbox="774 1791 1505 1900" data-label="Text"> <p>AUTHORIZED REPRESENTATIVE</p> <p><i>J. B. Wallace</i></p> </div>

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4HH

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Exelead, Inc.

Physical Address: 6925 Guion Road

City: Indianapolis State: IN Zip Code: 46268

Telephone Number: (317) 612-2900 Fax Number: (317) 612-2922

Toll Free Number: N/A

E-mail: EXL@slsny.com Website: Exeleadbiopharma.com

Facility Manager: John Paul Rigg

Professional qualifications and experience of facility manager: CEO of company since May 2014.
Manufacturing Site Head for manufacturing facility, responsible for Operations, Quality, Engineering and Scientific functions.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☒ Other: Manufacturers

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☒ Other: Biologics

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☒ No ☐

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Leadiant Biosciences, Inc

Address: 9841 Washingtonian Blvd Ste 500
Gaithersburg, MD 20878-7352

Name: Servier Pharmaceuticals LLC

Address: 200 Pier Four Blvd. Boston, MA 02210

Name: Teva Pharmaceuticals USA, Inc.

Address: 1090 Horsham Ave. North Wales, PA 19454-1505

Name: Horizon Pharmaceuticals

Address: 150 Saunders Rd, Ste 400 Lake Forest, IL 60045-
2509

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Bradley Jay Wynja

Print Name of Authorized Person

6 MAY 2020

Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: Essetifin S.p.A.Mailing Address: Via Sudafrica 20, CAP 00144City: Rome Country: Italy State: Italy Zip: Telephone: +39 06 542 77332 Fax: N/AContact Person: Lorenza Laureti

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) <u>Paolo Cavazza</u>	<u>Via Sudafrica 20</u> <u>Rome, Italy</u>
Name	Business Address
b) <u>Enrico Cavazza</u>	<u>same as above</u>
Name	Business Address
c) <u>Silvia Cavazza</u>	<u>same as above</u>
Name	Business Address
d) <u>Francesca Cavazza</u>	<u>same as above</u>
Name	Business Address

2) Provide the number of shares issued by the corporation. 1003) What was the price paid per share? \$0.01A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A**Include with the application for a non-publicly traded corporation**List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane

Reno, NV 89509

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. POA1003038

Application/License No. _____

Exelead, Inc, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
6925 Guion Rd., Indianapolis, IN 46268, as
Address of Applicant/Principal
 PRINCIPAL, and Seneca Insurance Company, Inc., a
Surety Company
 corporation organized under the laws of the state of New York
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
160 Water Street, New York, NY 10038 - 4922 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 17, 2020
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this
17th day of July, 20 20.

APPLICANT/PRINCIPAL
 Exelead, Inc

SURETY COMPANY
 Seneca Insurance Company, Inc.

 Authorized Representative


 Surety Company's Representative

Joshua Sanford, Attorney-in-fact
 print name

SIGNED and SEALED in the presence of:

SIGNED and SEALED in the presence of:

 Witness


 Witness Brendan Fletcher

 Witness


 Witness Phillip Knowler

Countersigned by:


 Nevada*Resident Agent Aimee R Perondine
 *NON- License No. 3134182

POWER OF ATTORNEY
SENECA INSURANCE COMPANY, INC.
PRINCIPAL OFFICE, NEW YORK, NEW YORK

92001

KNOW ALL MEN BY THESE PRESENTS: That SENECA INSURANCE COMPANY, INC., a corporation duly organized and existing under the laws of the State of New York, has made, constituted and appointed, and does hereby make, constitute and appoint:

Aimee R. Perondine, Aiza Anderson, Bethany Stevenson, Danielle D. Johnson, Donna M. Planeta, Jenny Rose Belen Phothirath, Joshua Sanford Mercedes Phothirath Samuel E. Begun, Melissa J. Stanton, Lorina Monique Garcia, Nicholas Turecamo, Michelle Anne McMahon

each, its true and lawful Attorney(s)-In-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver: Any and all bonds and undertakings of surety and other documents that the ordinary course of surety business may require, and to bind the Corporation thereby as fully and to the same extent as if such bonds or undertakings had been duly executed and acknowledged by the regularly elected officers of the Corporation at its principal office, in amounts or penalties not exceeding Fifty Million Dollars (\$50,000,000).

This Power of Attorney limits the act of those named therein to the bonds and undertakings specifically named therein, and they have no authority to bind the Company except in the manner and to the extent therein stated.

This Power of Attorney revokes all previous Powers of Attorney issued on behalf of the Attorneys-In-Fact named above and expires on 31 day, of January month, 2021 year.

This Power of Attorney is granted pursuant to unanimous written consent passed the 19th day of September 2011 by the directors of Seneca Insurance Company, Inc. in accordance with Article II, Section 12 of the By-Laws of Seneca Insurance Company, Inc.


Resolved that the President, Vice President, Secretary and Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signatures, which may be attested or acknowledged by any officer or attorney of the Company, qualifying the attorney or attorneys named in the given power of attorney to execute on behalf of, and acknowledge as the act and deed of the Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto.

IN WITNESS WHEREOF, SENECA INSURANCE COMPANY, INC. has caused these presents to be signed and attested by its appropriate officer and its corporate seal hereunto affixed this 11th day of March, 2019.

Corporate Seal:



SENECA INSURANCE COMPANY, INC.

By 

Daniel Sussman
Senior Vice President

STATE OF NEW JERSEY,
ss.
COUNTY OF MORRIS

On this 11th day of March, 2019 before me, a Notary Public, personally appeared the above named officers, Daniel Sussman and Laura Schneider, who, being duly sworn, acknowledged that they signed the above Power of Attorney as Senior Vice President and Vice President of the said SENECA INSURANCE COMPANY, INC. and acknowledged said instrument to be the voluntary Act and Deed of said Company. They are both personally known to me.

Attest: 

Laura Schneider
Senior Vice President



SONIA SCALA
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES 3/25/2024

Sonia Scala, Notary Public

No. 2163686

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal of Seneca Insurance Company, Inc. on the 17th day of July, 2020

Delaware

The First State

Good Standing
462
(Incorp State)

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY "EXELEAD INC." IS DULY INCORPORATED
UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND
HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS
OFFICE SHOW, AS OF THE FIFTEENTH DAY OF JULY, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "EXELEAD INC."
WAS INCORPORATED ON THE SECOND DAY OF NOVEMBER, A.D. 2009.



4748764 8300

SR# 20206167172

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBULLOCK", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 203287824

Date: 07-15-20



Exelead, Inc.

Corporate Address: 6925 Guion Road, Indianapolis, IN 46268 USA
FEIN: 27-1331690
Exeleadbiopharma.com

Drug Labeler Code: N/A
Incorporation State: DE
Incorporation Date: 11/02/2009

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
6925	6925 Guion Road Indianapolis, IN 46268 County: Marion	1000517970	N/A	961822389	No	(317) 612-2900	(317) 612-2922

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
John Paul Rigg	Irishmans Run Lane Zionsville, IN 46077	Chief Executive Officer	No			

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Essetifin S.p.A.	Via S. Stefano CA, Rome, Italy	N/A	100%	N/A	N/A	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
John Paul Rigg	Irishmans Run Lane Zionsville, IN 46077	Chief Executive Officer	No			IN
Bradley Jay Wynja	Bluefin Capital Indianapolis, IN 46203	Chief Financial Officer and Treasurer	No			
John Barry Landis	Sugar Pine Lane Zionsville	President and Chairman of the Board	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CSC			



Indiana Board of Pharmacy

402 West Washington Street, Room W072
Indianapolis, Indiana 46204
Telephone: (317) 234-2067
Fax: (317) 233-4236
Website: www.bop.IN.gov

Governor Mitchell E. Daniels, Jr.

June 23, 2011

To Whom It May Concern:

This letter serves as written notice that the following company is not required to hold a Wholesale Drug Distributor (WDD) license in the State of Indiana in order to distribute legend drugs to licensed entities in the state as the company is an FDA approved manufacturer and therefore exempt from licensure requirements in Indiana:

Sigma-Tau PharmaSource, Inc
6925 Guion Road
Indianapolis, Indiana 46268

It is the Indiana Board of Pharmacy's (Board) understanding that the aforementioned company manufactures and distributes legend drugs within or into Indiana and that the company only distributes legend drugs that it manufactures, i.e. the company does not distribute legend drugs manufactured by a company other than itself.

Indiana Code 25-26-14-1 states, "(a) This chapter applies to any individual, partnership, limited liability company, corporation, or business firm: (1) located in or outside Indiana; and (2) engaging in the wholesale distribution of legend drugs in Indiana... (b) Except as required by federal law or regulation, the requirements of this chapter do not apply to a manufacturer that is approved by the federal Food and Drug Administration." [emphasis added].

The Board therefore does not require licensure for entities that are FDA approved manufacturers who only distribute legend drugs the company itself manufactures.

If there is any question or clarification necessary regarding the status of this company, please contact Indiana Board of Pharmacy staff for further assistance.

Sincerely,

Amy M. Phillips
Assistant Director
Indiana Board of Pharmacy



Exelead

Complex Drug Product Formulations

April 16, 2020

To Whom It May Concern,

Due to the current COVID 19 situation, Exelead has been unable to obtain an updated letter of exemption from the Indiana Board of Pharmacy. We certify that Exelead continues to meet the requirements to remain exempt as stated in the attached letter, which indicated that Exelead is not required to hold a Wholesale Drug Distributor (WDD) license in the State of Indiana in order to distribute legend drugs to licensed entities in the state as the company is an FDA approved manufacturer and therefore exempt from licensure requirements in Indiana.

Sincerely,

A handwritten signature in blue ink, appearing to read 'JR', followed by a long horizontal line.

John Rigg

CEO

Exelead, Inc.

Drug Establishments Current Registration Site

f SHARE (<https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm>)

🐦 TWEET ([https://twitter.com/intent/tweet?text=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm](https://twitter.com/intent/tweet?text=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm))

in LINKEDIN ([https://www.linkedin.com/shareArticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&title=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&source=fda](https://www.linkedin.com/shareArticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&title=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&source=fda))

@ PIN IT ([https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&description=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&description=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE))

✚ EMAIL ([MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm](mailto:?subject=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&body=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)) **🖨** PRINT

New Search (default.cfm)

Search Results for Exelead

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Exelead, Inc.	1000517970	961822389	ANALYSIS; LABEL; MANUFACTURE; PACK; RELABEL; REPACK;	6925 Guion Road, Indianapolis, Indiana (IN) 46268, United States (USA)	12/31/2020

*Verified
8/10/20
NLS*

Showing 1 to 1 of 1 entries

[Previous](#)1Next

Data Current through: Wednesday, Nov 13, 2019

[**Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)**](#)

John Rigg

Irishmans Run Lane, Zionsville, Indian:

Tel.

| Email

gmail.com

Education

BACHELOR SCIENCE, | 1993 | JOHN MOORES UNIVERSITY, LIVERPOOL, UK

- Major: Applied Chemistry (Hons)

Skills & Abilities

LEADERSHIP

- Gained a deep understanding of Biotechnology Active Pharmaceutical Ingredient (API) and Biologic (drug product) manufacturing through leadership assignments within General Management, Operations, Technical Services (Manufacturing Sciences and Technology), Quality Assurance, and Quality Control.
- Responsible for the successful development and of a bio similar insulin, an orally delivered biologic drug product, and commercialization of numerous E.coli produced drug substances and pegylated drug products.
- Network leader within Biotech API manufacturing required the demonstration of strong interpersonal skills with individuals at all levels of the organization within Manufacturing, Development and with External Business Partners.
- Proven track record of building strong organizations by recognizing talent through both the development of existing employees, and the recruitment of Scientists from targeted Universities.
- Driven productivity and significant GMP change agendas, across multiple culturally different sites (United Kingdom, United States, Puerto Rico), and with Contract Manufacturing Organizations.

TECHNICAL

- Comprehensive understanding of E.coli and transgenic rice derived protein manufacturing, from fermentation and field harvest through to final purified API. Managed the change agendas and ongoing operations for large scale (+2000Kg per annum) insulin purification facilities, and small scale (10 Kg per annum) hormone production units.
- Ever increasing levels of leadership skills developed from foundational and first line supervisory assignments within Manufacturing, Development and Quality functions to Vice President and General Manager Responsibilities, have provided a comprehensive knowledge of GMP manufacturing, Quality Systems.
- Developed, implemented, and refined manufacturing Control Strategies for multiple biotechnology products, ensuring manufacturing robustness and minimizing factory losses.
- Lead and participated in due diligence reviews for new Business Opportunities, Contract Manufacturing Organizations and Raw Material Suppliers.
- Demonstrated high learning agility and pragmatic approach to understanding and solving complex technical and business problems that have ensured business growth no interruption to product supply.

COMMUNICATION

- Successfully facilitated relationships across the development, manufacturing and commercialization nodes of a Diabetes Business Unit, to successfully lead the transfer and development of API from phase 2 to commercial scale batches.
- In a supply constrained environment, developed a significant Technical Agenda across the Science, Quality, and Operations functions by calling on perspectives gained while working within each function. Put in place a four tier governance process that incorporated a dashboard set of metrics to track and communicate progress to all levels of the organization.
- Accountable person for multiple interactions with regulatory agencies from both a GMP inspection of the manufacturing facilities, and CMC submission for an aggressive change agenda standpoint.

DIRECTOR QUALITY, INDIANAPOLIS | ELI LILLY & CO | SEP 2005 – JUN 2006

- Site Quality functional leader that provided manufacturing oversight to two insulin commercial drug substances.
- Lead the site through two successful EMA and FDA inspections.
- Implemented a Triage system for CAPA investigations to improve Quality and Science within manufacturing, and significantly reduce the number of manufacturing deviations and associated backlog.

NUMEROUS LEADERSHIP POSITIONS, SPEKE OPERATIONS, UK| ELI LILLY & CO | 1995–2005

- Site Leader for MS&T responsible for the internal and external manufacture of 2 human health and 24 animal health drug substance and drug product items.
- Site Six Sigma champion with responsibility for the Black Belts and Green Belts.
- QCL Manager responsible for the in process and batch release testing of all site and externally manufactured products.
- Lead a site project to successfully implement Site Operational Standards for Supply Chain Excellence (OSSCE).
- Production Leader for hGH manufacturing facility.
- Shift leader for a bulk fermentation manufacturing facility (22 x 225K liter vessels).

411

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: RVL Pharmaceuticals, Inc.

Physical Address: 2500 Main Street Extension, Suite 6

City: Sayreville State: NJ Zip Code: 08872

Telephone Number: (908) 809-1300 Fax Number: (908) 809-1302

Toll Free Number: N/A

E-mail: RVLstatelicense@osmotica.com

Website: _____

Facility Manager: Cassia Riccioni

Professional qualifications and experience of facility manager: _____

See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☒ Other: Specialty Pharmacies

Type of Products to be handled or wholesaled by firm:

<input checked="" type="checkbox"/> Legend Pharmaceuticals, Supplies or Devices	<input type="checkbox"/> Hypodermic Devices
<input type="checkbox"/> Poisons or Chemicals	<input type="checkbox"/> Veterinary Legend Drugs
<input type="checkbox"/> Controlled Substances (include copy of DEA)	
<input type="checkbox"/> Other: _____	

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA?
(If yes, provide a copy of your FDA registration)

Yes ☒ No ☐

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Christopher Klein

Print Name of Authorized Person

8/5/2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: Osmotica Pharmaceutical Corp.Mailing Address: 895 Sawyer RoadCity: Marietta State: GA Zip: 30062Telephone: 9088091300 Fax: _____Contact Person: Christopher Klein

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Addressb) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/AA Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A**Include with the application for a non-publicly traded corporation**List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.



**NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE**

P.O. Box 369, Trenton, New Jersey 08625-0369

0741276

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of \$20.00 shall accompany such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

2500 MAIN STREET EXT, STE 6 SAYREVILLE, NJ 08872-

Reg. No.
5005820

OSMOTICA PHARMACEUTICAL CORP
RVL PHARMACEUTICALS, INC.
2500 MAIN STREET EXT, STE 6
SAYREVILLE, NJ 08872-

**ISSUED PURSUANT TO
N.J.S.A. 24:6B**

EXPIRES: January 31, 2021

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 8/25/2020

Registration Number: 5005820

Registered as: Wholesale

Parent Company Name: OSMOTICA PHARMACEUTICAL CORP

Trade Name: RVL PHARMACEUTICALS, INC.

Original Issue Date: 08/18/2020

Expiration Date: 01/31/2021

Current Issue Date: 08/18/2020

Disciplines: No

RVL PHARMACEUTICALS, INC.**Ownership Information**

Osmotica Pharmaceutical Corp.

400 Crossing Blvd.

Bridgewater, NJ 08807

Owns 100% of RVL Pharmaceuticals, Inc.

Corporate Officers

Brian Markison, CEO

400 Crossing Blvd.

Bridgewater, NJ 08807

Ownership 0%

Andrew Einhorn, CFO

400 Crossing Blvd.

Bridgewater, NJ 08807

Ownership 0%

James Schaub, Vice President

400 Crossing Blvd.

Bridgewater, NJ 08807

Ownership 0%

Chris Klein, General Counsel and Secretary

400 Crossing Blvd.

Bridgewater, NJ 08807

Ownership 0%



Description of Operations

RVL Pharmaceuticals, Inc. ("RVL") is wholly owned by Osmotica Pharmaceutical Corp., which is a privately held corporation. RVL's products are manufactured and packaged by a contract manufacturer and will be distributed to specialty pharmacies.

Labeler Code: 73687

*verified
8/22/20
MS*

RVL Pharmaceuticals, Inc. distributes its own products from their facilities located at:
2500 Main Street Extension, Suite 6
Sayreville, NJ 08872

Contract Manufacturer:

We are using the following contract manufacturer to produce our product:

Nephron Pharmaceuticals Corporation

4500 12th Street Extension
West Columbia, SC 29172
FEIN: 3011158388

Products:

The above contract manufacturers produce RVL's product and packages finished product. At no time do they own the product, contract with RVL's customers, invoice, nor sell an RVL product. RVL's products are not Controlled Substances.

RVL's hours of operation are 8:00 a.m. – 5:00 p.m. (Eastern Time), Monday through Friday

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RVL PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF AUGUST, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RVL PHARMACEUTICALS, INC." WAS INCORPORATED ON THE NINTH DAY OF AUGUST, A.D. 2011.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.



5022283 8300

SR# 20206916272

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 203529933

Date: 08-25-20

From: [CDER Electronic Drug Registration and Listing](#)
To: [Teriko Molina](#)
Cc: [Joann Stavole](#)
Subject: RE: RevitaLid Labeler Code Request
Date: Friday, April 3, 2020 5:26:33 PM
Attachments: [image002.png](#)

Your labeler code was assigned on March 6, 2020 and we have been waiting for you all to confirm your labeler code. Once you confirm it you can begin listing.

Email

[Back](#)

Status : Assigned

Assigned Code : 73687

Labeler Name : RevitaLid, Inc.

DUNS : 081365086

SPL Root ID : 9fa6ac5a-7ea9-1366-e053-2995a90a6760

Contact Name : George Wagner

Contact Phone : 1-908-809-1357

Contact Email : gwagner@osmotica.com

Contact Address : 400 Crossing Blvd

Contact City : Bridgewater

Contact State : NJ

Contact Zip : 08807

Contact Country : USA

Physical Name : RevitaLid, Inc.

Physical DUNS : 081365086

Physical Address : 400 Crossing Blvd

Physical City : Bridgewater

Physical State : NJ

Physical Zip : 08807

Physical Country : USA

Business : distributes drug products under own private label - Distributes human prescription drug
Operations : products

eDRLS - Electronic Drug Registration & Listing System

Current Date: 06-MAR-2020
Labeler DUNS: 081365086
Labeler Name: RevitaLid, Inc.
Labeler Code: 73687

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit [Drug Registration and Listing System](#) or reply back to this email (edrls@fda.hhs.gov).

From: Teriko Molina <molina@osmotica.com>

Sent: Friday, April 03, 2020 4:24 PM

To: CDER Electronic Drug Registration and Listing <EDRLS@fda.hhs.gov>

Cc: Joann Stavole <jstavole@osmotica.com>

Subject: Revitalid Labeler Code Request

Good Evening,

I completely understand that we have public health emergency and that you all are busy with the hand sanitizer issues at hand. We are trying to begin labeling for our product that is NOT a hand sanitizer and need a labeler code in order to do so. I submitted a labeler code request for our company Revitalid, Inc. on Friday, February 28th. Any kind of estimate of a response would help us to be able to put a timeline together for our team. Thank you so much for your time.

Ps. I have also reached out to cderrdirect@fda.hhs.gov as well and haven't heard back. I'm sure everyone is busy with this situation.

Teri Molina

Regulatory Associate, Labeling

Osmotica Pharmaceuticals

1904 Eastwood Road, Suite 205

Wilmington, NC 28403

Office: (770) 509-4603

Fax: (910) 509-0121

Email: molina@osmotica.com

www.osmotica.com

Banner



CONFIDENTIALITY NOTE: This e-mail and any files transmitted are intended only for the use of the individual or entity to whom they are addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or use of any of the information is PROHIBITED.

A	B	C	D	E	F	G	H	I	J	K	L	M
NDC/NHR IC	Labeler Firm Name	IC	Firm Name									
1	1444974788		Mirth Company LLC									
	1445051879		Tec Laboratories, Inc.									
	1445174043		Jackson Hole Distillery, LLC									
	1445276328		Lotus Brands, Inc.									
	1445363798		Hunter's Specialties									
	1445451065		Kyongbo Pharmaceutical Co., Ltd									
	1445570098		GK COSMETIC CO., LTD									
	1445669696		Daddy Wank LLC									
	1445710130		Ben Venue Laboratories Inc.									
	1445814513		Elder Health Care Ltd									
	1445977037		Heady Vapes & Lounge									
	1446075381		AMC Standard Inc									
	144610254		Par Pharmaceutical Inc.									
	1446273575		OBA PHARMACEUTICALS INC									
	1446375364		CrudeChem Technology LLC									
	1446470238		Peak Inc									
	1446564052		Pfizer Ireland Pharmaceuticals									
	1446677110		Biominerals Pharma, LLC									
	144671122		Morin Inc.									
	1446873687		RVL Pharmaceuticals Inc									
	1446974914		Foggy Mountain Spirit Company									
	1447005133		Neighborcare									
	1447170436		Slate Run Pharmaceuticals									
	1447224057		Lester E Cox Medical Centers dba CoxHealth Home Support									
	1447376605		Pecan Bayou Enterprises, LLC									
	1447462673		Neoteric Cosmetics, Inc.									
	1447577032		EZ-Groom									
	1447652936		Planet (Shanghai) International Co., Ltd.									
	1447776362		Maquilas y Logistica Integral S.A. de C.V.									
	1447813633		Mountaineer Home Medical LLC									
	1447957889		Sun Enterprise									
	1448054748		Small World Trading Company									
	1448142358		Sentynl Therapeutics, Inc.									
	1448253703		Enterahhealth, Inc.									
	1448377890		Angel Tree Products Inc.									
	1448458982		OZ SOAP TREE									
	1448577138		Lizzy James Designs Inc.									
	1448665190		Huangshi Shixing Pharmaceutical Co., Ltd.									

NDCLabelerCodeAutoReport +



Product List

UPNEEQ - Oxymetazoline HCl Ophthalmic Solution, 0.1% - Labeler code: 73687

CASSIA RICCIONI

Keyport, NJ 07735

.gmail.com | www.linkedin.com/CassieRiccioni

QUALITY ASSURANCE | PHARMACEUTICAL | MANUFACTURING

Quality Assurance Professional with broad experience in pharmaceutical quality processes and problem solving. Expertise in reviewing complaints, SOPs, Batch Records, and other documentation for accuracy and completeness. Skilled in preparing for internal or external audits and correcting deficiencies. Demonstrated ability to bring new facilities into FDA compliance. Proficient in SAP and TrackWise.

CORE COMPETENCIES

PQMS | Batch Record Review | Controlled Substances/DEA | Document Control FDA Regulations | Metrics Reporting | GMP/GLP/GXP | OSHA | Manufacturing Drug Products | Outstanding Communication Skills | Team Collaboration

PROFESSIONAL EXPERIENCE

Vertical Pharmaceuticals Sayreville, NJ

07/2019 to present

Quality Assurance Associate

- Perform documentation review (i.e. batch manufacturing and/or packaging records, Certificate of Compliance, Certificate of Analysis, etc.)Based on review, perform product release and disposition within company ERP system.
- Initiate, write, drive/lead deviations and investigations to ensure that all critical and major quality issues are thoroughly addressed and documented with appropriate associated CAPA.
- Participate in Change Control activities affecting procedures, processes and systems.
- Receive product quality complaints and perform activities to lead to closure and customer satisfaction.
- Write, review, and approve standard operating procedures (SOPs) and other applicable operation related GMP documents.
- Support and participate in trending of quality measures, CAPA plans, and annual reports.
- Escalate potential issues and concerns immediately to QA Management.
- Participate and assist in the GMP auditing program for internal and external audits including FDA, DEA, and FL-DBPR.
- Support the development, improvement and maintenance of Quality Systems including procedure development, process mapping in collaboration with other technical and business areas.
- Guide, develop and train others in areas of subject matter expertise.

TaroPharmaceuticals,Cranbury,NJ

04/2019 -

07/2019

Quality Specialist (contract)

- SOP Development
- Participate in Site Quality Council Team
- Review shipping documents, in-transit conditions, release documents from sites and FDA-releases for products received from manufacturing facilities
- Upon success of the document reviewed, release products
- Interact with Quality release teams in order to coordinate and ensure accurate release of products
- Inspect, verify and document the transport condition of any products received from manufacturing sites.
- Review and ensure compliance of the batch manufacturing records associated to the CMO received batches
- Inspect the returns goods and define the recommended status
- Coordinate and document the pre-authorized destruction of products
- Create, maintain files related to products and master data in SAP
- Act as Quality primary point of contact for subjects related to SAP
- Initiate, review and close investigations in Trackwise

Oncobiologics, Cranbury, NJ

02/2018 - 11/2018

Quality Associate

- Issuing, reviewing and archiving executed manufacturing batch records (MBR) for biologics manufacturing of clinical supplies and licensed products.
- Review and comment on draft documentation relevant to manufacturing, such as MBRs, Specifications and SOPs
- Initiate and participate in investigations, including non-conformance events, deviations, CAPA's and investigations.
- Inspect and observe the manufacturing units
- Ensure that the organization is compliant with relevant cGMPs, participate in internal audit teams and ensure readiness for global health authority's inspections
- Implement Quality Plan and associated policies and procedures required for the Quality Assurance function
- Specification & Materials Management.

Actinium Pharmaceuticals Inc., Edison, NJ

01/2016 – 07/2016

Senior Quality Associate (contract)

- Reviewed Manufacturing Records and released product for clinical use.
- Participated in SOP development, training and implementation.
- Entered, checked, monitored stability data in Excel.
- Reviewed and approved Master Batch Records, Deviations and CAPA's.
- QA advisor for product development at external sites.

JANSSEN SUPPLY GROUP, a division of J&J, Raritan, NJ

2007 – 2015

Quality Associate

- Reviewed product complaints in the PQMS system, ensuring complaint was categorized correctly for metrics reporting and escalating as needed.
- Requested investigations from internal and external manufacturing sites, reviewing results for accuracy and completeness and closing complaint.
- Monitored metrics for trends by analyzing reports, identifying defects and escalating as

needed for investigation or recall.

- Created weekly and monthly reports in Excel which demonstrated number of complaints for each site, providing data for site managers and quality management team.
- Assisted in Audits.

JEIVEN PHARMACEUTICAL CONSULTING, INC., Scotch Plains, NJ

2003 – 2007

Senior Quality Compliance Associate

- Batch record review and release
- Quality control for contract sites, pulling samples during runs and for retians
- 3rd party monitor at contract packaging sites
- SOP Development
- Audit Prep

NOVADEL PHARMA, INC., Flemington, NJ

Production Supervisor, Compliance Coordinator

2002 - 2003

Nexmed, East Windsor NJ

Operations Line Leader

2001-2002

Medarex, Clinton, NJ

Laboratory Technician

1998-2001

EDUCATION

Microsoft Office Specialist, Avtech Institute of Technology, Eatontown, NJ, 2017

Registered Nurse Coursework, Belmont Technical College, Saint Clairsville, OH

Mental Health / Human Services coursework, Franciscan University of Steubenville, Steubenville, OH

SKILLS

SAP, Excel, PowerPoint, Access, SharePoint, TrackWise, ComplianceWire, WebEx, Master Control, Veeva Vault

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. BLY2020177

Application/License No. _____

RVL Pharmaceuticals, Inc. _____, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
 2500 Main Street Extension, Suite 6, Sayreville, New Jersey 08871 _____, as
Address of Applicant/Principal
 PRINCIPAL, and The Hanover Insurance Company _____, a
Surety Company
 corporation organized under the laws of the state of New Hampshire _____
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
 440 Lincoln Street, Worcester, Massachusetts 01653-0002 _____ as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 24, 2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statute (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are imposed pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of July, 2020.

APPLICANT/PRINCIPAL
RVL PHARMACEUTICALS, INC.


Authorized Representative

SURETY COMPANY
THE HANOVER INSURANCE COMPANY

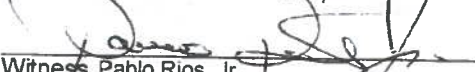

Surety Company's Representative

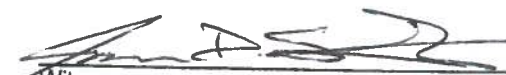
Wendy Lee Wadkins, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:


Witness

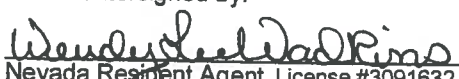
SIGNED and SEALED in the presence of:


Witness Pablo Rios, Jr.


Witness


Witness Danielle M. Bechard

Countersigned by:


Non- Nevada Resident Agent License #3091632
Wendy Lee Wadkins

**THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA**

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Wendy Lee Wadkins, Christopher F. Mulvaney, Charles N. Parsons, Vincent J. Mancini and/or Pablo Rios, Jr.

Of Willis of Pennsylvania, Inc. of Radnor, PA each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Twenty Five Million and No/100 (\$25,000,000) in any single instance

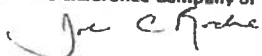
That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 - The Hanover Insurance Company; Adopted April 14, 1982 - Massachusetts Bay Insurance Company; Adopted September 7, 2001 - Citizens Insurance Company of America)

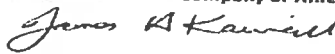
IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this 14th day of February, 2018.

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America


John C. Roche, EVP and President

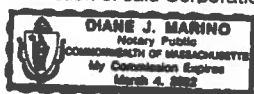


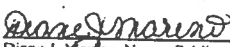
The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America


James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this 14th day of February, 2018 before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

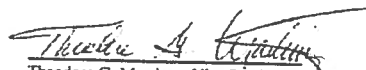



Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 24th day of July 2020

CERTIFIED COPY


Theodore G. Martinez, Vice President



August 11, 2020

Via Fed Ex

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

To Whom It May Concern:

On behalf of RVL Pharmaceuticals, Inc., attached is RVL Pharmaceuticals, Inc.'s initial application for licensure.

RVL Pharmaceuticals, Inc. is a privately held pharmaceutical company located in Sayreville, New Jersey. RVL Pharmaceuticals, Inc. distributes its products directly to wholesalers from its facility in Sayreville, New Jersey. The products RVL Pharmaceuticals, Inc.'s ships out of the Sayreville, New Jersey location are not controlled substances. Accordingly, RVL Pharmaceuticals, Inc. is not required to obtain a DEA registration. At the time of this filing, RVL Pharmaceuticals, Inc. only holds a license in their home state of New Jersey.

I hope this narrative is helpful as you review RVL Pharmaceuticals, Inc.'s application. If you have a question regarding this application, please contact me at 614-370-2801 or via email at stacie.borngrebe@twolabs.com. Please also address all written communication to me. My address is 2123 English Turn Dr., Grove City, OH 43123.

Thank you in advance for your consideration.

Stacie Borngrebe
Licensing Analyst
PharmaLicense

4JJ

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler or ☒ **Ownership Change** (Provide current license number if making changes: WH 02628)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Slayback Pharma, LLC

Physical Address: 301 Carnegie Center, Suite 303

City: Princeton State: NJ Zip Code: 08540

Telephone Number: (609) 945-3443 Fax Number: (609) 455-1514

Toll Free Number: (844) 566-2505

E-mail: SLY@slsny.com Website: www.slayback-pharma.com

Facility Manager: Rafal Czapla

Professional qualifications and experience of facility manager: Director of marketing at Slayback Pharma, LLC since 2017

Responsibilities include 3PL setup, customer setup including contract review, managing launch meeting and sterile pipeline product analysis and support, label creation, IMS data market analysis; working with pricing and compendia to establish WAC, and Customer pricing and offer letters.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Distributors

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA? Labeler Code: 71225
(If yes, provide a copy of your FDA registration)

Yes ☒ No ☐

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: GP Pharma, SA

Address: Pl. Els Vinyets - Els fogars 2, Ctra. Comarcal C-244 Km.22,
08777 Sant Quinti de Mediona, Barcelona, Spain

Name: Corden Pharma, SpA

Address: Viale Dell'Industria 3, Caponago, Monza E della
Brianza, IT

Name: _____

Address: _____

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Ajay K. Singh

Print Name of Authorized Person

03/06/2020

Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Slayback Pharma, LLC
 Parent Company if any: N/A
 Mailing Address: 301 Carnegie Center, Suite 303
 City: Princeton State: NJ Zip: 08540
 Telephone: (609) 945-3443 Fax: (609) 455-1514
 Contact Person: Rafal Czapla

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a)	<u>Armour Investments, LLC</u>	<u>41 Armour Road, Princeton, NJ 08540</u>	31.9%
	<small>Name</small>	<small>Business Address</small>	
b)	<u>KKR Sail Investors LLC</u>	<u>2800 Sand Hill Road, Suite 200, Menlo Park, CA 94025</u>	30.2%
	<small>Name</small>	<small>Business Address</small>	
c)	<u>Everpharma Inc.</u>	<u>213 Little Falls Drive, Wilmington, DE 19808</u>	22.8%
	<small>Name</small>	<small>Business Address</small>	
d)	<u>Remaining 15.1% consists of multiple entities/people that own less than 5%.</u>		
	<small>Name</small>	<small>Business Address</small>	
- 2) Provide the number of shares issued by the corporation. 159,116,815
- 3) What was the price paid per share? \$1.02

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporationList of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.



Slayback Pharma, LLC

Corporate Address: 301 Carnegie Center, Suite 303, Princeton, NJ 08540 USA
 FEIN: 27-5210842
www.slayback-pharma.com

Drug Labeler Code: 71225
 Incorporation State: DE
 Incorporation Date: 12/27/2016



FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
JCT	301 Carnegie Center Suite 303 Princeton, NJ 08540 County: Mercer	N/A	N/A - No CS	967770848	No	(609) 945-3443 (609) 455-1514	

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Rafal Czaplak	2546 E. Clearfield Street Philadelphia, PA 19134	Director, Marketing	Yes			

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
KKR Sail Investors LLC	2800 Sand Hill Road Suite 200 Menlo Park, CA 94025	N/A	30.2	N/A	81-4652475	N/A	N/A
Everpharma Inc.	213 Little Falls Drive Wilmington, DE 19808	N/A	22.8	N/A	84-4046026	N/A	N/A
Armour Investments, LLC	41 Armour Road Princeton, NJ 08540	N/A	31.9	N/A	83-6124797	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Ajay K. Singh	Armour Road Princeton, NJ 08540	President & CEO	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
InCorp Services, Inc.			

3PLS Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
-----------	---------	-------	-----------------------	-----	-----	------------------

Eversana Life Science Services LLC	4580 Mendenhall Road Memphis, TN 38141					
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Company
Particulars

Delaware

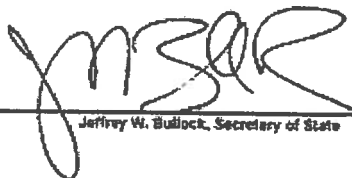
The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SLAYBACK PHARMA LIMITED LIABILITY COMPANY" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF MARCH, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SLAYBACK PHARMA LIMITED LIABILITY COMPANY" WAS FORMED ON THE TWENTY-SEVENTH DAY OF DECEMBER, A.D. 2016.




Jeffrey W. Bullock, Secretary of State

6262293 8300

SR# 20202038549

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202570241

Date: 03-12-20

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 8/17/2020

Registration Number: 5005359 **Registered as:** Manufacturer and Wholesale

Parent Company Name: SLAYBACK PHARMA, LLC

Trade Name:

Original Issue Date: 01/12/2018 **Expiration Date:** 01/31/2021

Current Issue Date: 11/29/2019

Disciplines: No

499
(NJ does not issue
Official
VOLS)



NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

0737595

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of \$20.00 shall accompany such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:
301 CARNEGIE CTR, STE 303 PRINCETON, NJ 08540-

Reg. No. 5005359
SLAYBACK PHARMA, LLC
c/o STATE LICENSE SERVICING
1751 STATE ROUTE 17A, STE 3
FLORIDA, NY 10921-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2021

Establishment Copy

500
License

National Drug Code Directory

f SHARE https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm

TWEEET [https://twitter.com/intent/tweet?text=NATIONAL DRUG CODE DIRECTORY&url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm](https://twitter.com/intent/tweet?text=NATIONAL%20DRUG%20CODE%20DIRECTORY&url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

in LINKEDIN [https://www.linkedin.com/shareArticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm&title=NATIONAL DRUG CODE DIRECTORY&source=fda](https://www.linkedin.com/shareArticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm&title=NATIONAL%20DRUG%20CODE%20DIRECTORY&source=fda)

@ PIN IT [https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm&description=NATIONAL DRUG CODE DIRECTORY](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm&description=NATIONAL%20DRUG%20CODE%20DIRECTORY)



EMAIL [mailto:77SUBJECT-NATIONAL DRUG CODE DIRECTORY&body=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm](mailto:mailto:77SUBJECT-NATIONAL%20DRUG%20CODE%20DIRECTORY&body=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)



Current through March 18, 2020

You have searched Finished drug products

Search Results: 71225

[Back to Search Page 0](#) | [Search Again 0](#)

CSV Excel

Display All records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
DEXMEDETOMIDINE HYDROCHLORIDE	71225-126-06	4 ug/mL	INJECTION	INTRAVENOUS	ANDA212791	Slayback Pharma LLC	71225-126	dexmedetomidine hydrochloride	DEXMEDETOMIDINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	12/06/2019	N/A	ANDA
DEXMEDETOMIDINE HYDROCHLORIDE	71225-126-05	4 ug/mL	INJECTION	INTRAVENOUS	ANDA212791	Slayback Pharma LLC	71225-126	dexmedetomidine hydrochloride	DEXMEDETOMIDINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	12/06/2019	N/A	ANDA
HYDROXYPROGESTERONE CAPROATE	71225-104-01	250 mg/mL	INJECTION	INTRAMUSCULAR	ANDA210618	Slayback Pharma LLC	71225-104	HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE	HUMAN PRESCRIPTION DRUG	12/28/2018	N/A	ANDA
Hydroxyprogesterone caproate	71225-105-01	250 mg/mL	INJECTION	INTRAMUSCULAR	ANDA210877	Slayback Pharma LLC	71225-105	Hydroxyprogesterone caproate	HYDROXYPROGESTERONE CAPROATE	HUMAN PRESCRIPTION DRUG	03/25/2019	N/A	ANDA

Showing 1 to 4 of 4 entries

Previous 1 Next

From: compliance@slsnysupport.com
Subject: Slayback Pharma, LLC - Notice of Change of Ownership
Date: January 27, 2020 at 12:24 PM
To: pharmacy@pharmacy.nv.gov

IMPORTANT NOTICE



State License Servicing, Inc.

1751 State Route 17A, Suite 3, Florida, NY 10921
 (845) 544-2482 Office, (845) 544-2481 Fax

Date: January 27, 2020
 To: Nevada State Board of Pharmacy
 Re: Slayback Pharma, LLC, 301 Carnegie Center, Suite 303, Princeton, NJ 08540, Permit #: WH02628

Dear Licensing Authority:

State License Servicing, Inc. represents Slayback Pharma, LLC in the servicing of their state licenses. This letter shall serve as notice that effective January 15, 2020, Slayback Pharma, LLC had a change in the ownership of their company. The ownership is as follows:

From: Ajay K. Singh 25.2%
 Gyan Ranjan Singh 5.85%
 KKR Sail Investors LLC 31.5%
 Nishtha G. Singh 26.2%

To: Armour Investments, LLC 31.9%
 KKR Sail Investors, LLC 30.2%
 Everpharma Inc. 22.8%
 Other Owners Each Holding < 5% Ownership

Please be assured that if your state requires any additional forms, filings and associated fees to effectuate this change, these are being completed and will be filed shortly.

If you need any additional information, please feel free to call or email me at the address below.

Kind Regards,

Jennifer Schneider
 V.P. Client Services
 (845) 544-2482 ext 207
 jennifers@slsnys.com

THIS ELECTRONIC MAIL AND ANY ATTACHMENT IS CONFIDENTIAL AND UNLAWFUL TO DISCLOSE TO ANY OTHER PERSON. IF YOU ARE NOT A RECIPIENT OF THIS MESSAGE, YOU SHOULD NOT DISCLOSE IT TO ANY OTHER PERSON. IF YOU HAVE RECEIVED THIS MESSAGE IN ERROR, PLEASE CONTACT THE SENDER AND DELETE THIS MESSAGE FROM YOUR SYSTEM.

[Click Here to Respond to this Email](#)

IMPORTANT NOTICE

Slayback Pharma

Connecting the Dots ...

**Slayback Pharma, LLC**Ownership

Armour Investments, LLC- 31.9%
FEIN:83-6124797

KKR Sail Investors, LLC-30.2%
FEIN:81-4652475

Everpharma, Inc- 22.8%
FEIN:84-4046026

The remaining 15.1% of ownership is held by numerous shareholders who hold various shares not amounting to more than 4% each

2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 810006299

Application/License No. W4102628

Slyback Pharma LLC, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
301 Carnegie Ctr. Suite 303, Princeton, New Jersey 08540-6586, as
Address of Applicant/Principal
PRINCIPAL, and Atlantic Specialty Insurance Company, a
Surety Company
 corporation organized under the laws of the state of New York
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is

One State Street Plaza, 31st Floor, New York, NY 10004 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 27, 2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statute (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of August, 2020.

APPLICANT/PRINCIPAL

Slayback Pharma LLC

[Signature]
Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

```
print name
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SIGNED and SEALED in the presence of:

Witness Gyan Ranjan
GYAN RANJAN
(VP - OPERATIONS)

Witness Rhina Guntzky
(operation manager)

SIGNED and SEALED in the presence of:

Witness

Witness Ann Powell

Countersigned by:

Nevada Resident Agent



Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Robyn Rost, Raymond C. Carman, Theresa A. Lanfranco, Kim Spinello, Dan E. Ries, Denese Thompson, Marlana Brower, Jessica J. Bentley, Laura L. Brown**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **sixty million dollars (\$60,000,000)** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-ninth day of April, 2019.

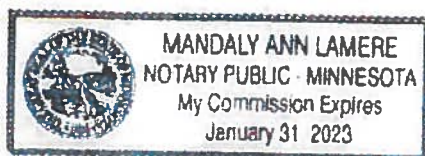


STATE OF MINNESOTA
HENNEPIN COUNTY

By

Paul J. Brehm, Senior Vice President

On this twenty-ninth day of April, 2019, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.



Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated _____ day of _____.



Christopher V. Jerry, Secretary

This Power of Attorney expires
January 31, 2023



Atlantic Specialty Insurance Company
Period Ended 12/31/2019

Dollars displayed in thousands

Admitted Assets		Liabilities and Surplus	
Investments		Liabilities	
Bonds	\$ 1,219,332	Loss Reserves	\$ 750,516
Preferred Stocks	-	Loss Adjustment Expense Reserves	243,193
Common Stocks	791,167	Total Loss & LAE Reserves	<u>993,709</u>
Mortgage Loans	-		
Real Estate	-	Unearned Premium Reserve	520,053
Contract Loans	-	Total Reinsurance Liabilities	17,061
Derivatives	-	Commissions, Other Expenses, and Taxes due	40,497
Cash, Cash Equivalents & Short Term Investments	62,383	Derivatives	-
Other Investments	17,350	Payable to Parent, Subs or Affiliates	-
Total Cash & Investments	<u>2,090,232</u>	All Other Liabilities	165,932
		Total Liabilities	<u>1,737,252</u>
Premiums and Considerations Due	261,176		
Reinsurance Recoverable	51,892	Capital and Surplus	
Receivable from Parent, Subsidiary, or Affiliates	21,095	Common Capital Stock	9,001
All Other Admitted Assets	59,800	Preferred Capital Stock	-
		Surplus Notes	-
Total Admitted Assets	<u>2,484,105</u>	Unassigned Surplus	49,392
		Other Including Gross Contributed	688,460
		Capital & Surplus	<u>746,853</u>
		Total Liabilities and C&S	<u>2,484,105</u>

State of Minnesota
County of Hennepin

I, Christopher Jerry, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said OneBeacon Insurance Company, on the 31st day of December, 2019, according to the best of my information, knowledge and belief.

Christopher Jerry

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 27th day of February, 2020.



Shannon Marie Lauby-Wolf

Notary Public

Rafal Czapla, PharmD, MBA

E. Clearfield Street
Philadelphia, PA 19134
Phone
E-mail :om

OBJECTIVE

To obtain a management position with an organization that will gain from my knowledge and experience while allowing me to explore new challenges and facilitating professional growth.

PROFESSIONAL EXPERIENCE

Director, Marketing (July 2017 – Present)
Slayback Pharma, LLC
Princeton, NJ

Responsibilities:

- 3PL setup
- Customer setup including contract review
- Managing launch meeting and sterile pipeline product analysis and support
- Label creation
- IMS data market analysis
- Working with Pricing compendia to establish WAC
- Customer pricing and offer letters
- Working with finance to prepare annual forecast, budget, LE and Strat Plan
- Working with BD to analyze potential product opportunities and acquisitions

Director, Marketing (July 2016 – July 2017)
Renaissance Lakewood, LLC
Newtown, PA

Responsibilities:

- 3PL setup
- Customer setup including contract review
- Managing launch meeting and sterile pipeline product analysis and support
- Label creation
- Marketing lead for Serialization project
- IMS data market analysis
- Working with Pricing compendia to establish WAC
- Customer pricing and offer letters
- Working with finance to prepare annual forecast, budget, LE and Strat Plan
- Working with BD to analyze potential product opportunities and acquisitions

Results: 1st sterile product approval in Jan 2017 and successful preparedness for product launch

Sr. Marketing Manager (April 2015 – June 2016)
Renaissance Pharma & Prestium Pharma
Newtown, PA

Additional Responsibilities:

- Hired Brand Manager to support Prestium Brands and sales force
- Hired Product Manager to support IMS data, market analysis and Trade show support
- Worked with finance to prepare annual forecast, budget, LE and Strat Plan
- Managed Care analysis and support
- Transition of newly acquired brands (Zonalon, Prudoxin, Erygel, Phenergan) and generics (Lithium Capsules, Prednisone Tablets)
- Managed AG launches (Doxepin Cream, Naftifine Cream, Erythromycin Gel, Promethazine Suppositories)
- Support of sterile pipeline projects
- Preparation and transfer of data and knowledge for acquisition

Results: Net sales grew to \$161M in 2015 and company was acquired by Mylan

Marketing Manager (June 2013 – March 2015)
Renaissance Pharma & Prestium Pharma
Newtown, PA

Responsibilities:

- 3PL setup
- Customer setup including contract review (Prestium and Renaissance)
- Transition of products acquired from GSK into Prestium labeler code
- Creation of labeling and launch communication
- Working with Pricing compendia to establish WAC
- Customer pricing and offer letters
- AG launch to establish Renaissance labeler
- Managing customer service and supporting customer needs
- Managing 3rd party indirect pricing including chargebacks and reporting
- Managing government pricing via 3PL
- Creation of marketing programs, sales materials and sales force support
- IMS data analysis and reporting
- Forecasting and supply management
- Trade show management and support
- Website creation, transition and support

Results: Net sales grew from \$16.6M prior to 2013, to \$119M in 2014

Sr. Product Manager (December 2012 – June 2013)
Teva Pharmaceuticals USA
North Wales, PA

Responsibilities:

- Increased responsibilities as well as project involvement

Projects:

- Inventory Optimization Initiative (Commercial Operations representative)
 - Understand and optimize inventory across the E2E supply chain while maintaining and improving required service levels
 - Reduce inventory-related expense (write-off, warehousing cost and capital requests, insurance, etc)
- Forecasting Initiative (Project Spring)

- Revamp forecasting process at Teva with a goal to reach 70% accuracy
- Streamlining
 - Decrease complexity of the portfolio through obsolescence of unnecessary counts
 - Reduce waste by decreasing batch size or splitting a batch across several presentations
 - Introduce counts that put Teva inline with competition and if possible introduce counts that give Teva an advantage over competition

Product Manager (October 2010 – December 2012)

Teva Pharmaceuticals USA

North Wales, PA

Responsibilities:

- Management, analysis and review of inline product portfolio, brand generic competitors and similar markets to ensure a strong portfolio
- Management, analysis of market activities and NAM support around New Business Opportunities, Awards and Losses
- Product Supply Allocation (supply constraint)
- Supporting targeted market opportunities (Upside, Strategic, and Competitive safety stock)
- Working closely with QA, Market Planners, Plant Managers, Warehouse Management, Customer Service, Regulatory Affairs, Marketing and GPNO to ensure smooth transition during product transfers and customer transitions
- Portfolio analysis with the goal of product improvement (Proper count, label, medication guide, packaging etc.)
- Forecast analysis and recommendations to Demand Planning (annual workplan)
- Creation and support of exit strategies around product deletion/unavailability
- Marketing voice within Supply chain, Quality, Regulatory
- Analysis and presentation of IMS data

Projects:

- Budesonide Samples launch
- Warfarin Tablets Launch (alternate formulation)
- SMX/TMP Tablets & Sertraline Tablets relaunch

Clinical Research Scientist (August 2008 – July 2010)

Teva Pharmaceuticals USA

North Wales, PA

Medical Affairs Associate (July 2006 – August 2008)

Teva Pharmaceuticals USA

North Wales, PA

EDUCATION

- | | |
|-----------|---|
| 2009-2012 | MBA with a certificate in Public Health
Keller Graduate School of Management, DeVry University |
| 2000-2006 | Doctor of Pharmacy
Temple University School of Pharmacy
Philadelphia, Pennsylvania |

ACHIEVEMENTS & AFFILIATIONS

- Registered Pharmacist in the State of Pennsylvania
- Fluent in Polish, spoken and written

References available upon request

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RISING PHARMA HOLDINGS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF SEPTEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RISING PHARMA HOLDINGS, INC." WAS INCORPORATED ON THE FIRST DAY OF MARCH, A.D. 2019.



7304068 8300

SR# 20206925923

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JB", written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed in a small font.

Authentication: 203551787

Date: 09-02-20

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Time-Cap Laboratories, Inc.

Physical Address: 2600 Spagnoli Rd

City: Melville State: NY Zip Code: 11747

Telephone Number: 631-753-9090 Fax Number: 631-753-2220

Toll Free Number: _____

E-mail: akhandaker@timecaplabs.com Website: www.timecaplabs.com

Facility Manager: Anm Khandaker

Professional qualifications and experience of facility manager: see attached

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: OTC, dietary supplements

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☒ No ☐

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Time-Cap Laboratories, Inc.

Address: 7 Michael Ave, Farmingdale, NY 11735

Name: Marksons Pharma Inc, 11th Floor Grandeur,

Address: Opp. Gunderha Symphony, Veera Desai Extension Rd
Oshiwara, Andheri (W) Mumbai, India 500 0053

Name: _____

Address: _____

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

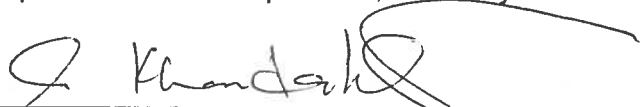
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Anm Khandaker
Print Name of Authorized Person

05/13/2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: New York
 Parent Company if any: Marksans Pharma Inc
 Corporation Name: Time-Cap Laboratories, Inc
 Mailing Address: 7 Michael Ave
 City: Farmingdale State: NY Zip: 11735
 Telephone: 631-753-9090 Fax: 631-753-2220
 Contact Person: Joanne Whelan

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: Marksans Pharma Inc
 Registration number issued: 4678821
 Stock Exchange: India Stock Exchange

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: n/a

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Mark I. Sedar

From: Anm Khandake n>
Sent: Tuesday, August 11, 2020 1:16 PM
To: Mark I. Sedar
Subject: RE: Nevada Out-of-State Wholesaler application - Tim-Cap Laboratories, Inc.

Hello Mark,

The labeler code for TimeCap Labs, Inc. is **49483**.

Best Regards,

Anm Khandaker
Director of Quality Assurance



Time-Cap Labs, Inc.

Providing a Solid Dose of Innovation®
7 Michael Avenue | Farmingdale | New York | 11735
631-753-9090 ext 122 | 631-753-2220 (Fax)
akhandaker@timecaplabs.com

*Verified
8/11/20
MS*

From: Mark I. Sedar [<mailto:msedar@pharmacy.nv.gov>]
Sent: Tuesday, August 11, 2020 4:05 PM
To: Anm Khandaker
Subject: RE: Nevada Out-of-State Wholesaler application - Tim-Cap Laboratories, Inc.

Hi Anm,

One last piece of information I will need verification on as we finalize the review of your application. Can you please provide the labeler code?

Thank you,

Mark Sedar
Chief Operating Officer
Nevada State Board of
Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARED/SHARED.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDCC/OSP_SEARCHRESULTCFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDCC/OSP_SEARCHRESULTCFM)

LINKEDIN (HTTPS://WWW.LINKEDIN.COM/SHARE/ARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDCC/OSP_SEARCHRESULTCFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA)

PRINT (HTTPS://WWW.PRINTEREST.COM/PW/CREATE/BUTTON?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDCC/OSP_SEARCHRESULTCFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY)

±

EMAIL (MAILTO:SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDCC/OSP_SEARCHRESULTCFM)

PRINT

Current through June 24, 2020

You have searched Finished drug products

Search Results '49483'

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Display 50 records per page

Search for text in the table:

	Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+	ACETAMINOPHEN	49483-342-10	500 mg/1	TABLET FILM COATED	ORAL	part343	TIME CAP LABORATORIES INC	49483-342	ACETAMINOPHEN	ACETAMINOPHEN	HUMAN OTC DRUG	05/01/2012	N/A	OTC MONOGRAPH NOT FINAL	1000 TABLET FILM COATED in 1 BOTTLE PLASTIC (49483-342-10)
+	ACETAMINOPHEN	49483-341-01	500 mg/1	TABLET FILM COATED	ORAL	part343	TIME CAP LABS INC	49483-341	ACETAMINOPHEN	ACETAMINOPHEN	HUMAN OTC DRUG	07/18/2011	N/A	OTC MONOGRAPH NOT FINAL	100 TABLET FILM COATED in 1 BOTTLE PLASTIC (49483-341-01)
+	ACETAMINOPHEN	49483-342-00	500 mg/1	TABLET FILM COATED	ORAL	part343	TIME CAP LABORATORIES INC	49483-342	ACETAMINOPHEN	ACETAMINOPHEN	HUMAN OTC DRUG	05/01/2012	N/A	OTC MONOGRAPH NOT FINAL	100000 TABLET FILM COATED in 1 CARTON (49483-342-00)
+	ACETAMINOPHEN	49483-342-01	500 mg/1	TABLET FILM COATED	ORAL	part343	TIME CAP LABORATORIES INC	49483-342	ACETAMINOPHEN	ACETAMINOPHEN	HUMAN OTC DRUG	05/01/2012	N/A	OTC MONOGRAPH NOT FINAL	100 TABLET FILM COATED in 1 BOTTLE PLASTIC (49483-342-01)
+	ACETAMINOPHEN	49483-340-01	325 mg/1	TABLET	ORAL	part343	TIME CAP LABS INC	49483-340	ACETAMINOPHEN	ACETAMINOPHEN	HUMAN OTC DRUG	12/15/2011	N/A	OTC MONOGRAPH NOT FINAL	100 TABLET in 1 BOTTLE PLASTIC (49483-340-01)
+	ACETAMINOPHEN	49483-252-01	500 mg/1	TABLET	ORAL	part343	TIME CAP LABORATORIES INC	49483-252	ACETAMINOPHEN	ACETAMINOPHEN	HUMAN OTC DRUG	07/12/2011	N/A	OTC MONOGRAPH NOT FINAL	100 TABLET in 1 BOTTLE PLASTIC (49483-252-01)
+	Aller	49483-343-44	200 mg/1	TABLET FILM COATED	ORAL	part340	Time Cap Labs Inc	49483-343	Caffeine	CAFFEINE	HUMAN OTC DRUG	11/30/2011	N/A	OTC MONOGRAPH FINAL	40 TABLET FILM COATED in 1 BOTTLE (49483-343-44)
+	ALLER-G-TIME	49483-061-10	25 mg/1	TABLET FILM COATED	ORAL	part341	TIME CAP LABORATORIES INC	49483-061	DIPHENHYDRAMINE HYDROCHLORIDE	DIPHENHYDRAMINE HYDROCHLORIDE	HUMAN OTC DRUG	05/01/2012	N/A	OTC MONOGRAPH FINAL	1000 TABLET FILM COATED in 1 BOTTLE PLASTIC (49483-061-10)
+	ALLER-G-TIME	49483-061-01	25 mg/1	TABLET FILM COATED	ORAL	part341	TIME CAP LABORATORIES INC	49483-061	DIPHENHYDRAMINE HYDROCHLORIDE	DIPHENHYDRAMINE HYDROCHLORIDE	HUMAN OTC DRUG	05/01/2012	N/A	OTC MONOGRAPH FINAL	100 TABLET FILM COATED in 1 BOTTLE PLASTIC (49483-061-01)
+	Allergy Time	49483-242-01	4 mg/1	TABLET	ORAL	part341	Time Cap Labs Inc	49483-242	Chlorpheniramine Maleate	CHLORPHENIRAMINE MALEATE	HUMAN OTC DRUG	02/08/2011	N/A	OTC MONOGRAPH FINAL	100 TABLET in 1 BOTTLE PLASTIC (49483-242-01)
+	Allergy Time	49483-242-10	4 mg/1	TABLET	ORAL	part341	Time Cap Labs Inc	49483-242	Chlorpheniramine Maleate	CHLORPHENIRAMINE MALEATE	HUMAN OTC DRUG	02/08/2011	N/A	OTC MONOGRAPH FINAL	1000 TABLET in 1 BOTTLE PLASTIC (49483-242-10)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ EXTRA PAIN RELIEF	49483-370-20	250 mg/1, 250 mg/1, 65 mg/1	TABLET, FILM COATED	ORAL	part343	TIME CAP LABS	49483-370	ACETAMINOPHEN, ASPIRIN AND CAFFEINE	ACETAMINOPHEN, ASPIRIN, CAFFEINE	HUMAN OTC DRUG	11/01/2013	N/A	OTC MONOGRAPH NOT FINAL	200 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (49483-370-20)
+ GABAPENTIN	49483-605-01	100 mg/1	CAPSULE	ORAL	ANDA090007	TIME CAP LABORATORIES, INC	49483-605	GABAPENTIN	GABAPENTIN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	100 CAPSULE in 1 BOTTLE (49483-605-01)
+ GABAPENTIN	49483-605-50	100 mg/1	CAPSULE	ORAL	ANDA090007	TIME CAP LABORATORIES, INC	49483-605	GABAPENTIN	GABAPENTIN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	500 CAPSULE in 1 BOTTLE (49483-605-50)
+ GABAPENTIN	49483-606-01	300 mg/1	CAPSULE	ORAL	ANDA090007	TIME CAP LABORATORIES, INC	49483-606	GABAPENTIN	GABAPENTIN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	100 CAPSULE in 1 BOTTLE (49483-606-01)
+ GABAPENTIN	49483-606-50	300 mg/1	CAPSULE	ORAL	ANDA090007	TIME CAP LABORATORIES, INC	49483-606	GABAPENTIN	GABAPENTIN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	500 CAPSULE in 1 BOTTLE (49483-606-50)
+ GABAPENTIN	49483-607-01	400 mg/1	CAPSULE	ORAL	ANDA090007	TIME CAP LABORATORIES, INC	49483-607	GABAPENTIN	GABAPENTIN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	100 CAPSULE in 1 BOTTLE (49483-607-01)
+ GABAPENTIN	49483-607-50	400 mg/1	CAPSULE	ORAL	ANDA090007	TIME CAP LABORATORIES, INC	49483-607	GABAPENTIN	GABAPENTIN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	500 CAPSULE in 1 BOTTLE (49483-607-50)
+ IBUPROFEN	49483-601-10	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091239	TIME CAP LABORATORIES, INC	49483-601	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	03/22/2016	N/A	ANDA	1000 TABLET, FILM COATED in 1 BOTTLE (49483-601-10)
+ IBUPROFEN	49483-603-01	600 mg/1	TABLET, FILM COATED	ORAL	ANDA090796	TIME CAP LABORATORIES, INC	49483-603	IBUPROFEN	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	100 TABLET, FILM COATED in 1 BOTTLE (49483-603-01)
+ IBUPROFEN	49483-612-05	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091237	TIME CAP LABORATORIES, INC	49483-612	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	11/16/2016	N/A	ANDA	50 TABLET, FILM COATED in 1 BOTTLE (49483-612-05)
+ IBUPROFEN	49483-600-01	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091239	TIME CAP LABORATORIES, INC	49483-600	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	03/22/2016	N/A	ANDA	100 TABLET, FILM COATED in 1 BOTTLE (49483-600-01)
+ IBUPROFEN	49483-602-01	400 mg/1	TABLET, FILM COATED	ORAL	ANDA090796	TIME CAP LABORATORIES, INC	49483-602	IBUPROFEN	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	100 TABLET, FILM COATED in 1 BOTTLE (49483-602-01)
+ IBUPROFEN	49483-602-50	400 mg/1	TABLET, FILM COATED	ORAL	ANDA090796	TIME CAP LABORATORIES, INC	49483-602	IBUPROFEN	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	500 TABLET, FILM COATED in 1 BOTTLE (49483-602-50)
+ IBUPROFEN	49483-600-50	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091239	TIME CAP LABORATORIES, INC	49483-600	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	03/22/2016	N/A	ANDA	500 TABLET, FILM COATED in 1 BOTTLE (49483-600-50)
+ IBUPROFEN	49483-603-03	600 mg/1	TABLET, FILM COATED	ORAL	ANDA090796	TIME CAP LABORATORIES, INC	49483-603	IBUPROFEN	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	30 TABLET, FILM COATED in 1 BOTTLE (49483-603-03)
+ IBUPROFEN	49483-604-05	800 mg/1	TABLET, FILM COATED	ORAL	ANDA090796	TIME CAP LABORATORIES, INC	49483-604	IBUPROFEN	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	50 TABLET, FILM COATED in 1 BOTTLE (49483-604-05)
+ IBUPROFEN	49483-611-00	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091237	TIME CAP LABORATORIES, INC	49483-611	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	11/16/2016	N/A	ANDA	6500 TABLET, FILM COATED in 1 BAG (49483-611-00)
+ IBUPROFEN	49483-611-01	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091237	TIME CAP LABORATORIES, INC	49483-611	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	11/16/2016	N/A	ANDA	100 TABLET, FILM COATED in 1 BOTTLE (49483-611-01)
+ IBUPROFEN	49483-601-00	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091239	TIME CAP LABORATORIES, INC	49483-601	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	03/22/2016	N/A	ANDA	6500 TABLET, FILM COATED in 1 BAG (49483-601-00)
+ IBUPROFEN	49483-601-50	200 mg/1	TABLET, FILM COATED	ORAL	ANDA091239	TIME CAP LABORATORIES, INC	49483-601	IBUPROFEN	IBUPROFEN	HUMAN OTC DRUG	03/22/2016	N/A	ANDA	500 TABLET, FILM COATED in 1 BOTTLE (49483-601-50)
+ IBUPROFEN	49483-603-05	600 mg/1	TABLET, FILM COATED	ORAL	ANDA090796	TIME CAP LABORATORIES, INC	49483-603	IBUPROFEN	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/30/2015	N/A	ANDA	50 TABLET, FILM COATED in 1 BOTTLE (49483-603-05)

Showing 1 to 50 of 133 entries

Previous 1 2 3 Next

[Background Information \(https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm\)](https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV
(mailto:DRUGINFO@FDA.HHS.Gov)

See also: [Drug Registration and Listing Instructions \(https://www.fda.gov/Drugs\)](https://www.fda.gov/Drugs)



Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

RE: Out-of-State Wholesaler Application

Officers:

Mark Saldanha, Chief Executive Officer:
7 Michael Avenue, Farmingdale, NY 11735

James Carroll, Chief Financial Officer:
7 Michael Avenue, Farmingdale, NY 11735

Please note; the New York State Board of Pharmacy will not verify licenses upon request. Online verification is available; please see attached letter from the Board and a copy of the verification search.

If you have any questions, please contact me at 631-753-9090 ext. 123 or at jwhelan@timecaplabs.com.

Sincerely,

A handwritten signature in cursive script that reads 'Joanne Whelan'.

Joanne Whelan
Regulatory Affairs Associate

Page 1 of 1

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

NAME OF SUPERVISOR
ANM KHANDAKER



2020-23

THIS IS TO CERTIFY

TIME-CAP LABORATORIES, INC.
260 SPAGNOLI RD.
MELVILLE, NY 11747

is duly recorded as a

REGISTERED WHOLESALER
OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE THIRTIETH DAY OF APRIL, 2020.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF MARCH, 2023.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

037860



Kimberly A. Leonard
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

Send to State Board of Pharmacy for Completion: A separate letter is acceptable.
Do not return with application unless it has been completed by the licensing agency.

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

LICENSE VERIFICATION

Name: <u>Time - Cap Laboratories, Inc</u>			
Address: <u>see attached</u>			
City: _____	State: _____	Zip: _____	
I hereby authorize the _____ to furnish to the Nevada State Board of Pharmacy, the information requested below.			
Signature of Applicant _____			

**THIS FORM MUST BE FORWARDED TO THE HOME STATE
LICENSING AGENCY FOR COMPLETION. DO NOT WRITE BELOW THIS LINE**

License Number	License Status	Date License Issued	Date License Expires

Has this license been encumbered in any way? <input type="checkbox"/> Yes <input type="checkbox"/> No	Type of Encumbrance: (if any) <input type="checkbox"/> Revoked <input type="checkbox"/> Surrendered <input type="checkbox"/> Limited <input type="checkbox"/> Suspended <input type="checkbox"/> Restricted <input type="checkbox"/> Probation Please attach copies of any pertinent legal documents
--	---

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain) <input type="checkbox"/> Yes <input type="checkbox"/> No				
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain) <input type="checkbox"/> Yes <input type="checkbox"/> No				
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain) <input type="checkbox"/> Yes <input type="checkbox"/> No				
Has applicant met all licensing requirements of your state? (If no, please explain) <input type="checkbox"/> Yes <input type="checkbox"/> No				
Signature of State Official	Title	State	Date	State Seal



Office of the Professions

Verification Searches

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

Pharmacy Establishment Information *

05/01/2020

Type : WHOLESALER

Legal Name : TIME-CAP LABORATORIES, INC.

Trade Name :

Street Address :

260 SPAGNOLI RD.

MELVILLE, NY 11747-0000

Registration No : 037860

Date First Registered : 04/30/20

Registration Begins : 04/30/20

Registered through : 03/31/23

Supervisor : KHANDAKER ANM

Establishment [Status](#) : ACTIVE

Successor : NONE

* Use of this online verification service signifies that you have read and agree to the [terms and conditions of use](#). See [HELP glossary](#) for further explanations of terms used on this page.

- Use your browser's back key to return to establishment list.
- You may [search](#) to see if there has been recent disciplinary action against this registered establishment.



Ann Khandaker
Avenue
Jamaica, NY
Email: ahoo.com
Cell:

CAREER PROFILE & ACHIEVMENT

Results oriented professional with skills in quality, compliance, regulatory affairs, and cGMP training fields. Have extensive experience in leading & guiding the team involved in the initial set up of cGMP systems & controls for newly built companies in the recent years. Excellent academic & pharmaceutical regulatory background and project management skills. Dependable leadership, communication, organizational, and motivational skills. Demonstrated outstanding leadership in the teams involved in revamping the quality systems, controls and salvaging companies from FDA 483 & warning letters and other regulatory burdens.

CAREER OVERVIEW

DIRECTOR OF QA, Time-Cap Labs, Inc., Farmingdale, NY 04/2019 - to Present

- Planning, developing, and coordinating the activities of the QA/RA/QC departments and assisting COO to achieve production and other company objectives.
- Leading the QA, RA, & QC units to establish and implement the initial set up of GMP systems & controls for compliance with FDA requirements and 3rd party certification.
- Planning & implementation of the facility, equipment, and process qualifications activities.
- Develop, review & approval of policies, procedures, protocols, report, BMRs, BPRs, & labeling, etc. as required for compliance with all regulatory requirements & marketing requirements.
- Manage the day-to-day compliance of the facility, operations and oversee all functions related to manufacturing, packaging, document control, SOPs, change control, internal audits and vendor qualification.
- Review client Quality Control requirements and ensure that Quality Control documentation for the project meets contractual requirements.
- Responsible for licensing, registration, renewal and certification by appropriate regulatory agencies and certification bodies.
- Liaison with the FDA and customers on all technical matters like product recall, complaints and hosting the FDA & other regulatory audits.
- Handling of product complaints with documentation, investigation, and response to customers accordingly.
- Responsible for approving or rejecting all procedures or specifications impacting identity, strength, quality, and/or purity of materials and products manufactured and packaged at AHF.
- Responsible for review and approval or rejection of incoming components, packaging, and labeling materials for use in the manufacturing and packaging.
- Ensure timely & adequate QA/QC coverage in the manufacturing, packaging, testing, and release of products for distribution.
- Train & groom personnel on the cGMP, safety, HACCP, specific job functions & team building in order to meet company objectives.

DIRECTOR OF QA & RA, American Health Formulations, Inc., Hauppauge, NY 11/2018 - to April 2019

- Planning, developing, and coordinating the activities of the QA/RA/QC departments and assisting COO to achieve production and other company objectives.
- Leading the QA, RA, & QC units to establish and implement the initial set up of GMP systems & controls for compliance with FDA requirements and 3rd party certification.
- Planning & implementation of the facility, equipment, and process qualifications activities.
- Develop, review & approval of policies, procedures, protocols, report, BMRs, BPRs, & labeling, etc. as required for compliance with all regulatory requirements & marketing requirements.

- Manage the day-to-day compliance of the facility, operations and oversee all functions related to manufacturing, packaging, document control, SOPs, change control, internal audits and vendor qualification.
- Review client Quality Control requirements and ensure that Quality Control documentation for the project meets contractual requirements.
- Responsible for licensing, registration, renewal and certification by appropriate regulatory agencies and certification bodies.
- Liaison with the FDA and customers on all technical matters like product recall, complaints and hosting the FDA & other regulatory audits.
- Handling of product complaints with documentation, investigation, and response to customers accordingly.
- Responsible for approving or rejecting all procedures or specifications impacting identity, strength, quality, and/or purity of materials and products manufactured and packaged at AHF.
- Responsible for review and approval or rejection of incoming components, packaging, and labeling materials for use in the manufacturing and packaging.
- Ensure timely & adequate QA/QC coverage in the manufacturing, packaging, testing, and release of products for distribution.
- Train & groom personnel on the cGMP, safety, HACCP, specific job functions & team building in order to meet company objectives.

REGULATORY AFFAIRS PROJECT MANAGER, Altaire Pharmaceuticals, Inc. Riverhead, NY 07/2018 – 11/2018

- Assisted General Counsel in the development and planning of regulatory strategies and led the implementation of those strategies to deliver agreed product registration milestones to support the business in a timely and effective manner.
- Independently performed and managed day-to-day product registration operations and ensured timely completion of the registration tasks assigned, in compliance with local applicable laws, regulations, guidelines, and policies and SOPs.
- Drafted product registration strategy plan for review and approval.
- Compiled registration eCTD dossier and prepare other regulatory documents and ensured timely regulatory submission upon review and approval by General Counsel.
- Coordinated internal departments in product registration process.
- Communicated with regulatory agencies/institutes on product registration.
- Timely /closely monitored regulations and reviewed processes for ensuring the data presented fully represented what is practically required and the constantly changing regulations to be followed.
- Met and accelerated Regulatory milestones.
- Properly maintained all regulatory documentation
- Other projects assigned by General Counsel.

DIRECTOR, QA&RA, Spirit Pharmaceuticals LLC, Ronkonkoma, NY

09/2016 – 06/2018

- Lead the development, implementation, and maintenance of the company's quality and regulatory compliance management systems & operational strategies in alignment with business objectives and capacity in compliance with cGMPs, regulatory agencies and corporate expectations.
- Streamlined process for waste reduction & increase productivity.
- Provided the leadership and guidance on taking quality decisions poised with the business requirements in times of need.
- Involved in planning, developing, and coordinating the activities of the QA/RA department.
- Directed and managed the QA/RA personnel to develop quality policy, procedures/protocols/documents, etc. and prioritized work flow to maximize efficiency.
- Assured facility, equipment & process qualification (IQ, OQ & PQ, temperature mapping, etc.).
- Managed & guided the vendor/supplier qualification program.
- Daily communication & coordination with the vendors/suppliers/distributors/retailers (packaging, labeling, testing & bulk drug products) located in the USA, China, & India.
- Routinely monitored/scheduled third party GMP & social audits (UL, InterTek, Bureau Veritas, NSF, etc.) of supplier facilities located overseas and guided them for preparation of an adequate & compliant response.

- Hosted successful FDA & other regulatory & 3rd party audits at Spirit and prepared responses appropriately.
- Communicated with the FDA & state agencies on various regulatory issues.
- Handled & coordinated product recall activities efficiently.
- Reviewed & approved SOPs, Protocols, reports, BPR/controlled documents, etc. and any amendments to the established procedures.
- Ensured that the procedures specified are followed, assessed and documented the impact of any deviations from the established procedures and to devise appropriate corrective action when necessary; acknowledged deviations from BPRs, SOPs, & protocols etc.
- Ensured timely completion & documentation of all required investigation reports for OOS, deviations, as well as product market complaints etc. at firm & to coordinate with all applicable departments regarding them.
- Handled & ensured investigation & reporting of product complaints, returned goods, OOS, Deviation & Incidents in a timely manner in collaboration & coordination with Spirit Operations & manufacturers/suppliers.
- Ensured that all QA/RA department personnel are well trained to perform their jobs effectively and other administrative functions to ensure an efficient operation that are cost effective & well integrated.
- Prepared, reviewed, & approved regulatory, compliance, CMC documents & labeling/artworks for FDA registration, drug listing & new marketing opportunities.
- Guided new business partners on the regulatory requirements for marketing drugs, dietary supplements, and medical device marketing registration & listing requirements.
- Fostered team environment and facilitate the building of positive, productive relationships for achieving company goals.
- Conducts QA internal audits in order to identify possible gaps & pitfalls for compliance & continuous improvement. Also, conducts periodic reviews of the products & processes to ensure & meet cGMP & OSHA requirements via conducting QRB meeting.
- Assured compliance with all applicable local, state & federal regulations, quality & regulatory standards & other applicable customer's requirements.
- Performed other projects as need by the corporate management.

DIRECTOR, QA & RA, PolyGen Pharmaceuticals, Inc., Edgewood, NY
ASSOCIATE DIRECTOR, QA & RA, PolyGen Pharmaceutical, LLC.,

01/02/16 – 08/2016
04/09/14 – 12/2015

- Involved in planning, budgeting, and coordinating the activities of QA/RA departments. Managed the QA/RA groups to establish and maintain the quality systems & controls, policies, and procedures in order to comply with the cGMP & other local, state, & federal regulations.
- Planned & executed regulatory strategy for licensing, registration and regulatory submissions for ANDAs.
- Coordinated the compilation, review, and submission process for ANDA's, subsequent amendments, including SPL/PLR (labeling), and related CR letters & responses, all interactions and communications with the FDA from product inception to approval, including regulatory support during Pre-Approval Inspections for assigned projects.
- Reviewed and approved SOPs, specifications, protocols, reports, BMRs/BPRs and other GMP documents for accuracy, completeness and compliance.
- Ensured procedures are followed, assessed, and documented the impact of any deviations from the established procedures and took appropriate corrective action based on routine inspection, review, and audits.
- Ensured timely completion & documentation of activities related to CC, OOS, OOT, deviations, product complaints, etc. and related CAPA activities on a timely basis.
- Ensured cGMP, OSHA and other regulatory trainings are conducted for all related personnel in a timely fashion.
- Conducted QA internal audits to identify risks and gaps in the quality systems & controls.
- Ensured OSHA, EPA, and other agency regulations are enforced in the company.
- Coordinated all licensing, registration and reporting activities related to procurement, storage, handling and distribution of controlled drug substances (DEA). Routine inspection & review of BPRs, logs, inventories & DEA cage & bolts.
- Ensured compliance with all applicable local, state & federal regulations, quality & regulatory standards & other applicable customer requirements.
- Other projects as assigned by the corporate management.

MANAGER OF REGULATORY AFFAIRS, Contract Pharmacal Corporation, Hauppauge, NY 10/2010 – 03/2014

- Managed states & federal licensing, certification, and registration activities such as state board of pharmacies, FDA/FEI registration, FSC, CPP, Medical device, USDA - import/export, organic certifications & maintaining program, etc.
- DEA registration, renewals and worked with operations for procurements, storage, inventory, distribution & destruction of controlled substances & listed chemicals. Prepared & submitted ARCOS & yearend reports. Routine inspection & review of logs, inventories & DEA cage & bolts.
- Prepared, reviewed, and approved product labeling and printed components (labeling, medication guide, inserts & IFCs) for compliance with 21 CFR parts 101 & 201 as well as customer requirements.
- Managed supplier qualification programs.
- Prepared, reviewed, and approved the annual product review (APR) reports and process validation reports using statistical charts and graphs.
- Coordinated customer and regulatory agency audits.
- Investigated and responded to customer queries on product formulation, packaging, allergens and drug/supplemental/nutritional facts.
- Prepared, reviewed, and approved CMC documentation and Dossiers for local and international product registration and submissions.

DIRECTOR OF QUALITY ASSURANCE, Contract Pharmacal Corporation, Hauppauge, NY 08/2008 – 10/2010

- Developed and managed SOPs, protocols, quality agreements and other related documentation systems.
- Initiated, reviewed/managed documents and reports related to deviation and OOS investigation, product complaints, change controls and related CAPA activities.
- Reviewed and approved formulation records and finished product specification and ingredient listings.
- Developed and managed corporate training matrix for new employees in light of cGMP, safety and other related FDA, OSHA & DEA regulations.
- Performed quality audits on CMC documents of ANDA & other marketing registration with emphasis on data verification, source document accuracy, and clear messaging within and between documents.
- Ensured all quality-based deliverables complied with regulatory and quality policies and procedures and timelines are met and observations are corrected.
- Conducted internal & external audits.

QA DOCUMENT CONTROL MANAGER, Forest Laboratories, Inc. (Currently Allergan), NY 01/2007 – 08/2008

- Managed SOPs, master batch records, deviation/investigation reports, test methods, specifications, protocols, reports & forms using EDMS.
- Conducted complaint investigation, prepared APRs, and managed change controls and CAPA activities.

SUPERVISOR OF QA, Forest Laboratories, Inc. (Currently Allergan), NY 02/1995 – 12/2006

- Supervised QA Associates & Technicians for accomplishing daily QA activities in the manufacturing and packaging operations & ensured timely inspection, sampling, line clearance, review and release of finished product batches for packaging and distribution including CS.
- Reviewed and approved IND/stability/bio batches for R&D clinical packaging and regulatory submissions.
- Assisted regulatory group for compilation of CMC data & assisted in the preparation of site master validation plan, technical agreement and site DMF.
- Prepared, reviewed, and approved process & cleaning validation protocols and reports.
- Involved in the IQ, OQ & PQ of the newly procured manufacturing equipment, facilities, & QA inspection devices. Audited equipment calibration, qualification, & preventive maintenance programs.
- Prepared, reviewed, and revised SOPs. Conducted deviation investigation, customer product complaint investigations using the TrackWise Quality Management software.
- Assisted head of QA in registration and reporting activities related to procurement, storage, handling and distribution of controlled drug substances. Routine inspection & review of related BPRs, logs, inventories, DEA cage & bolts.

- Initiated, coordinated, and documented change control and CAPA activities.
- Conducted internal and external/vendor audits for compliance with the cGMPs.
- Involved in the teams established for FDA, PAI, EIR inspections, product recalls, and field alert activities.
- Prepared, reviewed, and approved the annual product review reports using statgraphics software.
- Conducted cGMP training for QA/QC, PR&D and Production personnel.
- Coordination of online GMP training programs sponsored by FDA & Eduneering, Inc.
- Represented QA department in the cross-functional meetings and projects.

QUALITY ASSURANCE ASSOCIATE, Forest Laboratories, Inc. (Currently Allergan), NY 03/1993 – 02/1995

Inspected and sampled incoming raw materials for QC testing. Performed QA line clearance & in-process inspection of manufacturing operation. Performed USP & Potable water systems, Compressed air systems, and environmental air sampling. Monitoring temperature/humidity in the manufacturing & stability rooms. Calibration of temp/humidity recorders, thickness gauges, hardness testers, and calipers. Monitored air-pressure differential in the manufacturing rooms. Reviewed and released batch records. Reviewed and released the IND/NDA/ANDA batches clinical packaging and regulatory submissions. Prepared & revised SOPs, deviation investigation reports and other procedures for compliance with cGMPs.

QUALITY ASSURANCE ASSOCIATE, Interpharm (Currently Amneal), Plainview, NY 08/1990 – 03/1993

Reviewed & released manufacturing batch records. Conducted line clearances prior to start of manufacturing & packaging operations. Reviewed executed batch records, packaging worksheets for accuracy and completeness, and released for distribution. Sampled raw materials and packaging components for QC testing and release. Conducted physical analysis of the in-process blends/granules and finished products using moisture analyzer, friabilator, disintegration apparatus, and bulk/tap density analyzer. Archived and maintained executed manufacturing batch records and QC analytical reports. Maintained stability and retained samples.

EDUCATION & TRAINING

MS – Drug Regulatory Affairs, Long Island University, New York.

BS & MS - Government and Administration, Jahangir Nager University, Bangladesh.

Minor degree course works: Economics, Chemistry, Biology, Physics, Geography, & Statistics.

Attended training courses on Validation, Change control, stability testing, GMP for bulk pharmaceutical, Writing validation protocols, application of GMPs to Microbiological Laboratories, Risk Management, FDA 483, Preparing FDA PAI/EIR inspection, Drug Recalls, Computer system validation, Electronic Records & Signatures, Evaluating Raw Materials for the Development of Pharmaceutical Products, Advance Practices in Pharmaceutical Tableting, SPC, Validation by Design, Quality Management Skills organized by University of Wisconsin, FDA/Eduneering, PDA, PTI, LP Resources & GMP Institute.

Trained on EDMS, SPC, SAP, TrackWise, AlphaLan, Microsoft Word/Excel/Outlook/PowerPoint, etc.

State of New York

Department of State } ss:

I hereby certify, that the Certificate of Incorporation of TIME-CAP LABORATORIES, INC. was filed on 10/15/1979, with perpetual duration, and that a diligent examination has been made of the Corporate index for documents filed with this Department for a certificate, order, or record of a dissolution, and upon such examination, no such certificate, order or record has been found, and that so far as indicated by the records of this Department, such corporation is an existing corporation. I further certify the following:

A Biennial Statement was filed 04/06/1999.

A Biennial Statement was filed 11/09/1999.

A Biennial Statement was filed 09/27/2001.

A Biennial Statement was filed 10/28/2003.

A Biennial Statement was filed 12/29/2005.

A Biennial Statement was filed 10/15/2007.

A Biennial Statement was filed 10/09/2009.

A Biennial Statement was filed 10/25/2011.

A Biennial Statement was filed 10/11/2013.

A Biennial Statement was filed 10/02/2015.

A Biennial Statement was filed 10/13/2017.

A Biennial Statement was filed 03/11/2020.

I further certify that no other documents have been filed by such corporation.

(page 2) - TIME-CAP LABORATORIES, INC.



*WITNESS my hand and the official seal
of the Department of State at the City of
Albany, this 03rd day of April two
thousand and twenty.*

Brendan C. Hughes

*Brendan C Hughes
Executive Deputy Secretary of State*

VIGILANT INSURANCE COMPANY

License and Permit Bonds

Bond Adjustment Report

Date Generated:	07/01/2020	Bond Number:	K15341750
Field Office:	Home Office	Legacy Bond No:	82530463

Producer: IT4562
 HUB INTERNATIONAL NORTHEAST LIMITED
 55 WEST AMES COURT
 SUITE 400
 PLAINVIEW, NY 11803

Account Number: 037052099
 Account Name: TIME-CAP LABS INC.
 Principal: TIME CAP LABS, INC.
 7 MICHAEL AVENUE
 FARMINGDALE, New York, United States, 11735

Obligee: State of Nevada and to the Nevada State Board of Pharmacy
 985 Damonte Ranch Parkway
 Ste 206
 Reno, Nevada, United States, 89511

Class Code: 993
 Description: Pharmaceutical Wholesale Surety bond

Effective Date of Adjustment:	07/01/2020	Old Term Effective:	04/01/2020 - 04/01/2021
		NewTerm Effective:	04/01/2020 - 04/01/2021

	Old	Adjustment	NEW
Bond Amount:	\$100,000.00	\$0.00	\$100,000.00
Contract Price:	\$0.00	\$0.00	\$0.00
Premium Amount:	\$1,000.00	\$0.00	\$1,000.00
Premium Due:	\$0.00	Commission Due:	\$0.00
Surcharge:			
State:	\$0.00		
Municipal Tax:	\$0.00		
Total Premium Due Including Taxes And Surcharges:	\$0.00		

CHUBB Surety Service Center

CHUBB

Renewal Notice
VIGILANT INSURANCE COMPANY
License and Permit Bonds
 Report Of Execution

Assumed Reinsurance From:

Direct Writer Bond #:

Field Office: Home Office Bond Number: K15341750 Date Generated: 01/03/2020

Underwriter: Jane Bender Legacy Bond No: 82530463

Producer: IT4562 Billing Type: Producer Bill
 THE B&G GROUP INC
 55 WEST AMES COURT
 SUITE 400
 PLAINVIEW, NY 11803

SSC Branch: New York

Account Number: 037052099

Account Name: TIME-CAP LABS INC.

Principal: TIME CAP LABS, INC.
 7 MICHAEL AVENUE
 FARMINGDALE, New York, United States, 11735

Obligee: State of Nevada and to the Nevada State Board of Pharmacy
 431 W Plumb Lane
 Reno, Nevada, United States, 89509

Class Code: 993 Risk Location: NV

Type of Bond: License and Permit Bonds - All Other License And Permit Bonds

Description: Pharmaceutical Wholesale Surety bond

Bond Type Description	Bond Amount	Chubb Bond Amount
Non contract bond type	\$ 100,000.00	\$ 100,000.00

Effective Date: 04/01/2020 Expiration Date: 04/01/2021

Bond Type: Continuous

Renew Action: Renew

Cancellation Action: Non-Cancellable

Premium: \$1,000.00

Surcharge:
 State: \$0.00

Municipal Tax: \$0.00

Total Premium Including
 Taxes and Surcharges \$1,000.00



Chubb Producer Compensation Practices & Policies

Chubb believes that policyholders should have access to information about Chubb's practices and policies related to the payment of compensation to brokers and independent agents. You can obtain that information by accessing our website at <https://www2.chubb.com/us-en/agents-brokers/chubb-producer-compensation.aspx> or by calling the following toll-free telephone number:

1-866-512-2862.

4LL

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALE LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: QED Therapeutics, Inc.

Physical Address: 8000 Marina Blvd. #400

City: Brisbane State: CA Zip Code: 94005

Telephone Number: 650-231-4088 Fax Number: 650-529-4722

Toll Free Number: N/A

E-mail: Matt.outten@qedtx.com Website: www.qedtx.com

Facility Manager: Matthew D. Outten

Professional qualifications and experience of facility manager: See Attachment C

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Clinics

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA?
(If yes, provide a copy of your FDA registration)

Yes ☒ No ☐

See Attachment D

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attachment E

Address:

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Matthew D. Outten

Print Name of Authorized Person

9/4/2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: BridgeBio Pharma, LLC

Mailing Address: 8000 Marina Blvd. #400

City: Brisbane State: CA Zip: 94005

Telephone: 650-231-4088 Fax: 650-529-4722

Contact Person: Matthew D. Outten

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a)	BridgeBio Pharma, LLC, 421 Kipling Street, Palo Alto, CA 94301
	<div style="display: flex; justify-content: space-between;"> Name Business Address </div>

b) _____

Name	Business Address
------	------------------

c) _____
Name Business Address

d) _____
Name Business Address

- 2) Provide the number of shares issued by the corporation. 58,941,176
- 3) What was the price paid per share? \$3.00

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors See Attachment F

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment A

Attachment A**Delaware Certificate of Good Standing**

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "QED THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF SEPTEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.



6656546 8300

SR# 20207064092

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in blue ink, appearing to read "JBULLOCK", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 203579572

Date: 09-01-20

Attachment B**Regarding the Resident State License and Verification**

According to the resident state licensing agency, the California Department of Public Health (Department), a company that does not physically handle its prescription drugs is not required to hold a resident state manufacturer license. As a manufacturer that does not handle its product, QED Therapeutics, Inc. is not required to hold a resident state license. Enclosed please find confirmation from the Department regarding this policy. As such, a license verification form cannot be provided.

From: [Lauck, Susie E@CDPH](mailto:Lauck.Susie.E@CDPH)
To:
Subject: RE: Status of manufacturing license/exemption letter
Date: Wednesday, January 16, 2019 1:01:02 PM

Hi

Yes, you are correct.

I verified it with Dan Seid our Section Chief.

Confirms statement highlighted in yellow below.

Thank you,
 Susie Lauck
 Medical Device Safety Unit Analyst
 California Department of Public Health
 Food and Drug Branch
 1500 Capitol Ave MS 7602
 Sacramento, CA 95814
 Office 916.650.6604 | susie.lauck@cdph.ca.gov

From:
Sent: Monday, January 14, 2019 3:36 PM
To: Lauck, Susie E@CDPH <Susie.Lauck@cdph.ca.gov>
Subject: RE: Status of manufacturing license/exemption letter
Importance: High

I have sent an email to Daniel Seid for additional information but have not yet heard back from him. Pursuant to our conversation below perhaps you could obtain some additional clarity. Pursuant to his response in your email below and copied here for convenience, could you review my notes in red therein and provide a response?

True "virtual drug manufacturers" are not subject to CA Sherman Act licensing provisions which **[are]** administered by FDB. Furthermore, only those entities specified in law are "exempt" from licensure, and so no "exemption" letter will be issued to virtual drug firms, as they are not listed therein (HSC 111655).

If Virtual Manufacturers are not governed by the Sherman Act does that in turn mean they are (still not) required to hold a license? As you know, VMs have not been required to hold a license and would although they would apply for a Manufacturer's license, that application would be "rejected" and an Exemption Letter would be sent indicating that a license was not required because they did not physically manufacturer or store product on site.

Essentially, I am trying to confirm that the fact the Board will no longer issue Exemption Letters does not translate to mean Virtual Manufacturers are now required to have the actual Manufacturers license!

From everything I can gather both in the regulations and in the applications – everything still points to a license being required only of facilities that actually physically manufacturer the drug on site.

If you could provide clarity or ask Mr. Seid to advise on this issue, it would be greatly appreciated.

Attachment C**Facility Manager's Resume**

MATTHEW OUTTEN, MBA, MLA, CPC

Tiptoe Lane • Los Altos, CA 94024 • (540)

5 •

1@yahoo.com

COMMERCIAL EXECUTIVE

Highly-accomplished commercial executive specializing in Corporate Strategy / Marketing / Sales / and Market Access. Proven track record of successful product launches including the first FDA breakthrough designation. Strong history of driving oncology sales and gaining preferred market access coverage across all payers. This includes developing and implementing new sales/marketing programs, patient advocacy, creation of brand messaging, patient access programs, HUB operations, and product launch strategies. Integral member of the executive team conducting investor relations calls, and due diligence for mergers / acquisitions, and management of co-promotion efforts.

Core Competencies:

- Driving Sales Teams
- Market Access Strategy Development / Implementation
- New Product and Indication Launches
- In-Line Marketing Strategies
- Rebate & Pricing Structuring / Negotiations
- Patient Assistance Program Creation
- Strategic Alliances / Co-Promotions
- Specialty Pharmacy / Distributor Network Formation
- Mergers / Acquisitions / Due Diligence
- Investor Relations
- Brand Messaging/ NPP/ KOL Development
- Gross-to-Net Management
- P&L Accountability / Budget Administration
- Pipeline Strategy Development
- Personnel Recruitment / Management / Development
- Pharmacoeconomic Modeling

PROFESSIONAL EXPERIENCE

QED Therapeutics (A BridgeBio Company) – San Francisco, CA

July 2018- Present

Chief Commercial Officer

Responsible for all commercial activities including Market Access, Marketing, Trade, and Commercial Operations

PHARMACYCLICS (An AbbVie Company) – Sunnyvale, CA

March 2013-July 2018

Vice President of US Marketing and Market Access (2015-2018)

Responsible for US Hematology franchise with annual multi-billion dollar net sales. Lead US marketing, commercial operations, trade, managed markets, market research, and sales training for IMBRUVICA, a BTK inhibitor with nine FDA approvals in six indications (CLL, SLL, MCL, WM, MZL, cGvHd). This includes all pre and post launch activities including product distribution responsibility for managing third-party logistics provider relationships and ultimate responsibility for compliance with state and federal record keeping requirements. Oversee all US Marketing brand activities including P&L, speaker programs, KOL development, adherence, HCP, patient, and nursing in-line marketing activities. Manage 50 direct reports and administer a \$50MM+ budget.

Direct and execute strategies across marketing, commercial operations, and market access functions.

Selected accomplishments:

- Led the strategic market planning and launch for IMBRUVICA in previously treated MCL, del17pCLL, CLL, 2LMZL, WM, and cGvHd.
- Ran co-promote partnership (Janssen Biotech) to integrate US marketing teams and prepare for pipeline launches in FL, GvHd, and DLBCL.
- Launched new single tablet formulation including new packaging design and all pricing and contracting strategies.
- Led GPO, payer, federal, and state strategy including contracting execution.

Vice President of Market Access and Commercial Operations (2014-2015)

Created and drove commercial activities for the sale of Pharmacyclics to Abbvie. Continued to lead distribution, trade, pricing, contracting, SPP, SD, national accounts, reimbursement, patient assistance program, HUB, and federal markets. Responsibilities included overseeing distribution-related activities and ensuring that adequate processes were in place to comply with the various state and federal distribution record keeping requirements.

Selected accomplishments:

- Sole commercial executive to conduct merger discussions, perform due diligence, and lead Q&A sessions with 3rd parties, which led to company purchase for 21B (\$261 per share).
- Increased patient refill rates 10% per month for Imbruvica by devising and implementing an adherence program in conjunction with specialty pharmacies; highest grossing initiative to drive top-line performance in 2015.
- Led the ATO merger transition group, the Joint Commercial Committee, the Corporate Communications Review Committee, and the Compendia Strategy Committee.

Vice President Commercial Operations / Interim CCO (2014)

Led commercial division comprised of sales, marketing, and market access teams during launch of three new indications, (CLL2L+, CLLDel17p, and WM). Chosen to serve as Interim CCO and Company Officer, tasked with driving sales and marketing initiatives, meeting/ exceeding forecasts, and holding full P&L accountability for the commercial business unit. Managed and developed 100+ employees, and administered a \$100 million budget.

Owned strategy, tactics, and commercial development and distribution plans for all new potential indications. Represented commercial team and conducted quarterly investor earnings calls.

Selected accomplishments:

- Achieved the most successful hematology launch in history by devising innovative marketing campaigns and refocusing teams to a field support organization to drive sales and market share growth.

Continued...

MATTHEW OUTTEN, MBA, MLA, CPC

Page Two

- Led the strategic marketing planning and launch of the 2nd, 3rd, and 4th indications for IMBRUVICA in R/R CLL, WM, and CLL Del17p.
- Lowered attrition rate of commercial team from 15% to zero by creating a new incentive compensation plan structure.
- Selected as a member of the Executive Committee, charged with establishing commercial strategy for entire company.
- Chosen to serve as a member of the Joint Executive team with co-promotion partner.
- Played a key role on launch and investor calls to present product information and company strategy; presented all Board of Directors' meetings.

Executive Director Market Access/ Senior Director Market Access (2013)

Initially recruited to build market access team, create market access strategies, and develop innovative programs to ensure patient's ability to receive live-saving Hematology medication. Determined US launch price and pricing strategy for Imbruvica and created new and first-ever limited distribution platform in Hematology. Promoted within 8 months to Executive Director focused on formulating strategic plans to achieve higher Gross-to-Net margins, and expand the team. Built market access team including managed care, distribution, trade, and federal personnel. Handled contract negotiations for specialty pharmacies, specialty distributors, GPOs, and payer contracts.

Selected accomplishments:

- Saved company \$40 million in first year of product launch by devising innovative contracting strategies versus industry standard contracts.
- Instrumental in team earning 1st tier ranking by customers in Oncology Reimbursement Management survey across all metrics; first time in history of the survey a new company had achieved a first-tier ranking.
- Garnered 99% coverage for all indications and secured the first-ever agreement with the VA/DoD for a non-US sourced product, which resulted in a five year sole-source agreement.
- Achieved first-ever positive OIG ruling for new patient start program by building unique patient access program providing 30-day supply for individuals with insurance delays.

MILLENNIUM PHARMACEUTICALS – Cambridge, MA

July 2008-February 2013

Director - Managed Markets and Payer Marketing (2010-2013)

Hand-selected to construct and implement US commercial and federal payer strategy for buy and bill multiple myeloma product, including contracting strategy, messaging development and pull-through tactics. Supervised, evaluated, and developed National / Federal Account Managers, US Strategy, GPO and Reimbursement Managers.

Selected accomplishments:

- Won first-ever, exclusive hematology coverage for first-line formulary status versus competitor at several large regional plans by modifying focus from efficacy messaging to pharmacoeconomic modeling in collaboration with HEOR.
- Reduced denials below 5% within 3 months by creating national plan to improve uptake of newly launched Velcade SubQ product.

Associate Director Reimbursement Strategy and Marketing (2008-2010)

Recruited due to market access strategy, buy and bill, Medicare expertise, and payer marketing acumen to devise and execute US reimbursement strategy for Multiple Myeloma for Medicare, Commercial, and Medicaid channels. Constructed marketing pieces for payers, hospitals, federal government, and physicians, in addition to field-based pieces focused on patient out-of-pocket expenses.

Selected accomplishments:

- Revitalized an aging product and improved stakeholder engagement by creating US pharmacoeconomic strategy, messaging, and models.
- Chosen as point person to engage with co-promote partner, Amgen on pre-launch market access strategy for potential medicine for NSCLC.
- Initiated "Value of Velcade" payer advertising campaign.
- Formulated and implemented field-based RAM action plan to target large, important buy and bill and in-office dispensing accounts.

SCHERING PLOUGH – Kenilworth, NJ

May 2004-July 2008

US Managed Markets Senior Manager - Virology, Oncology, CNS, and New Product Development (2007-2008)

Promoted to lead development and execution of the US payer strategy for Hep C and Oncology divisions. Devised effective pricing and reimbursement strategy for launch of new melanoma product while maintaining integrity of existing product rebates / discounts / best price implications.

Selected accomplishments:

- Designed USMM strategy for new pipeline medications, including reimbursement, competitive positioning, and value development planning.

- Developed and implemented managed care marketing strategic plan for launch of new label indications for PegIntron, which encompassed managed markets brand positioning, customer communication plan, contract management, and field incentive strategy.
- Partnered with GMA department to develop and train pharmacoeconomic modeling for PegIntron.

Continued...

MATTHEW OUTTEN, MBA, MLA, CPC

Page Three

US Managed Markets Product Manager Virology and Oncology (2006-2007)

Chosen to devise and execute the US strategy, including contracting, and pricing and rebate structure for all Virology and Oncology products. Created product and disease-based pharmacoeconomic models for customer presentations

Selected accomplishments:

- Created new pricing option to prevent step-edit and prior authorization process for a Hep C medication with a new indication for melanoma

US Marketing Product Manager Virology (2005-2006)

Promoted to in-house marketing role to oversee all web-related marketing activities for virology products. Created new brand messaging and support pieces across target segments. Coordinated and led national business unit meetings.

Selected accomplishments:

- Improved time spent on site 500% by incorporating key search terms into and networking with related sites for integrated linking strategies.
- Redesigned brand sample program, including ordering process and target selection.

Virology Biologic Specialty Sales Representative (2004-2005)

Recruited to call on specialists, including hepatology, gastroenterology, and infectious disease physicians to promote Hepatitis C product.

GLAXOSMITHKLINE – Charlottesville, VA

January 2001-May 2004

Neurohealth Specialty Sales Representative (2002-2004)

Promoted to call on Psychiatrists and Neurologists to sell Paxil CR, Lamictal, and Requip.

Pharmaceutical Sales Representative / Field Trainer (2001-2002)

Recruited to promote Coreg, Avandia, and Baycol to Cardiology and Endocrinology physicians.

Selected accomplishments:

- Recognized as only sales representative to win the Chesapeake Award for leadership, initiative, and persistence to achieve results.

EDUCATION & CERTIFICATIONS

Master of Liberal Arts Concentration in International Relations • Harvard University
Master of Business Administration Concentration in Management • University of Delaware
Bachelor of Arts Major in Psychology • Hamilton College
 Certified Professional Coder

Attachment D**FDA Registration**

Verified
9/22/2020
MS

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Wednesday, November 28, 2018 12:10 AM
To: Marc Lesnick <marc.lesnick@qedtx.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 28-NOV-2018
Labeler DUNS: 081223065
Labeler Name: QED Therapeutics, Inc.
Labeler Code: 72730

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. **To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit [Drug Registration and Listing System](#) or reply back to this email (edrls@fda.hhs.gov).

[illegible]

Attachment E**Nature of Business**

QED Therapeutics, Inc. (QED) is a virtual manufacturer of prescription drugs. QED will use third parties to manufacture and ship its product. Below is the contact information for the contract manufacturer and third party logistics provider.

Contract Manufacturer:

Alcami Carolinas Corporation
1726 North 23rd Street
Wilmington, NC 28405

Third Party Logistics Provider:

RxCrossRoads 3PL LLC
1001 Cheri Way
Fairdale, KY 40118

Attachment F**Corporate Officer and Director Information**

QED Therapeutics, Inc.

Corporate Officers:

Matthew D. Outten
Chief Commercial Officer

Michael Henderson
Chief Business Officer

Neil Kumar
Chief Executive Officer

Susan Moran Arangio
Chief Medical Officer

Directors:

Neil Kumar
Frank McCormick

Attachment G**Surety Bond**

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0751783

Application/License No. _____

QED Therapeutics, Inc., doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
8000 Marina Blvd. #400, Brisbane, CA 94005, as
Address of Applicant/Principal
 PRINCIPAL, and Harco National Insurance Company, a
Surety Company
 corporation organized under the laws of the state of Illinois
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
818 West Seventh Street, Ste. 930 Los Angeles, CA 90017 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 09/02/2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statute (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are imposed pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this
2nd day of September, 2020.

APPLICANT/PRINCIPAL

QED Therapeutics, Inc.

Matthew Outten, Chief Commercial Officer
 Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Harco National Insurance Company

[Signature]
 Surety Company's Representative

Stephanie Thompson, Attorney-in-fact
 print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
 Nevada Resident Agent

see attached notary certificate

California Notarial Acknowledgement Certificate:

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California }

County of Santa Clara }

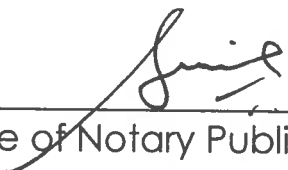
On 09.04.2020 before me, Sunil Jaswal, Notary Public

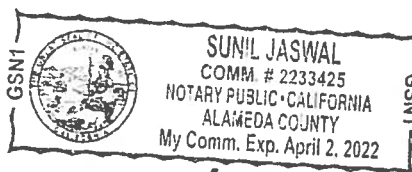
Personally appeared MATTHEW OUTTEN

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity (ies), and that by his/her/their signatures(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.


Signature of Notary Public





CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT**CIVIL CODE § 1189**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)
County of Contra Costa)

On 9/2/20 before me, Maegen I. Allhands, Notary Public
Date

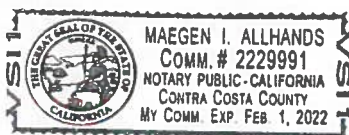
Here Insert Name and Title of the Officer

personally appeared Stephanie Thompson
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.



Signature Maegen I. Allhands
Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____ Document Date: _____

Number of Pages: _____ Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____

☐ Corporate Officer — Title(s): _____

☐ Partner — ☐ Limited ☐ General

☐ Individual ☐ Attorney in Fact

☐ Trustee ☐ Guardian or Conservator

☐ Other: _____

Signer Is Representing: _____

Signer's Name: _____

☐ Corporate Officer — Title(s): _____

☐ Partner — ☐ Limited ☐ General

☐ Individual ☐ Attorney in Fact

☐ Trustee ☐ Guardian or Conservator

☐ Other: _____

Signer Is Representing: _____

POWER OF ATTORNEY

Bond # 0751783

**HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY**

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

LORI A. BOSSHART, SAMANTHA MASCARENHAS, DOROTHY O'CONNOR, COLLEEN P. O'HARA, STEPHANIE THOMPSON, SUSANNA K.P. TRUONG, VICTORIA GLISSON

Walnut Creek, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"RESOLVED, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2019



STATE OF NEW JERSEY
County of Essex

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

STATE OF ILLINOIS
County of Cook



On this 31st day of December, 2019, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.



IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, September 02, 2020

B00016

Irene Martins, Assistant Secretary

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☒ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: McKesson Medical-Surgical Government Solutions LLC

Physical Address: 9954 Mayland Drive Ste 5176

City: Henrico State: VA Zip Code: 23233

Telephone Number: 804.486.1484 Fax Number: 804.264.7679

Toll Free Number: _____

E-mail: danna.sturgill@mckesson.com Website: www.mckesson.com

Facility Manager: Samir David

Professional qualifications and experience of facility manager: VP of Corporate Operations, Operations Manager for facility

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attached

Address:

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20081620620

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?

Yes ☒ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?

Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?

Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Stanton McComb

Print Name of Authorized Person

1/2/20
Date

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Deleware

Parent Company if any: McKesson Medical-Surgical Inc.

Corporation Name: McKesson Medical-Surgical Government Solutions LLC

Mailing Address: 9954 Mayland Drive, Suite 5176

City: Henrico State: VA Zip: 23233

Telephone: 804.486.1484 Fax: 804.264.7679

Contact Person: Danna Sturgill

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 07/07/1994

Registration number issued: 2417015

Stock Exchange: NYSE

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV19941093882

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines*

In 2014 **McKesson** disclosed to the Michigan Board of Pharmacy final agency orders from Colorado, Georgia and Oklahoma that were issued between 2009 and 2012. , The Michigan Board of Pharmacy subsequently filed a complaint alleging that it is a violation of Michigan pharmacy law for a licensee to be the subject of administrative action in another state and asked McKesson to prove compliance with the agency orders in Colorado, Georgia, and Oklahoma. McKesson promptly supplied proof of compliance to the Michigan Board of Pharmacy. The Michigan Board of Pharmacy determined that McKesson had accepted responsibility in Colorado, Georgia, and Oklahoma and taken corrective measures to prevent re-occurrences of the issues that gave rise to those agency orders and the matter was resolved via consent order, pursuant to which McKesson accepted a reprimand and a fine.

In 2014, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning its Landover, Maryland distribution center (the “Landover DC”) that had closed in May 2012. The Final Consent Order resolved allegations that, from January 2008 – November 2009, McKesson’s Landover DC purchased approximately \$2.95 million of prescription drugs/devices from a wholesale distributor that was not licensed in Maryland. McKesson paid a \$30,000 fine in November 2014.

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson’s Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In 2016 **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has

been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy at its Clear Brook, VA location for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective

1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** entered in a Settlement Agreement as disposition of an alleged violation of Section 499.012(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective

1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On November 7, 2018, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Denver, Colorado distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid November 29, 2018. The Board released McKesson Medical-Surgical Inc. from the terms and conditions of the December 6, 2018, Stipulation and Final Agency Order and restored the Registration to unencumbered status.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On March 1, 2019, the Ohio Board of Pharmacy sent a Notice of Opportunity for Hearing to the **McKesson Medical-Surgical Inc.** distribution center in Urbancrest, OH, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The allegations relate to an investigation that McKesson Medical-Surgical Inc. shipped dangerous drugs to an unlicensed site in September 2017. A monetary penalty of \$4,5000 was imposed and paid on March 27, 2019.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio, Aurora, Colorado and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to the Washington Court House, Ohio distribution center. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees, and On August 29, 2019 McKesson received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("McKesson Chicagoland"). The terms of the settlement included a fine in the amount of \$1,150.00.

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MCKESSON MEDICAL-SURGICAL GOVERNMENT SOLUTIONS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF NOVEMBER, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MCKESSON MEDICAL-SURGICAL GOVERNMENT SOLUTIONS LLC" WAS FORMED ON THE FOURTEENTH DAY OF NOVEMBER, A.D. 1969.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



733515 8300

SR# 20198045983

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JB", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 203989884

Date: 11-12-19



Virginia Department of Health Professions License Lookup

Current as of 01/15/2020 17:03

License Information

License Number	0215000432
Occupation	Wholesale Distributor
Name	Mckesson Medical-Surgical Government Solutions LLC
Address	9954 Mayland Drive Ste 5176 Henrico, VA 23233
Initial License Date	08/06/2018
Expire Date	02/28/2021
License Status	Current Active
Additional Public Information*	No

[Back to License Lookup Result](#)

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.G of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.

[Back to License Lookup](#)

Supplier Name	Address	Address: 2	City	State	Zip	Rx Type	Supplier Desc	Qty - Ship	Rank
SEQIRUS USA INC	1 HEALTH PLAZA	BUILDING 310	EAST HANOVER	NJ		7936 RX DRUG	SEQIRUS USA INC	92859	1
B. BRAUN MEDICAL INC	824 12TH AVENUE		BETHLEHEM	PA	180180000	RX DRUG	B BRAUN MEDICAL INC	73307	2
PFIZER INJECTABLES	CUST SRVC D 241 BLG H4	275 V FIELD DRIVE	LAKE FOREST	IL	600450000	RX DRUG	HOSPIRA WORLDWIDE INC	56261	3
MCKESSON CORPORATION	DC 8165	4012 SOUTH PURDUE	OKLAHOMA CITY	OK	731790000	RX DRUG	TEVA PHARMA USA	43939	4
BRISTOL MYERS SQUIBB COMPANY	777 SCUDDERS MILL ROAD		PLAINSBORO	NJ	853600000	RX DRUG	BRISTOL MYERS SQUIBB	26723	5
MCKESSON CORPORATION	DC 8165	4012 SOUTH PURDUE	OKLAHOMA CITY	OK	731790000	RX DRUG	FRESENIUS KABI USA LLC	24279	6
MCKESSON CORPORATION	DC 8165	4012 SOUTH PURDUE	OKLAHOMA CITY	OK	731790000	RX DRUG	AMNEAL/AKYMA PHARMACEUTICALS	19486	7
MCKESSON CORPORATION	DC 8165	4012 SOUTH PURDUE	OKLAHOMA CITY	OK	731790000	RX DRUG	PFIZER	17083	8
ASTELLAS PHARMA US INC	1 ASTELLAS WAY		NORTHBROOK	IL	600620000	RX DRUG	ASTELLAS PHARMA US INC	16819	9
WG CRITICAL CARE LLC	190 NORTH MILWAUKEE STREET		MILWAUKEE	WI	53202	RX DRUG	WG CRITICAL CARE LLC	14673	10
AMERICAN REGENT LABS, INC.	ONE LUITPOLD DRIVE		SHIRLEY	NY	119670000	RX DRUG	AMERICAN REGENT LAB	14512	11
BAXTER HEALTHCARE CORP	MEDICATION DELIVERY DIVISION	ONE BAXTER PARKWAY DF4 1E	DEERFIELD	IL	600150000	RX DRUG	BAXTER HEALTHCARE CORP	13506	12
MCKESSON CORPORATION	DC 8165	4012 SOUTH PURDUE	OKLAHOMA CITY	OK	731790000	RX DRUG	WEST WARD PHARMA	13313	13
AMGEN INC.	ONE AMGEN CENTER DRIVE		THOUSAND OAKS	CA	913201789	RX DRUG	AMGEN INC	11826	14
APP PHARMACEUTICALS LLC	3 CORPORATE DRIVE		LAKE ZURICH	IL	600470000	RX DRUG	APP PHARMACEUTICAL LLC	10380	15



**STATE OF NEVADA CERTIFICATE OF AUTHORITY
DEPARTMENT OF TAXATION**

Taxpayer ID: 1024570410-001
Correspondence ID: 1800012040759
Date: 10/30/2018

MOORE MEDICAL LLC
MCKESSON MEDICAL SURGICAL GOVERNMENT SOLUTIONS
6555 STATE HIGHWAY 161
IRVING TX 75039-2402

THIS PERMIT:
IS NOT TRANSFERABLE TO ANY OTHER PERSON.
IS VOID IF ALTERED.
IS NOT ISSUED IN LIEU OF ANY LOCALLY
REQUIRED BUSINESS LICENSE, PERMIT OR
REGISTRATION.

Permit Location:

MCKESSON MEDICAL SURGICAL GOVERNMENT
9954 MAYLAND DR STE 400
RICHMOND VA 23233-1464

Is authorized to collect Nevada sales tax at the following location.

MUST BE DISPLAYED IN PUBLIC VIEW AT PERMIT LOCATION

(Detach Here)

Attached is your Nevada Certificate of Authority.

A single number, the TID (Taxpayer Identification Number), identifies a taxpayer for MOST tax types. Please use your TID and LOC (Location Number) on resale certificates, in correspondence or telephone calls to the Department.

Based on your estimated monthly taxable receipts as stated on the Nevada Business Registration Supplemental application, your filing frequency will be quarterly.

As stated on the application, your business start date is 10/29/2018, making your first remittance due on or before 01/31/2019.

The Department of Taxation has forms, publications and information available via internet at <https://tax.nv.gov>.

The Department of Taxation is providing businesses with the ability to view and manage their accounts via the internet through its interactive website, NevadaTax, located at <http://nevadatanv.gov/>. Businesses can file tax returns, make payments, and view financials associated with their Sales and Use Tax, Modified Business Tax accounts, as well as make payments for other tax types.

A business must first register and receive a username and password before NevadaTax will allow access to view and manage accounts. If you are already registered to use NevadaTax, this tax type will be added to your existing account.

Your business should use the following Pre-approved NevadaTax Activation Code when registering to use NevadaTax:

Pre-approved NevadaTax Activation Code: **2F8199F9-81DF-43D8-9F36-5AA538741EC1**.

The Nevada Certificate of Authority has been issued pursuant to an application duly filed and payment of prescribed fees. This Certificate of Authority is subject to the provisions of Nevada Revised Statutes 372, 374, and 377. This Certificate of Authority shall be considered valid unless canceled, suspended or revoked for good cause in accordance with Title 32.

If you have questions concerning the permit please call our Department's Call Center at (866) 962-3707

DISTRICT OFFICE LOCATIONS

CARSON CITY MAIN OFFICE 1550 College Parkway, Suite 115 Carson City, Nevada, 89706	LAS VEGAS OFFICE Grant Sawyer Office Bldg, Suite 1300 555 E. Washington Avenue Las Vegas, Nevada, 89101	HENDERSON OFFICE 2550 Paseo Verde Parkway, Suite 180 Henderson, Nevada, 89074	RENO OFFICE 4600 Kietzke Lane Building L, Suite 235 Reno, Nevada, 89502
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Officers

Title	Name	Work Address	Work Phone	Fax	Email Address
President; Director	Stanton J. McComb	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2311	804-264-7520	Stanton.McComb@McKesson.com
VP & Treasurer; Director	Timothy Skansi	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2004	804-553-2004	Tim.Skansi@McKesson.com
VP & Secretary; Director	Michele Lau	1 Post Street San Francisco, CA 94104	415-983-8457	415-983-8380	Michele.Lau@McKesson.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 1-13252

McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

94-3207296
(I.R.S. Employer
Identification No.)

6555 State Hwy 161,
Irving, TX 75039
(Address of principal executive offices, including zip code)

(972) 446-4800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<i>(Title of each class)</i>	<i>(Trading Symbol)</i>	<i>(Name of each exchange on which registered)</i>
Common stock, \$0.01 par value	MCK	New York Stock Exchange

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒
Non-accelerated filer ☐

Accelerated filer ☐
Smaller reporting company ☐
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. 180,187,900 shares of the issuer's common stock were outstanding as of September 30, 2019.

Exhibit 21

SUBSIDIARIES OF THE REGISTRANT

There is no parent of the Company. The following is a listing of the significant subsidiaries of the Company.

	JURISDICTION OF ORGANIZATION
McKesson US Finance Corporation	United States
McKesson UK Finance I Limited	United Kingdom
McKesson International Bermuda IP2A Limited	Bermuda
McKesson International Holdings Unlimited Company	Ireland
McKesson International Bermuda IP3A Limited	Bermuda
McKesson UK Finance II Limited	United Kingdom
McKesson Strategic Services Limited	United Kingdom
ClarusONE Sourcing Services LLP	United Kingdom
McKesson Europe Holdings GmbH & Co. KGaA	Germany
McKesson Europe AG	Germany
McKesson Specialty Care Distribution LLC	United States
McKesson International Bermuda IP5A Limited	Bermuda
Northstar Healthcare Holdings Unlimited Company	Ireland
McKesson Medical-Surgical Inc.	United States
McKesson Medical-Surgical Supply Chain Services LLC	United States
McKesson Sourcing Services Inc.	United States

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☒ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: McKesson Medical-Surgical Minnesota Supply Inc

Physical Address: 9954 Mayland Drive Ste 5176A

City: Henrico State: VA Zip Code: 23233-1464

Telephone Number: 804.486.1484 Fax Number: 804.264.7679

Toll Free Number: _____

E-mail: danna.sturgill@mckesson.com Website: www.mckesson.com

Facility Manager: Michael Jarvis

Professional qualifications and experience of facility manager: Director Six Sigma (Distribution Operations)

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attached

Address:

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV19911022577

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Stanton McComb

Print Name of Authorized Person

Date

1/2/20

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Minnesota
 Parent Company if any: McKesson Medical-Surgical Holdings Inc
 Corporation Name: McKesson Medical-Surgical Minnesota Supply Inc.
 Mailing Address: 9954 Mayland Drive Ste 5176A
 City: Henrico State: VA Zip: 23233-1464
 Telephone: 804.486.1484 Fax: 804.264.7679
 Contact Person: Danna Sturgill

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 10/20/1975
 Registration number issued: 2R-377
 Stock Exchange: NYSE

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV19911022577

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines*

In 2014 **McKesson** disclosed to the Michigan Board of Pharmacy final agency orders from Colorado, Georgia and Oklahoma that were issued between 2009 and 2012. . The Michigan Board of Pharmacy subsequently filed a complaint alleging that it is a violation of Michigan pharmacy law for a licensee to be the subject of administrative action in another state and asked McKesson to prove compliance with the agency orders in Colorado, Georgia, and Oklahoma. McKesson promptly supplied proof of compliance to the Michigan Board of Pharmacy. The Michigan Board of Pharmacy determined that McKesson had accepted responsibility in Colorado, Georgia, and Oklahoma and taken corrective measures to prevent re-occurrences of the issues that gave rise to those agency orders and the matter was resolved via consent order, pursuant to which McKesson accepted a reprimand and a fine.

In 2014, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning its Landover, Maryland distribution center (the “Landover DC”) that had closed in May 2012. The Final Consent Order resolved allegations that, from January 2008 – November 2009, McKesson’s Landover DC purchased approximately \$2.95 million of prescription drugs/devices from a wholesale distributor that was not licensed in Maryland. McKesson paid a \$30,000 fine in November 2014.

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson’s Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In 2015 **McKesson Medical-Surgical Minnesota Supply Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy for selling hypodermic needles and syringes, classified as dangerous devices to an entity not licensed by the board. McKesson paid \$5,000 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state

of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Minnesota Supply Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy related to the fact that its distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since July 1, 2016 fully licensed. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement").

The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio, Aurora, Colorado and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to the Washington Court House, Ohio distribution center. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees, and On August 29, 2019 McKesson received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("McKesson Chicagoland"). The terms of the settlement included a fine in the amount of \$1,150.00.

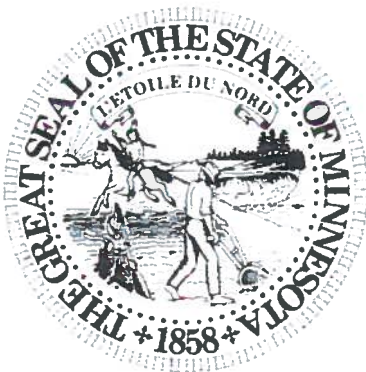
**Office of the Minnesota Secretary of State
Certificate of Good Standing**

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	McKesson Medical-Surgical Minnesota Supply Inc.
Date Filed:	10/20/1975
File Number:	2R-377
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on:

11/11/2019



A handwritten signature in black ink that reads "Steve Simon".

Steve Simon
Secretary of State
State of Minnesota



Virginia Department of Health Professions License Lookup

Current as of 01/15/2020 17:04

License Information

License Number	0215000433
Occupation	Wholesale Distributor
Name	McKesson Medical-Surgical Minnesota Supply Inc
Address	9954 Mayland Dr Ste 5176A Henrico, VA 23233
Initial License Date	08/06/2018
Expire Date	02/28/2021
License Status	Current Active
Additional Public Information*	No

[Back to License Lookup Result](#)

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.G of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.

[Back to License Lookup](#)

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Caroline D. Juran
Executive Director
(804) 367-4456

BOARD OF PHARMACY

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
www.dhp.virginia.gov/pharmacy

Wholesale Distributor Permit

McKesson Medical-Surgical Minnesota Supply Inc

9954 Mayland Dr Ste 5176A
Henrico VA 23233

Expires

02/29/2020

Number

0215000433

For Information About This License, visit our website: www.dhp.virginia.gov
To File a Complaint About a Licensee, Call: 1-800-533-1560

Supplier Name	Address	Address 2	City	State	Zip	Rank
SEQRUS USA INC	HEALTH PLAZA	BUILDING	EAST HANOVER	NJ	07936	1
B. BRAUN MEDICAL INC	TH AVENUE		BETHLEHEM	PA		2
PFIZER INJECTABLES	CUST SRVC D	BLG	LAKE FOREST	IL		3
MCKESSON CORPORATION	DC	SOUTH PURDUE	OKLAHOMA CITY	OK		4
BRISTOL MYERS SQUIBB COMPANY	SCUDDERS MILL ROAD		PLAINSBORO	NJ		5
MCKESSON CORPORATION	DC	SOUTH PURDUE	OKLAHOMA CITY	OK		6
MCKESSON CORPORATION	DC	SOUTH PURDUE	OKLAHOMA CITY	OK		7
ASTELLAS PHARMA US INC	ASTELLAS WAY		NORTHBROOK	IL		8
MCKESSON CORPORATION	DC	2 SOUTH PURDUE	OKLAHOMA CITY	OK		9
WG CRITICAL CARE LLC	NORTH MILWAUKEE STREET		MILWAUKEE	WI		10
AMGEN INC.	ONE AMGEN CENTER DRIVE		THOUSAND OAKS	CA		11
AMERICAN REGENT LABS, INC.	ONE LUITPOLD DRIVE		SHIRLEY	NY		12
BAXTER HEALTHCARE CORP	MEDICATION DELIVERY DIVISION	ONE BAXTER PARKWAY	DEERFIELD	IL		13
MCKESSON CORPORATION	DC	SOUTH PURDUE	OKLAHOMA CITY	OK		14
APP PHARMACEUTICALS LLC	3 CORPORATE DRIVE		LAKE ZURICH	IL		15

NEVADA TAX CENTER

a service of the Nevada Department of Taxation

Address Details

Business Name:MCKESSON MEDICAL-
SURGICAL MINNESOTA
SUPPLY INC**Tax Type:**

Business License

Taxpayer ID:

1001370791 - 000

Location Address:1 POST ST
SAN FRANCISCO, CA
94104-5203

Mailing Address

PO BOX 819066

DALLAS, TX 75381-9066

Contact: DONNA ADAMS**Phone:****Fax:**

Location of Tax Records

8121 N 10TH AVE

GOLDEN VALLEY, MN 55427-0000

Contact:**Phone:****Fax:**

If you are making changes to your account (other than your mailing or tax record address), you will need to complete the Nevada Business Registration form located on our Department's website and mail it to the Carson City District office. If you need assistance please call our Call Center at 1-866-962-3707.

OFFICERS

Title	Name	Work Address	Work Phone	Fax	Email Address
President; Director	Stanton J. McComb	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2311	804-264-7520	Stanton.McComb@McKesson.com
VP & Treasurer; Director	Timothy Skansi	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2004	804-553-2004	Tim.Skansi@McKesson.com
VP & Secretary; Director	Michele Lau	1 Post Street San Francisco, CA 94104	415-983-8457	415-983-8380	Michele.Lau@McKesson.com

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 1-13252

McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation or organization)

94-3207296

(I.R.S. Employer
Identification No.)

6555 State Hwy 161,

Irving, TX 75039

(Address of principal executive offices, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<i>(Title of each class)</i>	<i>(Trading Symbol)</i>	<i>(Name of each exchange on which registered)</i>
Common stock, \$0.01 par value	MCK	New York Stock Exchange

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. 180,187,900 shares of the issuer's common stock were outstanding as of September 30, 2019.

Exhibit 21**SUBSIDIARIES OF THE REGISTRANT**

There is no parent of the Company. The following is a listing of the significant subsidiaries of the Company.

	JURISDICTION OF ORGANIZATION
McKesson US Finance Corporation	United States
McKesson UK Finance I Limited	United Kingdom
McKesson International Bermuda IP2A Limited	Bermuda
McKesson International Holdings Unlimited Company	Ireland
McKesson International Bermuda IP3A Limited	Bermuda
McKesson UK Finance II Limited	United Kingdom
McKesson Strategic Services Limited	United Kingdom
ClarusONE Sourcing Services LLP	United Kingdom
McKesson Europe Holdings GmbH & Co. KGaA	Germany
McKesson Europe AG	Germany
McKesson Specialty Care Distribution LLC	United States
McKesson International Bermuda IP5A Limited	Bermuda
Northstar Healthcare Holdings Unlimited Company	Ireland
McKesson Medical-Surgical Inc.	United States
McKesson Medical-Surgical Supply Chain Services LLC	United States
McKesson Sourcing Services Inc.	United States

400

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada and Name - See Attachment B

☐ New Wholesaler or ☒ **Ownership Change** (Provide current license number if making changes: WH 02540)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded ~~Corporation~~ – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9
 (LLC)

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: MD Logistics LLC

Physical Address: 2370 Perry Road

City: Plainfield State: IN Zip Code: 46168

Telephone Number: 317-839-8900 Fax Number: 317-707-3219

Toll Free Number: N/A

E-mail: info@mdlogistics.com Website: www.mdlogistics.com

Facility Manager: Jeffrey R. Sorrell

Professional qualifications and experience of facility manager: Oversee management of operations to ensure all is running in the most cost effective manner within quality standards. Achieve optimum labor, and least amount of overhead and resource costs. Oversee maximum efficiency in design and production.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Nursing Home Pharmacies and Clinics.

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☒ No ☐

(If yes, provide a copy of the certificate) See Attachment C

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration) N/A

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Baxter Healthcare Corporation

Address: One Baxter Parkway, Deerfield, IL 60015

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20111305685

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

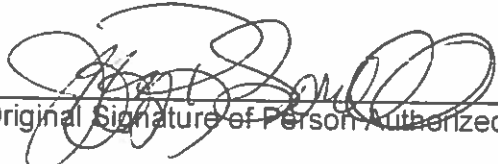
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps
Jeffrey R. Sorrell
Print Name of Authorized Person
16 JUL 2020
Date

Board Use Only	Date Processed: _____	Amount: _____
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APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

Formation
State of Incorporation: Indiana

Parent Company if any: Nippon Express U.S.A., Inc.

Mailing Address: 2370 Perry Road

City: Plainfield State: IN Zip: 46168

Telephone: 317-839-8900 Fax: 317-707-3219

Contact Person: Jeffrey R. Sorrell

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?
- a) Nippon Express U S A , Inc. - 24-01 44th Rd., 14th Floor, Long Island City, NY 11101
- | Name | Business Address |
|------|------------------|
| | |
- b) N/A - No additional parent companies at this level.
- | Name | Business Address |
|------|------------------|
| | |
- c) _____
- | Name | Business Address |
|------|------------------|
| | |
- d) _____
- | Name | Business Address |
|------|------------------|
| | |
- 2) Provide the number of shares issued by the corporation. N/A - The new company is an LLC.
- 3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV20111305685

Include with the application for a non-publicly traded corporation

List of officers and directors See Attachment D

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment E



Indiana Professional Licensing Agency
 Indiana Board of Pharmacy
 402 W. Washington Street, W072
 Indianapolis, IN 46204

Third Party Logistics Provider

License Number	Expire Date
94000147A	09/30/2022

MD Logistics, LLC

Eric J. Holcomb
 Governor
 State of Indiana

Deborah J. Frye
 Executive Director
 Indiana Professional Licensing Agency



Indiana Professional Licensing Agency
 402 W. Washington Street, W072
 Indianapolis, IN 46204

Third Party Logistics Provider

License Number	Expire Date
94000147A	09/30/2022

MD Logistics, LLC

Signature _____

State of Indiana

DEMOGRAPHIC INFORMATION

Name: MD Logistics, LLC

ADDRESS INFORMATION

Line 1: 2370 Perry Road
Line 2:
City/State/Zip: Plainfield IN 46168
County: Hendricks

LICENSE INFORMATION

Lic #: 94000147A Profession: Pharmacy Board Type: Third Party Logistics Provider Secondary:
Status: Active Issued: 7/15/2020 Expiration: 9/30/2022
Method: Change of Ownership

DISCIPLINE INFORMATION

RELATED LICENSES

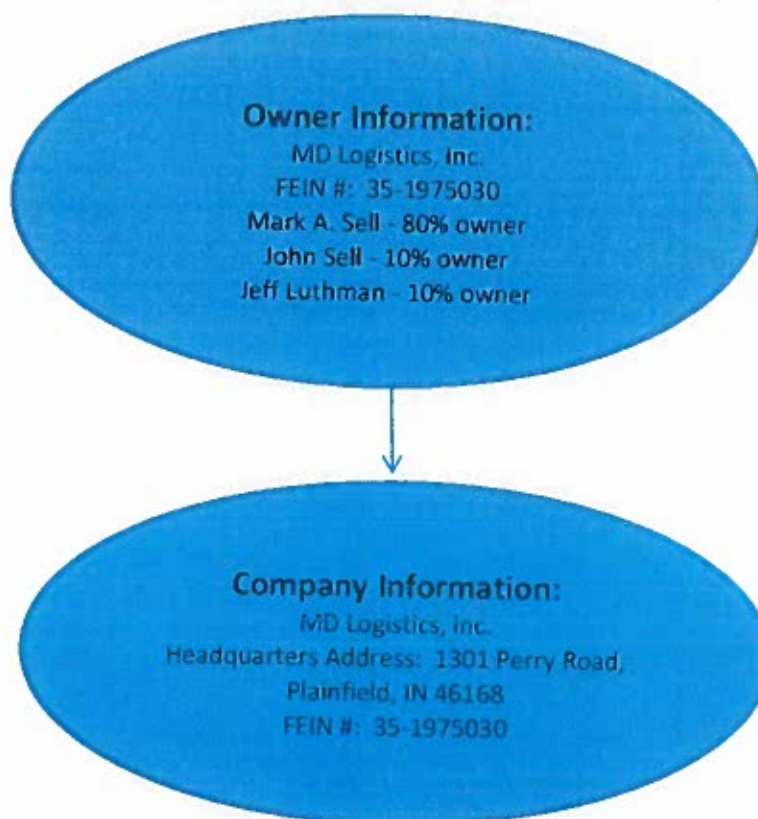
No Related Licenses

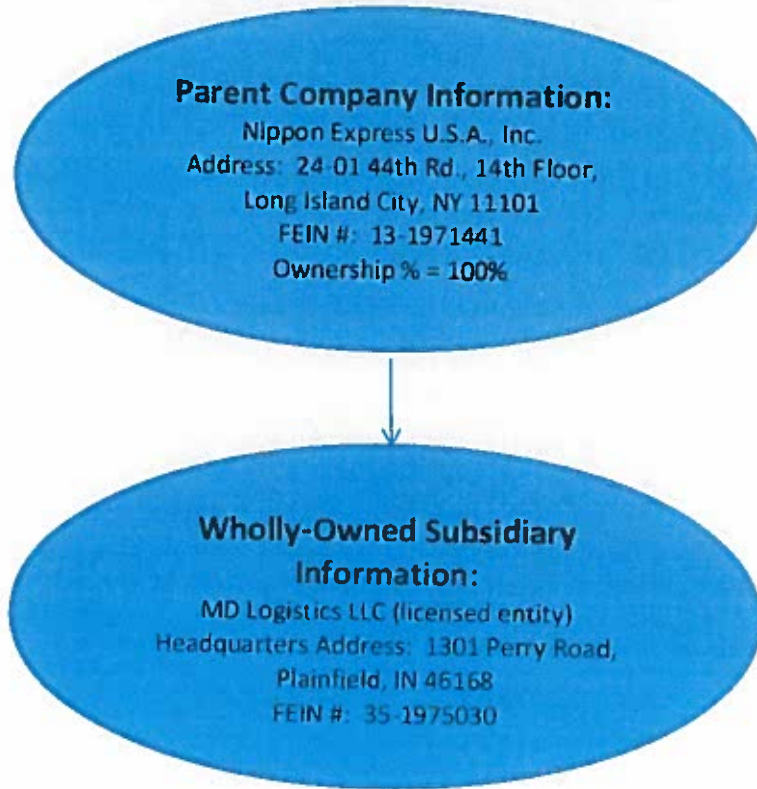
DOCUMENTS

No Public Documents Available

Attachment B**Regarding the Ownership and Name Changes**

Effective on or around August 31, 2020, MD Logistics, Inc. will undergo changes in name and ownership. The company will first undergo a name change/conversion to MD Logistics LLC. The LLC will then go from being a company that is majority-owned by an individual, Mark A. Sell, to a company that is a wholly-owned subsidiary of Nippon Express U.S.A., Inc. This will result in changes to the licensee's name and ownership. Note that there have been no changes to the company officers, federal Tax ID #, or facility addresses. Documentation of the changes will be provided once available. Provided below is the pre and post-ownership change information.

Pre-Ownership/Name Change Information (prior to 8/31/2020):

Attachment B**Regarding the Ownership and Name Changes (cont.)****Post-Ownership/Name Change Information (after 8/31/2020):**

Attachment C

Regarding the Drug Distributor Accreditation

This facility is currently certified with the National Association Boards of Pharmacy (NABP) and verification is available at the following website: <https://nabp.pharmacy/programs/drug-distributor/accredited-facilities/> under the previous ownership and name, MD Logistics, Inc.

Enclosed is a copy of the current DDA certificate for this facility. The name and ownership changes are pending with the NABP.

Drug Distributors

ACREDITATION

Find an Accredited Drug Distributor

Apply

Criteria

Drug Distributors

Facility Name

State

(All)

Search

Reset

Current list of 4 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation


Name	Address	Accreditation Date
MD Logistics, Inc	1301 Perry Rd Plainfield, IN 46168	04/26/19
MD Logistics, LLC	12125 Moya Blvd Reno, NV 89506	09/02/18
MD Logistics, LLC	2150 Stanley Road, Ste 100 Plainfield, IN 46168	03/31/19
MD Logistics, LLC	2370 Perry Rd Plainfield, IN 46168	11/01/18

NABP ACCREDITED

DRUG DISTRIBUTOR

located at

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.


Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary



11/1/2018 - 10/31/2021
Period of Accreditation

verified
2/11/20
MS

Attachment D**LLC Officer Information**

MD Logistics LLC

MD Logistics LLC is wholly-owned by Nippon Express U.S.A., Inc.

Mark A. Sell
President/CEO

Attachment E

Indiana Certificate of Existence

Enclosed please find the current company's certificate of existence. Once the new LLC is formed, a copy of that documentation can be provided to your office.

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, CONNIE LAWSON, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

MD LOGISTICS, LLC

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1995, and was in existence or authorized to transact business in the State of Indiana on August 25, 2020.

I further certify this Domestic Limited Liability Company has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana at the City of Indianapolis August 25, 2020.

Connie Lawson

CONNIE LAWSON
SECRETARY OF STATE

1995121421 / 20201592426

All certificates should be validated here: <https://bsd.sos.in.gov/ValidateCertificate>

Expires on September 24, 2020.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 60138507

Application/License No. _____

MD Logistics, LLC

Applicant/Principal

doing or intending to do business as a

pharmaceutical wholesaler, whose address for purposes of service is

1301 Perry Road Plainfield IN 46162

Address of Applicant/Principal

, as

PRINCIPAL, and Capitol Indemnity Corporation

Surety Company

, a

corporation organized under the laws of the state of Wisconsin

State of Incorporation

and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is

1600 Aspens Commons, Suite 300 Middleton WI 53562

Address of Surety,

as

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 31, 2020

Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are imposed pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

* Additional locations to be added to this bond

2150 Stanley Road, Plainfield, IN 46168

12125 Moya Blvd., Reno, NV 89506

BOND RIDER

To be attached to and form a part of **Pharmaceutical Wholesaler Surety Bond # 60138507** Dated **August 31, 2020**, with **MD Logistics, LLC**, as Principal, and **Capitol Indemnity Corporation**, as Surety, in favor of the **Nevada State Board of Pharmacy**, as Obligee.

It is understood and agreed that the Bond is changed or revised in the particulars as indicated below.

Additional Location listed below is covered under this bond:

2370 Perry Road, Plainfield, IN 46168

Said Bond shall be subject to all its terms, conditions, and limitations, except as herein expressly modified.

This Bond Rider shall become effective: **August 31, 2020**

Signed, Sealed and Dated August 31, 2020

Capitol Indemnity Corporation
SURETY

By:



Deborah M. Roth, Attorney-in-Fact

American Contracting Services, Inc.
P.O. Box 691
Danville, IN 46122
(317) 563-3228

BOND RIDER

To be attached to and form a part of **Pharmaceutical Wholesaler Surety Bond # 60138507** Dated **August 31, 2020**, with **MD Logistics, LLC.** as Principal, and **Capitol Indemnity Corporation.** as Surety, in favor of the **Nevada State Board of Pharmacy.** as Obligee.

It is understood and agreed that the Bond is changed or revised in the particulars as indicated below.

Additional Location listed below is covered under this bond:


2370 Perry Road, Plainfield, IN 46168

Said Bond shall be subject to all its terms, conditions, and limitations, except as herein expressly modified.

This Bond Rider shall become effective: **August 31, 2020**

Signed, Sealed and Dated August 31, 2020

Capitol Indemnity Corporation
SURETY

By: 
Deborah M. Roth, Attorney-in-Fact

American Contracting Services, Inc.
P.O. Box 691
Danville, IN 46122
(317) 563-3228

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of August, 2020.

APPLICANT/PRINCIPAL

SURETY

COMPANY

MD Logistics, LLC

Capitol Indemnity Company

Authorized Representative

Surety Company's Representative

Deborah L. Roth Attorney-in-fact

Print name

SIGNED and SEALED in the presence of

SIGNED and SEALED in the presence of

Witness

Witness

Witness

Witness

Countersigned by

N/A

Nevada Resident Agent

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

60138507

KNOW ALL MEN BY THESE PRESENTS, that I, CAPITOL INDEMNITY CORPORATION, do hereby certify that the following named persons are duly authorized to execute and deliver on my behalf all written instruments in an amount not to exceed: \$20,000,000.00

SARABETH SCOTT; ANTHONY BALZANO; DEBORAH M. ROHE; ROSALIE S. SMITH; JOANN SMITH

ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: \$20,000,000.00

IN WITNESS WHEREOF, I have hereunto set my hand and seal of office, this 1st day of May, 1994.

RESPECTFULLY,
BY _____

Secretary

Assistant Secretary

Treasurer

Vice President

Director

Director

Director

Director

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Madison

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2000-1-20-15

Jeffrey R. Sorrell

CGTQ

Perry Road Plainfield, Ste 105, IN 46168

EMPLOYMENT

Assoc. Director of Shared Pharmaceutical Services – MD Logistics – Plainfield, IN
June 2020 - Current

- Manages Operations Managers
- Ensures standards for product quality are maintained
- Manages budget and controls expenses
- Develops, monitors, and reports on operating costs
- Ensures quality standards

Operations Manager Shared Pharma – MD Logistics – Plainfield, IN
August 2017 – June 2020

- Ensures compliance
- Vendor relations and negotiations
- Reports on daily production, personnel, and quality statistics
- Reviews and approves reports, plans, schedules
- Prepare and manage projects
- Ability to confront and resolve conflict

National Ocean Operations and Compliance Manager – Horizon International Cargo, Inc. – Chicago, IL
August 2015 – August 2017

- Negotiate, execute and manage national ocean contracts with direct steamship lines.
- Provide guidance and oversight to all US offices regarding US FMC compliance
- Prepare and manage projects
- Facilitate and execute ocean shipments, negotiate pricing and provide general customer service.

National Ocean Gateway Manager – NNR Global Logistics USA, Inc. – Chicago, IL
August 2014 – August 2015

- Evaluate regional office capabilities
- Implement national ocean gateway program
- Track, verify and report on export shipments for the gateway stations
- Meet with corporate vendors to negotiate rates, contracts and VID's.

Jeffrey R. Sorrell



Perry Road Plainfield, Ste 105, IN 46168

Export Supervisor – NNR Global Logistics USA, Inc. – Indianapolis, IN
April 2007 – August 2014

- Departmental head for the Ocean Hub, responsible for ocean operations for 8 NNR offices across the U.S.
- Oversee office export operations
- Review and negotiate transportation rates with global vendors
- Provide Export training to local staff as well as national clients

Human Resource Manager – Advanced Testing Laboratory, Inc. – Blue Ash, OH
August 2005 – March 2007

- Responsible for coordinating company benefits for 250+ employees
- Negotiate health care insurance rates with vendors
- Recruited and on-boarded over 50 new employees
- Supplied management support and assistance with employee relations and discipline

Technical Skills

- Microsoft- Word, Excel, Outlook
- WMS proficiency - Red Prairie

CERTIFICATES & MEMBERSHIPS

- Previously held Certified Export Specialist - issued by the NCBFAA (National Customs Brokers & Forwarders Association of America, Inc.)
- Fork lift Certified

EDUCATION

- University of Cincinnati – Cincinnati, OH - **Bachelor of Arts / German Studies – Germanistik 1998**

4PP

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler or ☒ **Ownership Change** (Provide current license number if making changes: WH02255)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: RxCrossroads 3PL LLC

Physical Address: 4200 Binion Way, Suite 200

City: Mason State: OH Zip Code: 45036

Telephone Number: 866-447-9758 Fax Number: 877-464-5403

Toll Free Number: _____

E-mail: kevin.waite@mckesson.com Website: www.rxcrossroads.com

Facility Manager: Kevin Waite

Professional qualifications and experience of facility manager: See Attached Resume

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Repackager, Reverse Distributors, Manufacturers

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☒ Veterinary Legend Drugs
☒ Controlled Substances (include copy of DEA)
☒ Other: OTC's

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☒ No ☐

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Amici Pharmaceuticals LLC

Address: 425 Broadhollow Road, Suite 115, Melville, NY 11747

Name: Ascend Laboratories LLC

Address: 339 Jefferson Road, Suite 101, Parsippany, NJ 07054

Name: Hisun Pharmaceuticals USA Inc

Address: 200 Crossing Blvd 2nd FL, Bridgewater, NJ 08807

Name: Method Pharmaceuticals LLC

Address: 7333 Jack Newell Blvd N, Ste 300, Fort Worth, TX 76118

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau- VP/Secretary

Print Name of Authorized Person

2/7/2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: RxC Acquisition CompanyMailing Address: 6535 State Highway 161City: Irving State: TX Zip: 75039Telephone: 281-863-1000 Fax: _____Contact Person: Michele Lau

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A - No Individual Owners
Name Business Addressb) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address2) Provide the number of shares issued by the corporation. n/a3) What was the price paid per share? N/AA Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A**Include with the application for a non-publicly traded corporation**List of officers and directorsCertificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines*

In 2015, McKesson entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson's Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In 2016 McKesson Packaging Services, a business unit of McKesson Corporation was fined by the California Board of Pharmacy related to the fact that McKesson Packaging Services failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since February 2, 2016 fully licensed. McKesson paid a \$500 fine. The fine is related to a non-disciplinary action.

In 2016 McKesson Corporation was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In January 2017, McKesson entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to

January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for McKesson's Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of McKesson distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of McKesson's distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of McKesson distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of McKesson's distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and McKesson Corporation entered in a Settlement Agreement as

disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions of fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns

with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio, Aurora, Colorado and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with McKesson (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to the Washington Court House, Ohio distribution center. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees.

On August 29, 2019 McKesson received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

On August 29, 2019 McKesson entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("McKesson Chicagoland"). The terms of the settlement included a fine in the amount of \$1,150.00.

On January 7, 2020 McKesson entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

Pending Actions

The Indiana Board of Pharmacy issued a complaint and McKesson Corporation responded but have not had further communication with the Board.

The Georgia Board of Pharmacy issued a proposed consent order and McKesson Corporation is responding but have not finalized any agreement with the state.

The Delaware Board of Pharmacy issued a proposed consent order and McKesson Corporation is responding but have not finalized any agreement with the state.

The Illinois Department of Financial and Professional Regulation informed McKesson Corporation that the state would be seeking disciplinary action against Illinois licensed facilities. Please note that for the above-referenced pending actions, no final action has been taken and all



**STATE OF
OHIO**
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2021.

RxCrossroads 3PL LLC

4200 Binion Way Ste 200

Mason, OH 45036-9469

License Number: 0172000014

Third-Party Logistics - Category 3

Expiration Date: June 30, 2021

CLASS: Third-Party Logistics - Category 3
BUSINESS TYPE: 3PL - Third-Party Logistics

Responsible Person - Print, sign and keep license in a readily retrievable location at the address listed on this license.

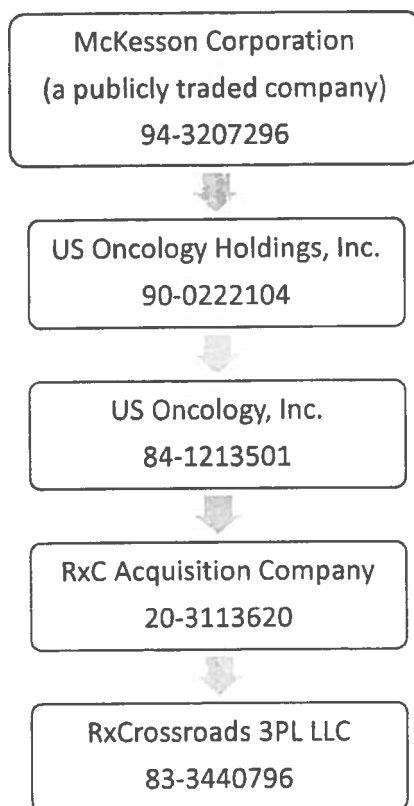
Responsible Person Name (Print) KEVIN WAITE	Signature of Responsible Person 
---	---

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

RxCrossroads 3PL LLC Organizational Chart

Organizational Chart:



Applicant: RxCrossroads 3PL LLC
4200 Binion Way STE 200
Mason, OH 45036
Warren County
Phone: 866-447-9758
Fax: 877-464-5403
FEIN: 83-3440796

Delaware Limited Liability Company incorporated on January 4th 2019

Parent Company: RxC Acquisition Company
6535 State Highway 161
Irving, TX 75039
FEIN #: 20-3113620

Michele Lau, VP/Secretary
Post Street, San Francisco, C.
SS# DOE

Kevin Waite, Inventory Manager
4200 Rinion Way STE 200 Mason. OH 45036
SS: DC
Phc: Email: ckesson.com

Beatrix Erdei, Sr. Manager, Compliance and Regulatory Affairs
Phone: 415-983-9247 Email: Beatrix.Erdei@mckesson.com
One Post Street, San Francisco, CA 94104

Our business operation is that of a third party logistics for various drug/medical device manufactures. We do not take title to the product, but rather provide warehouse, distribution, and other logistics services on behalf of the drug/medical device manufactures .

Type of Products: Human Prescription Drugs (Solid Dose, Liquids (Oral), Injectables, Topical, Ophthalmic)
 Veterinary Prescription Drugs, Controlled Substances (Sch II-V); Dangerous devices, OTC, Medical Food

Type of Customers: Wholesalers, Distributors, Drug Manufacturers, Drug Repackager, Reverse Distributor, Pharmacies, Hospitals

State Of Delaware

Entity Details

3/9/2020 8:18:08PM

File Number: 7223511

Incorporation Date / Formation Date: 1/4/2019

Entity Name: RXCROSSROADS 3PL LLC

Entity Kind: Limited Liability Company

Entity Type: General

Residency: Domestic

State: DELAWARE

Status: Good Standing

Status Date: 1/4/2019

Registered Agent Information

Name: CORPORATION SERVICE COMPANY

Address: 251 LITTLE FALLS DRIVE

City: WILMINGTON

Country:

State: DE

Postal Code: 19808

Phone: 302-636-5401

2/25/2020

National Association of Boards of Pharmacy Accreditation Information

Facility Name

State

(All)

Search Reset

Current list of 3 Verified-Accredited Wholesale Distributors®

VAWD accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
RxCrossroads 3PL LLC	1001 Cheri Way, Ste 100 Louisville, KY 40118	Reaccreditation in process
RxCrossroads 3PL LLC	5101 Jeff Commerce Dr Louisville, KY 40219	06/22/18
RxCrossroads 3PL LLC	4200 Binion Way Ste 200 Mason, OH 45036	08/31/18

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Contact

Verified
2/25/20



*The National Association of Boards of Pharmacy®
hereby awards*

*Verified-Accredited Wholesale Distributors®
Accreditation*

to

*Masters Drug Company, Inc
dba RXTPL*

located at

4200 Binion Way Ste 200, Mason, OH 45036

This facility has met all the Verified-Accredited Wholesale Distributors (VAD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting our VAD website, located at www.nabp-pharmacy.com.

Paula L. Lape

Paula L. Lape, Director of Secretary

August 31, 2018 - August 30, 2021

Period of Accreditation

National Association of Boards of Pharmacy | 1100 Exchange Blvd., Suite 1000 | Prospect Heights, IL 60070 | www.nabp-pharmacy.com

KEVIN WAITE

Firshade Tr. Cincinnati OH 9 ·
@gmail.com

Warehouse manager with management experience and exceptional people skills. Versed in inventory control and production management.

EXPERIENCE

JAN 2018 – CURRENT

WAREHOUSE AND INVENTORY MANAGER, MASTERS DRUG COMPANY, INC

As the warehouse manager for Masters, my job was to monitor and successfully manage an ever growing TPL company. Duties included: The hiring process of new employees, train and develop those employees, monitor and control inventory, coach and terminate when needed, work with executives on how to streamline production, resolve any client issues in a timely manner, record keeping and ensure day to day business was being completed in a timely manner.

AUG 2012 – DEC 2017

WAREHOUSE AND INVENTORY MANAGER, RXTPL, LLC

As the warehouse manager for RXTPL, my job was to monitor and successfully manage an ever growing TPL company. Duties included: The hiring process of new employees, train and develop those employees, monitor and control inventory, coach and terminate when needed, work with executives on how to streamline production, resolve any client issues in a timely manner, record keeping and ensure day to day business was being completed in a timely manner.

FEB 2008 – AUG 2012

SHIFT LEAD/MULTIPLE DIVISIONS, SAM'S CLUB

I Started with Sam's Club being third shift receiver. The job duties were to unload trailers with forklifts and locate throughout the store. I then moved to a shift lead after 4 months in the tire department. There, I was in charge of inventory control, supervising a team of 8 and scheduling shifts accordingly.

EDUCATION

2011

CONSTRUCTION MANAGEMENT, NORTHERN KENTUCKY UNIVERSITY

Started NKU in the fall of 2007, but did not graduate due to financial problems.

2007

HIGH SCHOOL DIPLOMA, NORTHWEST HIGH SCHOOL

3.7 GPA

Coursework in Construction for 2 years

SKILLS

- Results-oriented
- Operations management/Inventory Control
- Client-focused
- Hazmat Certified
- File/Records Maintenance
- Computer proficient

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane

Reno, NV 89509

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 070022483

Application/License No. _____

McKesson Corporation, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
One Post Street, San Francisco, CA 94104, as
Address of Applicant/Principal

PRINCIPAL, and Liberty Mutual Insurance Company, a
Surety Company

corporation organized under the laws of the state of Massachusetts
State of Incorporation

and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
71 Stevenson St, Suite 600, San Francisco, CA 94105 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 15, 2016.

Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.



This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8201331

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Heidi Bockus all of the city of Seattle, state of Washington, each individually if there be more than one named, its true and lawful attorney-in-fact, with full power and authority hereby conferred to sign, execute and acknowledge the above-referenced surety bond.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 30th day of May, 2019.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: David M. Carey

David M. Carey, Assistant Secretary



STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 30th day of May, 2019, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.



COMMONWEALTH OF PENNSYLVANIA

Notarial Seal
Teresa Pastella, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires March 28, 2021

Member, Pennsylvania Association of Notaries

By: Teresa Pastella

Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV - OFFICERS: Section 12. Power of Attorney.

Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.

Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation - The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization - By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of June, 2020.



By: Renee C. Llewellyn

Renee C. Llewellyn, Assistant Secretary

To confirm the validity of this Power of Attorney call

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

CHANGE RIDER

To be attached to and form a part of Bond No. 070022483

in the amount of \$100,000.00 issued by Liberty Mutual Insurance Company

on behalf of McKesson Corporation

in favor of Nevada State Board of Pharmacy

It is understood and agreed that the bond described above is hereby modified so as to

Add to the Bond:

RxCrossroads 3PL, LLC

4200 Binion Way, Suite 200
Mason, OH 45036

It is further expressly understood and agreed that the aggregate liability of the _____

Liberty Mutual Insurance Company under said bond to the obligee

herein mentioned shall not exceed the amount stated above.

Nothing herein contained shall be held to vary, alter, waive, or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, other than as above stated.

Signed, sealed and dated this 21st day of July, 2020.

Liberty Mutual Insurance Company



BY: _____

Heidi Bockus

Heidi Bockus

Attorney-in-Fact

CHANGE RIDER

To be attached to and form a part of Bond No. 070022483

in the amount of \$100,000.00 issued by Liberty Mutual Insurance Company

on behalf of McKesson Corporation

in favor of Nevada State Board of Pharmacy

It is understood and agreed that the bond described above is hereby modified so as to

Add to the Bond:

RxCrossroads 3PL, LLC

4200 Binion Way, Suite 200
Mason, OH 45036

It is further expressly understood and agreed that the aggregate liability of the _____

Liberty Mutual Insurance Company

under said bond to the obligee

herein mentioned shall not exceed the amount stated above.

Nothing herein contained shall be held to vary, alter, waive, or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, other than as above stated.

Signed, sealed and dated this 21st day of July, 2020

Liberty Mutual Insurance Company



BY: _____

Heidi Bockus

Heidi Bockus

Attorney-in-Fact

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane

Reno, NV 89509

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 070022483

Application/License No. _____

McKesson Corporation, doing or intending to do business as a
Applicant/Principal

pharmaceutical wholesaler, whose address for purposes of service is

One Post Street, San Francisco, CA 94104, as
Address of Applicant/Principal

PRINCIPAL, and Liberty Mutual Insurance Company, a
Surety Company

corporation organized under the laws of the state of Massachusetts
State of Incorporation

and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is

71 Stevenson St, Suite 600, San Francisco, CA 94105 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 15, 2016.

Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are imposed pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this
15th day of September, 2016.

APPLICANT/PRINCIPAL

McKesson Corporation

By:

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

By:

Surety Company's Representative

Heidi Bockus

print name

, Attorney-in-fact

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Heidi Bockus

Nevada Resident Agent Nonresident Agent License #503307
Heidi Bockus

THIS POWER OF ATTORNEY IS NOT VALID UNLESS IT IS PRINTED ON RED BACKGROUND.

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Certificate No. 7240835

American Fire and Casualty Company
The Ohio Casualty Insurance Company

Liberty Mutual Insurance Company
West American Insurance Company

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That American Fire & Casualty Company and The Ohio Casualty Insurance Company are corporations duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Heidi Bockus; Krista M. Lee

all of the city of Seattle, state of WA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 14th day of January, 2016.



American Fire and Casualty Company
The Ohio Casualty Insurance Company
Liberty Mutual Insurance Company
West American Insurance Company

By: David M. Carey
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 14th day of January, 2016, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of American Fire and Casualty Company, Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.



COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Teresa Pastella, Notary Public
Plymouth Twp., Montgomery County
My Commission Expires March 28, 2017
Member, Pennsylvania Association of Notaries

By: Teresa Pastella
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of American Fire and Casualty Company, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS – Section 12. Power of Attorney. Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts – SECTION 5. Surety Bonds and Undertakings. Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Gregory W. Davenport, the undersigned, Assistant Secretary, of American Fire and Casualty Company, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of Sep, 2016



By: Gregory W. Davenport
Gregory W. Davenport, Assistant Secretary

To confirm the validity of this Power of Attorney call 1-814-832-8240 between 9:00 am and 4:30 pm EST on any business day.

RxCrossroads 3PL LLC

November 26, 2019

VIA UPS**Nevada State Board of Pharmacy****431 W Plumb Lane****Reno, NV 89509**

RE: Change in Ownership – Masters Drug Company, Inc – 4200 Binion Way STE 200 Mason OH 45036
Nevada State Board of Pharmacy - WH02255

To Whom it May Concern:

McKesson underwent an internal multi-step transaction and re-organization on July 1, 2019. As a result, a new entity RxCrossroads 3PL LLC ("RXC 3PL") was formed with a parent company of RXC Acquisition Company, where RXC 3PL would be the entity holding the permit. As the Board is aware, Masters Drug Company, Inc's ultimate parent company is McKesson Corporation. Since the re-organization, Masters Drug Company Inc, Third Party Logistics Division will now become RxCrossroads 3PL LLC on January 1, 2020. Only the third-party logistics division licensed at 4200 Binion Way STE 200 Mason, OH 45036 will be affected by the internal change of ownership to the new entity RxCrossroads 3PL LLC. Accordingly, we will be sending a change of ownership application and the appropriate fee for processing.

Please feel free to contact Beatrix Erdei at Beatrix.Erdi@mckesson.com or me at 513-619-8041, Courtney.Phelps@mckesson.com if you have any questions or would like any additional information regarding this transaction. Thank you for your consideration.

Regards.

Courtney Phelps

Sr. Manager Regulatory Affairs, Quality Assurance

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane

Reno, NV 89509

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 070022483

Application/License No. _____

McKesson Corporation, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
One Post Street, San Francisco, CA 94104, as
Address of Applicant/Principal
 PRINCIPAL, and Liberty Mutual Insurance Company, a
Surety Company
 corporation organized under the laws of the state of Massachusetts
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
71 Stevenson St, Suite 600, San Francisco, CA 94105 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 15, 2016.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this
15th day of September, 2016.

APPLICANT/PRINCIPAL
McKesson Corporation

By:

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

By:

Surety Company's Representative

Heidi Bockus

print name

, Attorney-in-fact

SIGNED and SEALED in the presence of

Witness

Witness

SIGNED and SEALED in the presence of

Witness

Witness

Countersigned by:

Nevada Resident Agent Nonresident Agent License #503307
Heidi Bockus

American Fire and Casualty Company
The Ohio Casualty Insurance Company

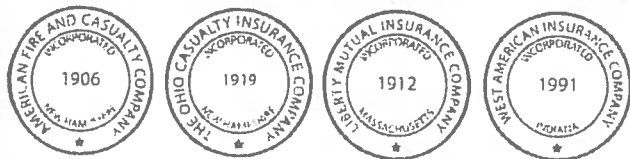
Liberty Mutual Insurance Company
West American Insurance Company

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That American Fire & Casualty Company and The Ohio Casualty Insurance Company are corporations duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Heidi Bockus; Krista M. Lee

all of the city of Seattle, state of WA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 14th day of January, 2016.



American Fire and Casualty Company
The Ohio Casualty Insurance Company
Liberty Mutual Insurance Company
West American Insurance Company

By: David M. Carey
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA
COUNTY OF MONTGOMERY

On this 14th day of January, 2016, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of American Fire and Casualty Company, Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.



COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Teresa Pastella, Notary Public
Plymouth Twp., Montgomery County
My Commission Expires March 28, 2017
Member, Pennsylvania Association of Notaries

By: Teresa Pastella
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of American Fire and Casualty Company, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV - OFFICERS - Section 12. Power of Attorney. Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

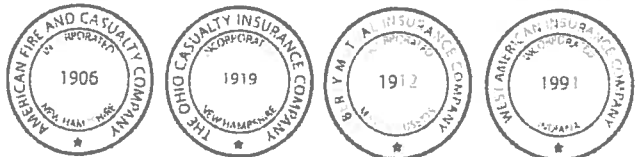
ARTICLE XIII - Execution of Contracts - SECTION 5. Surety Bonds and Undertakings. Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation - The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization - By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Gregory W. Davenport, the undersigned, Assistant Secretary, of American Fire and Casualty Company, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this th day of ep, 2016.



By: Gregory W. Davenport
Gregory W. Davenport, Assistant Secretary

To confirm the validity of this Power of Attorney call 1-610-832-8240 between 9:00 am and 4:30 pm EST on any business day.

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

CHANGE RIDER

To be attached to and form a part of Bond No. 070022483

in the amount of \$100,000.00 issued by Liberty Mutual Insurance Company

on behalf of McKesson Corporation

in favor of Nevada State Board of Pharmacy

It is understood and agreed that the bond described above is hereby modified so as to

Add to the bond

RxCrossroads 3PL, LLC

5101 Jeff Commerce Dr.
Louisville, KY 40219

1001 Cheri Way, Suite 100
Fairdale, KY 40118

It is further expressly understood and agreed that the aggregate liability of the _____

Liberty Mutual Insurance Company under said bond to the obligee

herein mentioned shall not exceed the amount stated above.

Nothing herein contained shall be held to vary, alter, waive, or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, other than as above stated.

Signed, sealed and dated this 26th day of June, 2020

Liberty Mutual Insurance Company



BY: Heidi Bockus
Heidi Bockus, Attorney-in-Fact

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8201331

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Heidi Bockus all of the city of Seattle, state of Washington each individually if there be more than one named, its true and lawful attorney-in-fact, with full power and authority hereby conferred to sign, execute and acknowledge the above-referenced surety bond.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 30th day of May, 2019.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company



By: David M. Carey

David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 30th day of May, 2019, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.



COMMONWEALTH OF PENNSYLVANIA

Notarial Seal
Teresa Pastella, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires March 28, 2021
Member, Pennsylvania Association of Notaries

By: Teresa Pastella

Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV - OFFICERS: Section 12. Power of Attorney.

Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.

Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

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Authorization - By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of June, 2020.



By: Renee C. Llewellyn

Renee C. Llewellyn, Assistant Secretary

4QQ

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada, and Name - See Attachment B

☐ New Wholesaler or ☒ **Ownership Change** (Provide current license number if making changes: WH 01172)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

(LLC)

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: MD Logistics LLC

Physical Address: 1301 Perry Road

City: Plainfield State: IN Zip Code: 46168

Telephone Number: 317-839-8900 Fax Number: 317-707-3214

Toll Free Number: N/A

E-mail: info@mdlogistics.com Website: www.mdlogistics.com

Facility Manager: Timothy C. Lawyer

Professional qualifications and experience of facility manager: Oversee management of operations to ensure all is running in the most cost effective manner within quality standards. Achieve optimum labor, and least amount of overhead and resource costs. Oversee maximum efficiency in design and production.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Nursing Home Pharmacies and Clinics.

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☒ No ☐

(If yes, provide a copy of the certificate) See Attachment C

Licensed as Manufacturer by the FDA?

Yes ☒ No ☐

(If yes, provide a copy of your FDA registration) See Attachment D

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Novo Nordisk Inc.

Address: 800 Scudders Mill Road, Plainsboro, NJ 08536

Name: CSL Behring LLC

Address: 1020 First Avenue, King of Prussia, PA 19406

Name: Jacobus Pharmaceuticals, Inc

Address: IRL Building Schalks Crossing Road, Plainsboro, NJ 08536

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20111305685

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Timothy C. Lawyer

Print Name of Authorized Person

Date

7/16/2020

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

Formation

State of ~~Incorporation~~: Indiana

Parent Company if any: Nippon Express U.S.A., Inc.

Mailing Address: 1301 Perry Road

City: Plainfield State: IN Zip: 46168

Telephone: 317-839-8900 Fax: 317-707-3214

Contact Person: Timothy C. Lawyer

For any corporation non-publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) Nippon Express U.S.A., Inc. - 24-01 44th Rd., 14th Floor, Long Island City, NY 11101

Name

Business Address

b) N/A - No additional parent companies at this level.

Name

Business Address

c).

Name _____

Business Address

d).

Name

Business Address

- 2) Provide the number of shares issued by the corporation. N/A - The new company is an LLC.

- 3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV20111305685

Include with the application for a non-publicly traded corporation

List of officers and directors * See Attachment E

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment F



Indiana Professional Licensing Agency
 Indiana Board of Pharmacy
 402 W. Washington Street, W072
 Indianapolis, IN 46204

Third Party Logistics Provider

License Number	Expire Date
94000148A	09/30/2022

MD Logistics, LLC

Eric J. Holcomb
 Governor
 State of Indiana

Deborah J. Frye
 Executive Director
 Indiana Professional Licensing Agency



Indiana Professional Licensing Agency
 402 W. Washington Street, W072
 Indianapolis, IN 46204

Third Party Logistics Provider

License Number	Expire Date
94000148A	09/30/2022

MD Logistics, LLC

Signature _____

State of Indiana

DEMOGRAPHIC INFORMATION

Name: MD Logistics, LLC

ADDRESS INFORMATION

Line 1: 1301 Perry Road
Line 2:
City/State/Zip: Plainfield IN 46168
County: Hendricks

LICENSE INFORMATION

Lic #:	94000148A	Profession:	Pharmacy Board	Type:	Third Party Logistics Provider	Secondary:
Status:	Active	Issued:	7/15/2020	Expiration:	9/30/2022	
Method:	Change of Ownership					

DISCIPLINE INFORMATION

RELATED LICENSES

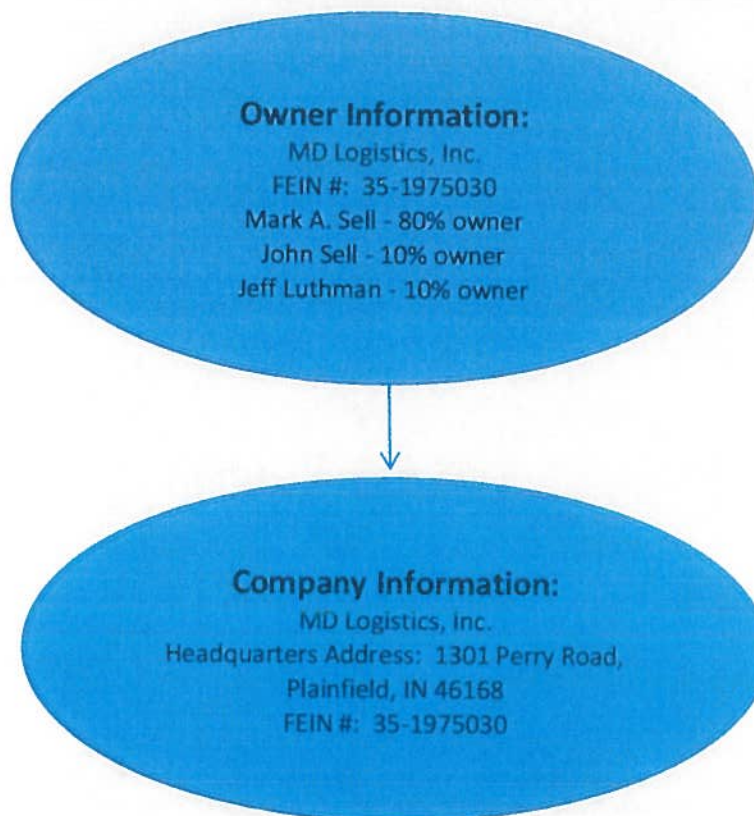
No Related Licenses

DOCUMENTS

No Public Documents Available

Attachment BRegarding the Ownership and Name Changes

Effective on or around August 31, 2020, MD Logistics, Inc. will undergo changes in name and ownership. The company will first undergo a name change/conversion to MD Logistics LLC. The LLC will then go from being a company that is majority-owned by an individual, Mark A. Sell, to a company that is a wholly-owned subsidiary of Nippon Express U.S.A., Inc. **This will result in changes to the licensee's name and ownership. Note that there have been no changes to the company officers, federal Tax ID #, or facility addresses.** Documentation of the changes will be provided once available. Provided below is the pre and post-ownership change information.

Pre-Ownership/Name Change Information (prior to 8/31/2020):

Attachment B**Regarding the Ownership and Name Changes (cont.)****Post-Ownership/Name Change Information (after 8/31/2020):****Parent Company Information:**

Nippon Express U.S.A., Inc.
Address: 24-01 44th Rd., 14th Floor,
Long Island City, NY 11101
FEIN #: 13-1971441
Ownership % = 100%

**Wholly-Owned Subsidiary
Information:**

MD Logistics LLC (licensed entity)
Headquarters Address: 1301 Perry Road,
Plainfield, IN 46168
FEIN #: 35-1975030

Attachment C

Regarding the Drug Distributor Accreditation

This facility is currently certified with the National Association Boards of Pharmacy (NABP) and verification is available at the following website: <https://nabp.pharmacy/programs/drug-distributor/accredited-facilities/> under the previous ownership and name, MD Logistics, Inc.

Enclosed is a copy of the current DDA certificate for this facility. The name and ownership changes are pending with the NABP.

NABP ACCREDITED

DRUG DISTRIBUTOR

located at

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.



Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary



4/26/2019 - 4/25/2022

Period of Accreditation

verified
8/11/20

Drug Establishments Current Registration Site

f SHARE ([HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm))

t TWEET ([HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM](https://twitter.com/intent/tweet?text=Drug%20Establishments%20Current%20Registration%20Site&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm))

in LINKEDIN ([HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM&TITLE=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&SOURCE=FDA](https://www.linkedin.com/sharearticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&title=Drug%20Establishments%20Current%20Registration%20Site&source=fda))

@ PIN IT ([HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM&DESCRIPTION=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&description=Drug%20Establishments%20Current%20Registration%20Site))



✉ EMAIL ([MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM](mailto:?subject=Drug%20Establishments%20Current%20Registration%20Site&body=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm))

🖨 PRINT

New Search (default.cfm)

Search Results for **MD Logistics**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
MD Logistics, LLC	3004026589	965636525	LABEL, PACK,	1301 Perry Road Ste 101, Plainfield, Indiana (IN) 46168, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

[Previous](#)[Next](#)

Data Current through: Tuesday, Sep 22, 2020

[Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)](#)

Verified
MS

9/22/2020, 8:03 AM

Attachment E

LLC Officer Information

MD Logistics LLC

MD Logistics LLC is wholly-owned by Nippon Express U.S.A., Inc.

Mark A. Sell
President/CEO

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

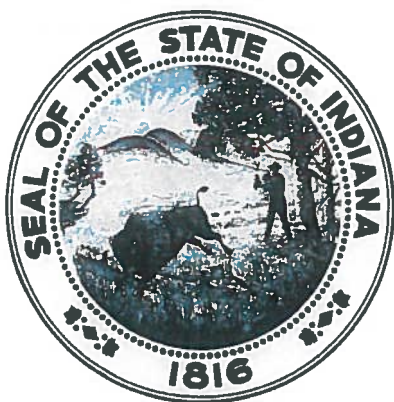
I, CONNIE LAWSON, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

MD LOGISTICS, LLC

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1995, and was in existence or authorized to transact business in the State of Indiana on August 25, 2020.

I further certify this Domestic Limited Liability Company has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, August 25, 2020

Connie Lawson

CONNIE LAWSON
SECRETARY OF STATE

1995121421 / 20201592426

All certificates should be validated here: <https://bsd.sos.in.gov/ValidateCertificate>

Expires on September 24, 2020.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 60138507

Application/License No. _____

MD Logistics LLC, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
1301 Perry Road, Plainfield, IN 46168, as
Address of Applicant/Principal
PRINCIPAL, and Capital Indemnity Corporation, a
Surety Company
 corporation organized under the laws of the state of Wisconsin
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1600 Aspens Commons, Suite 300 Middleton, WI 53562 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 31, 2020
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

* Additional locations to be added to this bond

2150 Stanley Road, Plainfield, IN 46168

12125 Moya Blvd., Reno, NV 89506

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of August, 2020.

APPLICANT/PRINCIPAL

SURETY

COMPANY

MD Logistics, LLC

Capitol Indemnity Company

Authorized Representative

Surety Company's Representative

Deborah M. Roth, Attorney-in-fact
print name

SIGNED and SEALED in the presence of

SIGNED and SEALED in the presence of.

Witness

Witness

Witness

Witness

Countersigned by

N/A

Nevada Resident Agent

Timothy Lawyer

com

Perry Road Plainfield, IN 46168

EMPLOYMENT

Assoc. Director of Shared Pharmaceutical Services – MD Logistics – Plainfield, IN January 2015 - Current

- Manages Operations Managers
- Ensures standards for product - quality are maintained
- Manages budget and controls expenses
- Develops, monitors, and reports on operating costs
- Ensures quality standards

Operations Manager Shared Pharma – MD Logistics – Plainfield, IN October 2010 – January 2015

- Ensures compliance
- Vendor relations and negotiations
- Reports on daily production, personnel, and quality statistics
- Reviews and approves reports, plans, schedules
- Prepare and manage projects
- Ability to confront and resolve conflict

Operations Manager Shared Logistics – MD Logistics – Plainfield, IN August 2007 – October 2010

- Able to navigate WMS
- Reviews and approves all operational SOP's, operational deviations, and corrective actions
- Facilitate and maintain departmental training records
- Prepare and manage projects

Lead Supervisor – Atlas Cold Storage March 2004 – August 2007

- Monitor employee production
- Enforce company policy
- Manage first shift operations
- Oversee the training and mentoring of employees

Technical Skills

- Microsoft- word, Excel, Publisher, Visio
- Red Prairie
- DOT Hazardous Materials Training

CERTIFICATES & MEMBERSHIPS

- Air National Guard Member: Honorably Discharged in 1995
- DOT Hazardous Materials Certificate
- Fork lift Certified

Timothy Lawyer

cs.com

Perry Road Plainfield, IN 46168

EDUCATION

- Indiana State University; Terre Haute, IN - **Business Management**
- Solano Community College; Fairfield, CA - **Business Management**
- Air Force Tech School; Lowry Air Force Base – Denver, CO

4RR

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.
 and Name - See Attachment C

☐ New Wholesaler or ☒ **Ownership Change** (Provide current license number if making changes: WH 02167)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

(LLC)

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: MD Logistics LLC

Physical Address: 2150 Stanley Road

City: Plainfield State: IN Zip Code: 46168

Telephone Number: 317-838-8900 Fax Number: 317-707-3219

Toll Free Number: N/A

E-mail: info@mdlogistics.com Website: www.mdlogistics.com

Facility Manager: Chad P. Hodges

Professional qualifications and experience of facility manager: Oversee management of operations to ensure all is running in the most cost effective manner within quality standards. Achieve optimum labor, and least amount of overhead and resource costs. Oversee maximum efficiency in design and production.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Nursing Home Pharmacies and Clinics.

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☒ Poisons or Chemicals ☐ Veterinary Legend Drugs
☒ Controlled Substances (include copy of DEA) See Attachment B
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☒ No ☐

(If yes, provide a copy of the certificate) See Attachment D

Licensed as Manufacturer by the FDA? Yes ☒ No ☐

(If yes, provide a copy of your FDA registration) See Attachment B

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Merck Sharp & Dohme Corp

Address: 770 Sumeytown Pike, Building 56, West Point, PA 19486

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20111305685

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Chad P. Hodges

Print Name of Authorized Person

16 Jul 2020
Date

Board Use Only

Date Processed: _____

Amount: _____



Indiana Professional Licensing Agency
 Indiana Board of Pharmacy
 402 W. Washington Street, W072
 Indianapolis, IN 46204

Third Party Logistics Provider

License Number	Expire Date
94000150A	09/30/2022

MD Logistics, LLC

Eric J. Holcomb
 Governor
 State of Indiana

Deborah J. Frye
 Executive Director
 Indiana Professional Licensing Agency



Indiana Professional Licensing Agency
 402 W. Washington Street, W072
 Indianapolis, IN 46204

Third Party Logistics Provider

License Number	Expire Date
94000150A	09/30/2022

MD Logistics, LLC

Signature _____

State of Indiana

DEMOGRAPHIC INFORMATION

Name: MD Logistics, LLC

ADDRESS INFORMATION

Line 1: 2150 Stanley Road
Line 2:
City/State/Zip: Plainfield IN 46168
County: Hendricks

LICENSE INFORMATION

Lic #:	94000150A	Profession:	Pharmacy Board	Type:	Third Party Logistics Provider	Secondary:
Status:	Active	Issued:	7/22/2020	Expiration:	9/30/2022	
Method:	Change of Ownership					

DISCIPLINE INFORMATION

RELATED LICENSES

No Related Licenses

DOCUMENTS

No Public Documents Available

Attachment B

Regarding the DEA and FDA Registrations

Please note that a name and ownership change application is currently pending with the Drug Enforcement Agency (DEA). In the interim, a Power of Attorney will be entered into between the seller and buyer to allow the buyer to use the seller's DEA registrations (list 1 chemical and distributor) for business continuity until the new registrations are issued by DEA. Enclosed please find the current DEA certificate. Upon receipt, a copy of the updated certificate will be forwarded to your office.

Additionally, this facility is currently registered with the Food and Drug Administration (FDA) under the previous ownership and name, MD Logistics, Inc. Enclosed is a copy of the current proof of FDA registration for this facility. The name and ownership changes are pending with the FDA.

Establishment Registration & Device Listing

- FDA Home
- Medical Devices
- Databases

New Search

[Back To Search Results](#)

Establishment:

MD LOGISTICS
2150 Stanley Rd
Plainfield IN 46168

Plainfield, IN 46168

Registration Number: 3012429058

FBI Number: 3012429058

Status: Active

Date Of Registration Status: 2020

Owner/Operator:

MD Logistics LLC

2150 Stanley Road
Plainfield, IN 46168

Owner/Operator Number: 10051797

Official Correspondent:

Robert A Grange

2150 Stanley Road

Plainfield, IN 46168


Phone: 1-317-7073214

* Firm Establishment Identifier (FEI) should be used for identification of entities within the Imports message set

Page Last Updated: 09/14/2020

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Drug Establishments Current Registration Site

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[Search Results for MD Logistics](#)

CSV

Excel

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
MD Logistics, LLC	3004026589	965536525	LABEL, PACK	1301 Penny Road Ste 101, Plainfield, Indiana (IN) 46168, United States (USA)	12/31/2020


Showing 1 to 1 of 1 entries

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Establishment Registration & Device Listing

[FDA Home](#) | [Medical Devices](#) | [Databases](#)


New Search

[Back To Search Results](#)

Establishment:
 MD LOGISTICS
 2150 Stanley Rd
 Plainfield, IN 46168
Registration Number: 3012429058
FEI Number*: 3012429058
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
[MD Logistics](#)
 2150 Stanley Road
 Plainfield, IN US 46168
Owner/Operator Number: [10051797](#)

Official Correspondent:
 Robert A Grange
 2150 Stanley Road
 Plainfield, IN 46168
Phone: 1-317-7073214

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 05/18/2020

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U.S. Food and Drug Administration

 10903 New Hampshire Avenue
 Silver Spring, MD 20993
 Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)
[For Government](#)[For Press](#)[Combination Products](#)[Advisory Committees](#)[Science & Research](#)[Regulatory Information](#)[Safety](#)[Emergency Preparedness](#)[International Programs](#)[News & Events](#)[Training and Continuing Education](#)[Inspections/Compliance](#)[State & Local Officials](#)[Consumers](#)[Industry](#)[Health Professionals](#)[FDA Archive](#)

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 SHH
 MS



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Establishment Registration & Device Listing

[New Search](#)

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Establishment:

MD LOGISTICS

2150 Stanley Rd

Plainfield, IN 46168

Registration Number: 3012429058

FEI Number*: 3012429058

Status: Active

Date Of Registration Status: 2020

Owner/Operator:

MD Logistics LLC⁶

2150 Stanley Road

Plainfield, IN US 46168

Owner/Operator Number: [10051797](#)⁷

Official Correspondent:

Robert A Grange

2150 Stanley Road

Plainfield, IN 46168

Phone: 1-317-7073214

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
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5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10051797&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10051797&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=

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U.S. Department of **Health & Human Services**

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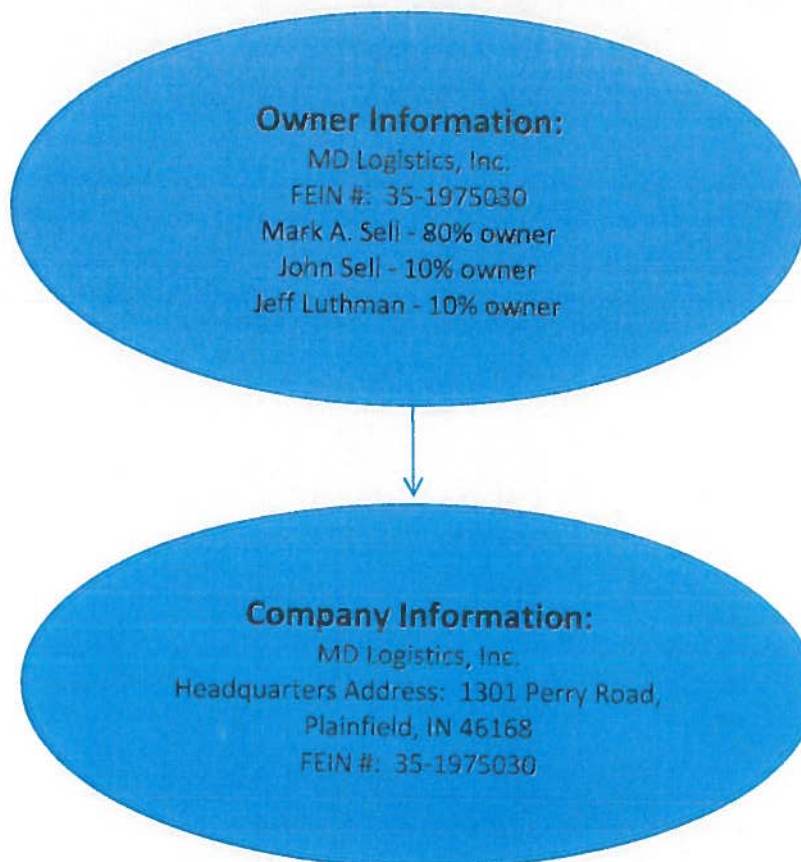
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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10051797&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10051797&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=

Attachment C

Regarding the Ownership and Name Changes

Effective on or around August 31, 2020, MD Logistics, Inc. will undergo changes in name and ownership. The company will first undergo a name change/conversion to MD Logistics LLC. The LLC will then go from being a company that is majority-owned by an individual, Mark A. Sell, to a company that is a wholly-owned subsidiary of Nippon Express U.S.A., Inc. This will result in changes to **the licensee's name and ownership**. **Note that there have been no changes to the company officers, federal Tax ID #, or facility addresses.** Documentation of the changes will be provided once available. Provided below is the pre and post-ownership change information.

Pre-Ownership/Name Change Information (prior to 8/31/2020):



Attachment C**Regarding the Ownership and Name Changes (cont.)****Post-Ownership/Name Change Information (after 8/31/2020):****Parent Company Information:**

Nippon Express U.S.A., Inc.
Address: 24-01 44th Rd., 14th Floor,
Long Island City, NY 11101
FEIN #: 13-1971441
Ownership % = 100%

**Wholly-Owned Subsidiary
Information:**

MD Logistics LLC (licensed entity)
Headquarters Address: 1301 Perry Road,
Plainfield, IN 46168
FEIN #: 35-1975030

Attachment D

Regarding the Drug Distributor Accreditation

This facility is currently certified with the National Association Boards of Pharmacy (NABP) and verification is available at the following website: <https://nabp.pharmacy/programs/drug-distributor/accredited-facilities/> under the previous ownership and name, MD Logistics, Inc.

Enclosed is a copy of the current DDA certificate for this facility. The name and ownership changes are pending with the NABP.

Drug Distributors

MD DISTRIBUTOR
ACCREDITATION

Apply

Criteria

Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State

(All)

Search

Reset

Current list of 4 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation

Name	Address	Accreditation Date
MD Logistics, Inc	1301 Perry Rd Plainfield, IN 46168	04/26/19
MD Logistics, LLC	12125 Moya Blvd Reno, NV 89506	09/02/18
MD Logistics, LLC	2150 Stanley Road, Ste 100 Plainfield, IN 46168	03/31/19
MD Logistics, LLC	2370 Perry Rd Plainfield, IN 46168	11/01/18

NABP ACCREDITED

DRUG DISTRIBUTOR

located at

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.



Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary



3/31/2019 - 3/30/2022

Period of Accreditation

verified
8/16/20
MS

Attachment E

LLC Officer Information

MD Logistics LLC

MD Logistics LLC is wholly-owned by Nippon Express U.S.A., Inc.

Mark A. Sell
President/CEO

**State of Indiana
Office of the Secretary of State**

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

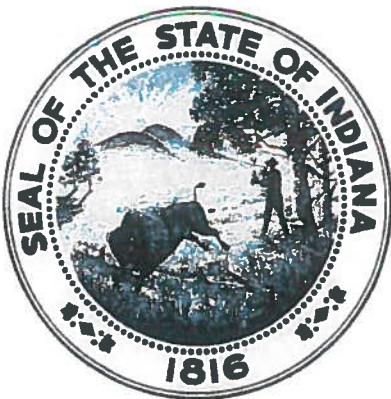
I, CONNIE LAWSON, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

MD LOGISTICS, LLC

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1995, and was in existence or authorized to transact business in the State of Indiana on August 25, 2020

I further certify this Domestic Limited Liability Company has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, August 25, 2020

Connie Lawson

CONNIE LAWSON
SECRETARY OF STATE

1995121421 / 20201592426

All certificates should be validated here: <https://bsd.sos.in.gov/ValidateCertificate>

Expires on September 24, 2020.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 60138507

Application/License No. _____

MD Logistics, LLC, doing or intending to do business as
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
1301 Perry Road, Plainfield, IN 46168, as
Address of Applicant/Principal
PRINCIPAL, and Capital Indemnity Corporation, a
Surety Company
 corporation organized under the laws of the state of Wisconsin,
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1600 Aspens Commons, Suite 300, Middleton, WI 53562, as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 31, 2020,
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are imposed pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

* Additional locations to be added to this bond:

2150 Stanley Road, Plainfield, IN 46168

12125 Moya Blvd., Reno, NV 89506

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of August, 2020.

APPLICANT/PRINCIPAL

SURETY

COMPANY

MD Logistics, LLC

Capitol Indemnity Company

Authorized Representative

Surety Company's Representative

Deborah M. Roth, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

SIGNED and SEALED in the presence of:

Witness

Witness

Witness

Witness

Countersigned by

N/A

Nevada Resident Agent

Posted February 20, 2020

Chad Hodges

.com

tanley Rd. Plainfield, IN 46168

EMPLOYMENT

Director of Pharma – MD Logistics – Plainfield, IN
August 2009 - Current

- Develops financial and operational objectives
- Ensures operational plans are in line with business objectives
- Manages resources to ensure financial objectives are met
- Develops relationships with key internal/external customers
- Leveraging knowledge of competitive advantage
- Resolves complex problems

Operations Manager – MD Logistics – Plainfield, IN
June 2006- August 2009

- Ensures compliance
- Reviews and approves reports, plans, schedules
- Vendor relations and negotiations
- Prepare and manage projects
- Reports on daily production, personnel, and quality statistics

Logistics Manager – Ryder Logistics – Plainfield, IN
March 2003 – February 2006

KEY SKILLS

- RedPrairie WMS Configuration
- RedPrairie Labor Management
- Microsoft Project, Excel, PowerPoint, Word, Visio
- QCBD
- RedPrairie Parcel
- Labelview
- EDI Flow

CERTIFICATES & MEMBERSHIPS

- DOT Security Training Certified
- Basic Operator Training for Basic Lift Trucks Certified
- Emergency Coordinator and Hazardous Waste Management Certified
- Red Prairie Training Certification

EDUCATION

- Indiana Wesleyan University – **Masters of Business Administration**
- Indiana State University – **Bachelor of Science in Business Management**
 - **Minor: Systems and Decision Sciences**
- Crawfordsville High School, Indiana – **HS Diploma**

4SS

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input checked="" type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Rhythm Pharmaceuticals, Inc.

Physical Address: 222 Berkeley Street 12th Floor

City: Boston State: MA Zip Code: 02116

Telephone Number: (857) 264-4294

Fax Number: _____

Toll Free Number: N/A

E-mail: licensing@rhythmtx.com

Website: http://www.rhythmtx.com/

Facility Manager: Jared Pray

Professional qualifications and experience of facility manager: _____

See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☒ Other: Specialty Pharmacies

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☒ No ☐

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A

Address:

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Nithya Desikan-Robertelli
Print Name of Authorized Person

7/15/20
Date

Board Use Only

Date Processed: _____

Amount: 600.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: N/ACorporation Name: Rhythm PharmaceuticalsMailing Address: 222 Berkeley StreetCity: Boston State: MA Zip: 02116Telephone: (857) 264-4294 Fax: N/AContact Person: Jared Pray

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 11/14/2019Registration number issued: 5287458Stock Exchange: RYTM

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114



CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000567	12/19/2019	12/19/2020	Virtual Drug Manufacturers

ISSUED TO

RHYTHM PHARMACEUTICALS, INC.
222 BERKELEY STREET
12TH FLOOR
BOSTON, MA 02116
ATTN: NITHYA DESIKAN CHIEF COMMERCIAL OFFICER

COMMISSIONER OF PUBLIC HEALTH

837522

RECIPIENT'S COPY

NEW



CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000567	12/19/2019	12/19/2020	Virtual Drug Manufacturers

ISSUED TO

RHYTHM PHARMACEUTICALS, INC.
222 BERKELEY STREET
12TH FLOOR
BOSTON, MA 02116
ATTN: NITHYA DESIKAN CHIEF COMMERCIAL OFFICER

NEW



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 Bureau of Health Professions Licensure
 Drug Control Program
 239 Causeway Street, Suite 500
 Boston, MA 02114

CHARLES D. BAKER
 Governor

KARYN E. POLITO
 Lieutenant Governor

MARYLOU SUDDERS
 Secretary
 MONICA BHAREL, MD, MPH
 Commissioner

Tel: 617-973-0949
 TTY : 617-973-0988
www.mass.gov/dph/boards

August 13, 2020

RE: Verification of Massachusetts Controlled Substances Registration (MCSR)

To whom it may concern:

Please be advised that **RHYTHM PHARMACEUTICALS, INC. (MA0000567)**, located at **222 BERKELEY STREET, 12TH FLOOR, BOSTON MA, 02116** has an active MCSR as a Drug Distributor and is in good standing. The current registration has an issue date of **12/19/2019** and expires on **12/19/2020**.

This Facility was last Reviewed by the Drug Control Program on **12/19/2019** and has met all the requirements for the Virtual Drug Manufacturer Controlled Substances Registration.

As of the date on this letter, there has been no disciplinary action issued by the Drug Control Program for this registrant.

Please note that the licensing authority for Drug Manufacturers and Distributors in Massachusetts is the Drug Control Program (DCP) and not the Massachusetts Board of Pharmacy.

Should you have any questions or concerns regarding the above information, please contact us at 617-973-0949.

Signed,

Ryan Walker, MPA
 Director, MCSR
 Massachusetts Department of Public Health

Online Licensure Verification Services: <https://www.mass.gov/service-details/registration-verification-for-mcsr>. The Information provided in this 'Certified Statement' is based on the records maintained by the Massachusetts Division of Health Professions Licensure and its licensing boards. Facilities are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the 'Certified Statement'. Disciplinary status is defined as voluntary surrender, revocation, suspension, or probation of a license.



OWNERSHIP

Rhythm Pharmaceuticals, Inc. ("Rhythm") is a publicly-held, Boston-based, clinical-stage pharmaceutical company that plans to develop and commercialize genetic obesity therapies across the United States. Rhythm is a publicly traded company (NASDAQ: RYTM).

COMPANY INFORMATION

Rhythm Pharmaceuticals, Inc.
222 Berkeley Street, 12th Floor
Boston, MA 02116
857-264-4280
Tax ID: 46-2159271

CORPORATE OFFICERS

Nithya Desikan, Chief Commercial Officer
222 Berkeley Street, 12th Floor
Boston, MA 02116
857-264-4280

Simon Kelner, Chief Human Resources Officer
222 Berkeley Street, 12th Floor
Boston, MA 02116
857-264-4280

Hunter Smith, Chief Financial Officer
222 Berkeley Street, 12th Floor
Boston, MA 02116
857-264-4280

Murray Stewart, Chief Medical Officer
222 Berkeley Street, 12th Floor
Boston, MA 02116
857-264-4280

DESCRIPTION OF OPERATIONS

Rhythm Pharmaceuticals, Inc. ("Rhythm") is a publicly held, Massachusetts-based, clinical-stage pharmaceutical company that plans to develop and commercialize genetic obesity therapies across the United States.

THIRD-PARTY LOGISTICS

Rhythm's products are manufactured by a contract manufacturer and distributed to customers by their third-party logistics provider, Cardinal Health Third Party Logistics Services. Rhythm utilizes the following facility for distribution of product:

Cardinal Health Third Party Logistics Services
501 Mason Road, Suite 200
La Vergne, TN 37086

CONTRACT MANUFACTURERS

Rhythm uses the following contract manufacturer to produce product:

Recipharm Monts
18 Rue de Montbazou
Monts, France 37 260
FEI Number: 1000171152
FEIN Expiration Date: 12/31/2020

PRODUCTS

As a virtual manufacturer, Rhythm does not manufacture, distribute or store product at their Massachusetts facility. At no time do contract manufacturers own Rhythm's products, contract with Rhythm's customers, invoice or sell Rhythm products. Rhythm's products are not controlled substances. Accordingly, Rhythm is not required to maintain DEA registration.

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RHYTHM PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF AUGUST, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.



5287458 8300

SR# 20206897370

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBULLOCK", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed in a small font.

Authentication: 203523740

Date: 08-24-20

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number 001-38223

RHYTHM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

46-2159271
(I.R.S. Employer
Identification No.)

500 Boylston Street
11th Floor
Boston, MA 02116
(Address of principal executive offices)
(Zip Code)

(857) 264-4280
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately \$640.8 million, based on the closing price of the registrant's Common Stock on June 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter.

There were 34,425,830 shares of Common Stock outstanding as of March 1, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2018. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

RHYTHM PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2018

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the “safe harbor” created by those sections. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. Some of the forward-looking statements can be identified by the use of forward-looking terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “might,” “likely,” “plans,” “potential,” “predicts,” “projects,” “seeks,” “should,” “target,” “will,” “would,” or similar expressions and the negatives of those terms include forward-looking statements that involve risks and uncertainties. Forward-looking statements include, but are not limited to, statements regarding our expectations regarding timing and enrollment of clinical trials, timing for the announcement of data and filing of regulatory applications, expectations regarding our indications for our product candidates, expectations regarding our strategy and commercial sales, anticipated expenses, the sufficiency of cash, and the impact of accounting pronouncements. We cannot guarantee future results, levels of activity, performance or achievements, and you should not place undue reliance on our forward-looking statements. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those set forth in “Item 1A. Risk Factors” and elsewhere in this Annual Report. Except as may be required by law, we have no plans to update our forward-looking statements to reflect events or circumstances after the date of this Annual Report. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.

Unless the content requires otherwise, references to “Rhythm Pharmaceuticals,” “Rhythm,” “the Company,” “we,” “our,” and “us,” in this Annual Report refer to Rhythm Pharmaceuticals, Inc. and its subsidiaries.

PART I

Item 1. Business

Overview

We are a biopharmaceutical company focused on the development and commercialization of therapeutics for the treatment of rare genetic disorders that result in severe, life-threatening metabolic disorders. Our lead product candidate is setmelanotide, a potent, first-in-class melanocortin-4 receptor, or MC4R, agonist peptide for the treatment of rare genetic disorders of obesity. We believe setmelanotide, for which we have exclusive worldwide rights, has the potential to serve as replacement therapy for the treatment of melanocortin-4, or MC4, pathway deficiencies. MC4 pathway deficiencies result in the disruption of satiety signals and energy homeostasis in the body, which, in turn, leads to intense feelings of hunger and to obesity. Our development efforts are initially focused on obesity related to six single gene-related, or monogenic, MC4 pathway deficiencies—pro-opiomelanocortin, or POMC, leptin receptor, or LEPR, Bardet-Biedl syndrome, Alström syndrome, POMC heterozygous, and POMC epigenetic disorders—for which there are currently no effective or approved treatments. We believe that the MC4 pathway is a compelling target for treating these genetic disorders because of its critical role in regulating appetite and weight by promoting satiety and weight control, and that peptide therapeutics are uniquely suited for activating this target.

We have demonstrated proof of concept in Phase 2 clinical trials in POMC deficiency obesity, LEPR deficiency obesity, Bardet-Biedl syndrome and Alström syndrome, four genetic disorders of extreme and unrelenting appetite and obesity, in which setmelanotide dramatically reduced both weight and hunger. The U.S. Food and Drug Administration, or the FDA, has acknowledged the importance of these results by giving setmelanotide Breakthrough Therapy designation for the treatment of obesity associated with genetic defects upstream of the MC4 receptor in the leptin-melanocortin pathway. This designation currently covers four Breakthrough Therapy designation indications: POMC deficiency obesity, LEPR deficiency obesity, Bardet-Biedl syndrome and Alström syndrome. Setmelanotide is currently in Phase 3 development for POMC deficiency obesity and LEPR deficiency obesity, and we have initiated a combined Phase 3 trial for Bardet-Biedl syndrome and Alström syndrome. In addition, in late June 2018 setmelanotide was designated as Priority Medicine, or PRIME, by the European Medicines Agency, or EMA, Committee for Medicinal Products for Human Use, or CHMP. We have completed enrollment in the pivotal cohorts for both our POMC deficiency obesity Phase 3 clinical

Cathy Folster

From: edrls@fda.hhs.gov
Sent: Thursday, January 31, 2019 7:13 AM
To: Cathy Folster
Subject: Labeler Code Request Approved

EXTERNAL EMAIL**eDRLS - Electronic Drug Registration & Listing System**

Current Date: 31-JAN-2019
Labeler DUNS: 061479535
Labeler Name: Rhythm Pharmaceuticals, Inc
Labeler Code: 72829

*Verified
8/27/20
MS*

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. **To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit [Drug Registration and Listing System](#) or reply back to this email (edrls@fda.hhs.gov).

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Font: Arial, 10, Bold, Italic, Underline, Color, Background Color, Paragraph: Bullets, Numbering, Indentation, Alignment, Styles: Clipboard, Font, Paragraph, Styles, Conditional Formatting, Data Validation, Protection, Comments, Help

ACROBAT

General

Number

Conditional Formatting

	A	B	C	D	E	F	G	H	I	J	K	L	M
		NDC/NHR											
1	Labeler	Firm											
2135	74105	Deviation Distilling LLC											
2136	61755	Regeneron Pharmaceuticals, Inc.											
2137	70859	Nucare Pharmaceuticals Inc											
2138	52128	Symbiotica Speciality Ingredients Sdn. Bhd.											
2139	73841	I G Sourcing, Inc.											
2140	78591	POLO LAND CORP											
2141	75847	IASO INC											
2142	69102	OWP Pharmaceuticals, Inc.											
2143	72531	YIRRH HEALTHY LIVING COMPANY											
2144	75098	Arrochem, Inc.											
2145	74199	Standard Spirit Corporation											
2146	66887	Endo Pharmaceuticals Inc.											
2147	62270	Tri-State Agri-Services, LLC											
2148	71517	Nutrastim Hair LLC											
2149	52381	Pluma Nacional, S.A. de C.V.											
2150	62037	Actavis Pharma, Inc.											
2151	67108	Baxter Healthcare Corporation											
2152	67194	Unit Dose, Ltd.											
2153	42534	Anshi Pharmaceutical (Zhongshan) Inc.											
2154	72829	Rhythm Pharmaceuticals, Inc.											
2155	62580	Frederick Memorial Hospital Home Medical Equipment & Supplies											
2156	50269	JC World Bell Wholesale Co., Inc											
2157	53145	Menper Distributors Inc											
2158	78376	Evaxo International Inc											
2159	74688	Marquis Energy-Wisconsin, LLC											
2160	80175	Central Packaging											
2161	52305	FRESHORIZE LTD											
2162	71178	S.P.O.R.T.S., LLC											
2163	52763	Golden Touch LLC											
2164	77804	KERN SANI, INC.											
2165	80198	SAI N M Ventures L L C											
2166	73197	Lunovus, LLC											
2167	55728	A&B Welding Supply Co.											
2168	66415	Antibiotice S.A.											
2169	79905	Beyond Environmental, LLC											
2170	61990	Apollo Pharmaceuticals Inc.											
2171	58839	VJAY FOOD PRODUCTS											
2172	78288	High Mark Distillery, Inc. DBA: High Mark Barrel House, Inc.											

Rhythm

PHARMACEUTICALS

Product List

Setmelanotide, subcutaneous injection – Labeler code - 72829

Executive Summary

A biotech professional with experience throughout the value chain, including:

- A key contributor to 4 different novel US drug launches in 3 therapeutic areas, from pre-launch planning and preparation through post-launch strategic adjustments and issue resolution
- Channel design and strategy, including the design and implementation of distribution channels for multiple drugs, encompassing a 3PL, specialty pharmacies, 340B customers, distributors, and a prescription & services Hub.
- Strategic marketing, with experience in developing strategy and tactics to be used with payers, including commercial, Medicaid and Medicare, and throughout the channel

Employment Experience

Rhythm Pharmaceuticals, Boston, Massachusetts

2018 - Present

Senior Director, US Market Access & Commercialization

- Building out US Market Access function to support the launch of novel rare disease therapy, including development of payer/channel strategy, pricing, and payer account management.
- Responsible for development of patient access strategy, including building a Patient Services Hub and integrated distribution channel
- Supported the development of Global Market Access & HEOR strategy, with a particular focus on EU5 markets
- Responsible for leading the commercialization in the first two indications for Rhythm's novel rare disease launch.

Wave Life Sciences, Cambridge, Massachusetts

2017 - 2018

Director, Market Access

- Responsible for the development and ultimately implementing all market access launch strategy, both US and ex-US, in support of Wave's rare neurology portfolio, including Payer Value Story, HEOR tactics, and Early Access Programs (EAP)
- As one of two commercially-focused employees, responsible for all early commercial launch planning, scheduling, & organizational strategy
- Developing strategy & operational plan for all Market Access Operations, including reimbursement and case management hub, 3PL, Distribution Channel, & Government Pricing systems.

Ironwood Pharmaceuticals, Cambridge, Massachusetts

2017

Director, Payer Marketing

- Led all payer marketing activities, development and launch of a Patient Assistance Program (PAP), and onboarding of a contract Account Management team for two launch products
- Joined the company at product launch, and left immediately after it became clear that the product would be pulled from the market

Biogen, Cambridge & Weston, Massachusetts

2006 - 2017

Associate Director, Hemophilia Payer & Channel Marketing

- Responsible for all marketing activities and tactics throughout the channel and to payers, including marketing to public and private payers as well as pharmacies and 340B treatment centers
- Developed payer strategies and ensured alignment on payer strategy throughout Market Access, Medical, and Brand
- Extensively supported account management team by traveling to key face-to-face payer and channel customer meetings, using learnings to inform future strategies and tactics
- Experience across the payer reimbursement spectrum, including buy-and-bill, medical benefit coverage and pharmacy benefit
- Managed external advertising agency in the development of tactics for field based personnel calling on payer and channel customers
- Represented hemophilia channel and payer strategies and customer perspectives on internal working groups for pricing and contracting
- Responsible for all aspects of Channel and Distribution in preparation for and leading through the launch of two Hemophilia brands (*ALPROLIX* & *ELOCTATE*), including implementation of Channel Strategy, Channel Marketing, oversight of 3PL and oversight of non-commercial (free goods) programs.

- Developed and implemented the distribution plan for the launch in support of overall brand & channel strategies. Channel customers include Specialty Pharmacies, 340B customers and Specialty Distributors. Coordinated with internal supply chain to establish commercially aligned processes for the market entry of the new products.

Manager, US Commercial Business Planning

- Overall project manager for the US Commercial Launch of *TECFIDERA*, called the "Holy mother of all launches" by analyst Mark Schoenebaum. Responsible for overseeing readiness and schedule for the commercialization of Biogen Idec's newest MS (Multiple Sclerosis) therapy across all areas of launch, including the Brand Team, HCP and Patient Marketing, Patient Advocacy, Managed Markets & Reimbursement, Sales, Medical Affairs, Marketing Analytics and Reporting, and Supply Chain.
- Tasked with identifying and highlighting any potentially misaligned strategies as discovered during weekly / bi-weekly meetings with key functional areas, and facilitating the discussion to ensure cross-functional strategic alignment.
- Responsible for leading the biweekly Launch Readiness meeting, as well as delivering an objective assessment of overall launch readiness and highlighting any areas of concern to US Commercial leadership
- Part of a team that designed a novel Commercial Distribution and Patient Support Strategy, implemented in a very tight timeline, ahead of launch.
- Post-launch, led the team that tracked & resolved Channel and Distribution challenges that resulted from patient volumes that far, far exceeded even the most optimistic forecasts.

Project Manager

- Overall Project Lead on Multiple Business-Critical Projects. Highlights include:
 - Led and managed the site-wide response to an unfavorable FDA inspection in Cambridge, MA. Ultimately, all response actions were successfully delivered on or ahead of schedule.
 - Communicated response progress to senior-level and executive management on an ongoing basis and incorporated their feedback.
 - For one key FDA-mandated project, built and managed a highly-productive, multi-disciplinary, and multi-national team of contractors and internal resources consisting of over 25 people. Through non-monetary incentives, created a high team moral and team pride in driving towards a very aggressive schedule. Overall result was a very successful project that delivered high-quality results ahead of schedule.

Process Engineer

- Managed smooth transition from development-scale to commercial-scale for multiple clinical drug products.
- Sent to Biogen's Hillerød, Denmark facility to scope design modifications and recommend staffing levels ahead of facility re-start
- Led cross-functional teams of four to ten people on regular basis

Stryker Corporation, Biotech Division, West Lebanon, NH and Hopkinton, MA

2004 - 2006

Project Engineer: Responsible for leading capital projects in support of Stryker's then-expanding Biotech Division

Akzo Nobel, Pasadena, Texas

2002 - 2004

Kvarntorp, Sweden

2000

Production Engineer: Responsibilities included overseeing production, project management, troubleshooting, and day-to-day process supervision in a large chemical plant

EDUCATION

Bentley University, Waltham, Massachusetts

Master of Business Administration (MBA), with Distinction

International Experience: Completed three separate intensive study-abroad programs in China, Eastern Europe (Hungary, Austria and the Czech Republic), and France

Dartmouth College (Tuck School of Business and Thayer School of Engineering,) Hanover, New Hampshire

Master of Engineering Management

The MEM is a professional degree offered jointly through the Tuck School of Business and Thayer School of Engineering.

Bucknell University, Lewisburg, Pennsylvania

Bachelor of Science in Chemical Engineering

August 12, 2020

Via Fed Ex

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

To Whom It May Concern:

On behalf of Rhythm Pharmaceuticals, Inc., attached is Rhythm Pharmaceuticals, Inc.'s application for licensure.

Rhythm Pharmaceuticals, Inc. is a biopharmaceutical company aimed at developing and commercializing therapies for the treatment of rare genetic disorders of obesity.

Rhythm Pharmaceuticals, Inc. is a "Virtual Manufacturer" whose products are manufactured by a contract manufacturer and distributed by a Third-Party Logistics Provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Rhythm Pharmaceuticals, Inc.'s office. Rhythm Pharmaceuticals, Inc.'s product is not a controlled substance. Accordingly, Rhythm Pharmaceuticals, Inc. is not required to obtain a DEA registration. At the time of this filing, Rhythm Pharmaceuticals, Inc. only holds a license in their home state of Massachusetts.

I hope this narrative is helpful as you review Rhythm Pharmaceuticals, Inc.'s application. If you have a question regarding this application, please contact me at 614-370-2801 or via email at stacie.borngrebe@twolabs.com. Please also address all written communication to me. My address is 2123 English Turn Dr., Grove City, OH 43123.

Thank you in advance for your consideration.

Stacie Borngrebe
Licensing Analyst
PharmaLicense

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 208, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 4027 Martinsburg Pike

City: Clear Brook, VA State: Zip Code: 22624 Telephone

Number: 540.409.3400 Fax Number:

Toll Free Number:

E-mail: Elaine.Stutman@McKesson.com Website: www.mckesson.com

Facility Manager: Benjamin Harper

Professional qualifications and experience of facility manager: see attached

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☐ Other:

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other:

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☒ No ☐

Licensed as Manufacturer by the FDA?
(If yes, provide a copy of your FDA registration)

Yes ☐ No ☒

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: see attached

Address:

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV19951055144

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐


4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Stanton McComb

Print Name of Authorized Person

Date

5/24/20

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATIONState of Incorporation: VirginiaParent Company if any: see attached, ultimate parent McKesson CorporationCorporation Name: McKesson Medical-Surgical Inc.Mailing Address: 6651 Gate ParkwayCity: Jacksonville State: FL Zip: 32256Telephone: 904.332.4179 Fax: 904.332.3349Contact Person: Elaine Stutman

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 7.7.1994Registration number issued: 2417015Stock Exchange: NYSE

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV19951055144

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions.*

In 2013, **McKesson** entered into a consent order with the Virginia Board of Pharmacy based on the discovery of McKesson product in a non-McKesson warehouse that did not have proper security or temperate controls. Without McKesson's knowledge, an independent courier had placed McKesson customer returns in a warehouse used by the courier. After a default on the lease, McKesson was informed that its product was in the warehouse, but when McKesson attempted to retrieve the product, the owner of the warehouse denied entry. The Virginia Board was informed of the issue and ultimately held McKesson responsible for the courier's activity. A \$4,000 penalty was assessed against McKesson's Landover, Maryland distribution center (this facility closed as of May 31, 2012).

In 2014 **McKesson** disclosed to the Michigan Board of Pharmacy final agency orders from Colorado, Georgia and Oklahoma that were issued between 2009 and 2012. , The Michigan Board of Pharmacy subsequently filed a complaint alleging that it is a violation of Michigan pharmacy law for a licensee to be the subject of administrative action in another state and asked McKesson to prove compliance with the agency orders in Colorado, Georgia, and Oklahoma. McKesson promptly supplied proof of compliance to the Michigan Board of Pharmacy. The Michigan Board of Pharmacy determined that McKesson had accepted responsibility in Colorado, Georgia, and Oklahoma and taken corrective measures to prevent re-occurrences of the issues that gave rise to those agency orders and the matter was resolved via consent order, pursuant to which McKesson accepted a reprimand and a fine.

In 2014, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning its Landover, Maryland distribution center (the “Landover DC”) that had closed in May 2012. The Final Consent Order resolved allegations that, from January 2008 – November 2009, McKesson’s Landover DC purchased approximately \$2.95 million of prescription drugs/devices from a wholesale distributor that was not licensed in Maryland. McKesson paid a \$30,000 fine in November 2014.

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson’s Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In April 2016 the **McKesson Medical-Surgical Inc.** Clear Brook, VA facility, which is a wholly-owned subsidiary of McKesson Corporation, was fined by the California Board of Pharmacy for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In September 2016, **McKesson Medical Surgical, Inc.** entered into a Consent Agreement for a \$2,750 fine with the Louisiana Board of Drug and Device concerning its St. Rose, Louisiana distribution center (the "St. Rose DC"). McKesson Medical Surgical, Inc agreed that it failed to maintain copies of current licenses for customers that are shipped or sold drugs or devices, or, if customer licenses are maintained offsite, by failing to maintain at the licensed distribution location a list of customer names, addresses, license numbers, and license expiration dates for all customers that are shipped or sold drugs or devices.

In 2016 **McKesson Packaging Services, a business unit of McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that McKesson Packaging Services failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since February 2, 2016 fully licensed. McKesson paid a \$500 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy at its Clear Brook, VA location for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by

Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On November 7, 2018, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Denver, Colorado distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid November 29, 2018. The Board released McKesson Medical-

Surgical Inc. from the terms and conditions of the December 6, 2018, Stipulation and Final Agency Order and restored the Registration to unencumbered status.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On March 1, 2019, the Ohio Board of Pharmacy sent a Notice of Opportunity for Hearing to the **McKesson Medical-Surgical Inc.** distribution center in Urbancrest, OH, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The allegations relate to an investigation that McKesson Medical-Surgical Inc. shipped dangerous drugs to an unlicensed site in September 2017. A monetary penalty of \$4,5000 was imposed and paid on March 27, 2019.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees.

On July 31, 2019 **McKesson Medical-Surgical Inc.** received a citation from the California Board of Pharmacy regarding its Urbancrest, OH location for failure to report a new Designated Representative within 30 days of change. No fine was assessed.

On August 29, 2019 **McKesson** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("**McKesson St. Louis**").

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of \$1,150.00.

On January 7, 2020 **McKesson** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

On January 14, 2020 **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of \$1,000 was imposed and paid on January 14, 2020.

On February 20, 2020, in response to the DEA Settlement, **McKesson** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 29, 2020 the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a

timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid in June 2020.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**



ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2020

OR



TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 1-13252

McKESSON

McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

94-3207296

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

6555 State Hwy 161,

Irving, TX 75039

(Address of principal executive offices, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)
Common stock, \$0.01 par value	MCK	New York Stock Exchange
0.625% Notes due 2021	MCK21A	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act: Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer



Accelerated filer



Non-accelerated filer



Smaller reporting company



Emerging growth company



If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act: ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report: ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2019, was approximately \$25 billion.

Number of shares of common stock outstanding on April 30, 2020: 161,853,218

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

SUBSIDIARIES OF THE REGISTRANT

There is no parent of the Company. The following is a listing of the significant subsidiaries of the Company.

	JURISDICTION OF ORGANIZATION
ClarusONE Sourcing Services LLP	United Kingdom
McKesson Europe AG	Germany
McKesson International Bermuda IP5A Limited	Bermuda
McKesson Medical-Surgical Inc.	United States
McKesson Medical-Surgical Supply Chain Services LLC	United States
McKesson Sourcing Services Inc.	United States
McKesson Specialty Care Distribution LLC	United States
McKesson Strategic Services Limited	United Kingdom
McKesson UK Finance I Limited	United Kingdom
McKesson US Finance Corporation	United States
Northstar Healthcare Holdings Unlimited Company	Ireland
US Oncology Holdings, Inc.	United States

Benjamin Harper

@hotmail.com
McWharton Way, Bunker Hill,

Objective To work for a company that allows you to manage your area of responsibility and grow your internal business to help the overall success of the company!

Skills & Abilities I have been associated with the transportation field for over 10 years now and I know that I bring a creative outlook on producing result and maximizing my resources.

Experience **Transportation Manager | McKesson Medical |**
July 2014 - Present

I manage 3 Trans supervisors with a total of 48 drivers that operate out of 6 different cross dock in the Mid-Atlantic area.

Projects:

- Moving from using outside carriers to our own McKesson drivers to deliver to our cross docks – I was able to save the company \$308,000 Annually. This entailed hiring 6 Class A CDL drivers.
- Worked to remove from a courier service that made deliveries for us in the Roanoke, VA market to an LTL carrier saving 225,000 Annually.

Operational Supervisor (Transportation) | FedEx Freight |
June 2010 – July 2014

- While as a city planner I was responsible for planning and prioritizing all city loads
- I was able to reduce our miles between stops from 5.3 to 2.4, I accomplished this by make sure I was routed their last delivery near their first pick up for the day.

Education **Shepherd University – Shepherdstown WV – Chemistry Major 2004-2006**
Some College – was a double major in Chemistry/Biology

Leadership/Volunteer Experience I currently help to promote growth in my locale community by holding a position on our youth soccer board for South Berkeley Soccer.

References **Reference Name**
Jason Baiana, McKesson
540-664-6128

Commonwealth of Virginia



State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.



Signed and Sealed at Richmond on this Date:

April 22, 2020

Joel H. Peck

Joel H. Peck, Clerk of the Commission

Ownership Information

McKesson Medical-Surgical Inc. (Federal ID 94-2640465), located at 4027 Martinsburg Pike Clear Brook, VA 22624 is 100% owned by

McKesson Medical-Surgical Inc., (Federal ID 94-2640465), 9954 Mayland Drive, Suite 4000, Richmond, VA 23233 which is 100% owned by

McKesson Medical-Surgical Holdings Inc., (Federal ID 13-3734754), 9954 Mayland Drive Suite 4000 Richmond, VA 23233 which is 100% owned by

McKesson Medical-Surgical Top Holdings Inc., (Federal ID 59-2280364), 6651 Gate Parkway, Jacksonville, FL 32256 which is 100% owned by:

McKesson Corporation, (Federal ID 94-3207296), 6535 N. State Highway 161, Irving, TX 75039– a publicly held company

McKesson Medical-Surgical Inc.
Officer Listing

Title	Name	Address	Phone	DOB
President; Director	Stanton J. McComb	9954 Mayland Drive, Suite 4000 Richmond, VA 23233		
VP & Treasurer; Director	Timothy Skansi	9954 Mayland Drive, Suite 4000 Richmond, VA 23233		
VP & Secretary; Director	Michele Lau	1 Post Street San Francisco, CA 94104		

LISTING OF SECURITY FEATURES ON REVERSE SIDE

COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Caroline D. Juran
Executive Director
(804) 367-4456

BOARD OF PHARMACY

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
www.dhp.virginia.gov/pharmacy

Wholesale Distributor Permit**Mckesson Medical-Surgical Inc.**

4027 Martinsburg Pike
Clear Brook VA 22624

Number
0215000405

To verify the status of this permit, visit our website www.dhp.virginia.gov, which is a primary source verification of the credential issued by the Commonwealth of Virginia. To File a Complaint About a Licensee, Call: 1-800-533-1560.

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

Wholesale Distributor**Number 0215000405****Mckesson Medical-Surgical Inc.**

To verify the current status of any license, permit or registration, visit our website at www.dhp.virginia.gov.

Verified
6/25/20
MS



Virginia Department of Health Professions License Lookup

Current as of 06/25/2020 17:47

License Information

License Number	0215000405
Occupation	Wholesale Distributor
Name	Mckesson Medical-Surgical Inc.
Address	4027 Martinsburg Pike Clear Brook, VA 22624
Initial License Date	12/06/2013
Expire Date	02/28/2021
License Status	Current Active
Additional Public Information*	No

[Back to License Lookup Result](#)

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.

[Back to License Lookup](#)

Facility Name

State

(All)



Search

Reset

Current list of 1 Verified-Accredited Wholesale Distributors[®]

VAWD accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
McKesson Medical-Surgical Inc	4027 Martinsburg Pike Clear Brook, VA 22624	Reaccreditation in process

Copyright © 2018 National Association of Boards of Pharmacy[®] (NABP[®]).

Verified
6/25/20
MS



The National Association of Boards of Pharmacy[®]
hereby awards

Verified-Accredited Wholesale Distributors[™]

Accreditation

to

McKesson Medical-Surgical Inc

located at

4027 Martinsburg Pike, Clear Brook, MD 20624

This facility has met all the Verified-Accredited Wholesale Distributors (VAD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAD section of the NABP website, located at www.nabp.pharmacy

Reaccreditation in Process

March 10, 2017 - March 9, 2020

Carleen A. Calzone, Executive Director/Secretary

Carleen Calzone

Period of Accreditation

National Association of Boards of Pharmacy | 1600 Federation Drive, Alexandria, VA 22304-1100 | www.nabp.org

Survey on hold due to COVID-19

Top 4 Rx Suppliers

1	26891 B. BRAUN MEDICAL INC	824 12TH AVENUE	BETHLEHEM	PA	180180000
2	4535800 MCKESSON CORPORATION	DC 8120	RUTHER GLEN	VA	225460000
3	27004 PFIZER INJECTABLES	CUST SRVC D 241 BLG H4	LAKE FOREST	IL	600450000
4	26650 BAXTER HEALTHCARE CORP	MEDICATION DELIVERY DIVISION	DEERFIELD	IL	600150000

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 208, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 885 Paragon Way

City: Rock Hill, SC State: SC Zip Code: 29730 Telephone

Number: 803.832.0132 Fax Number: _____

Toll Free Number: _____

E-mail: Elaine.Stutman@McKesson.com Website: www.mckesson.com

Facility Manager: Bradford Pittman

Professional qualifications and experience of facility manager: see attached

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☒ No ☐

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: see attached

Address:

Name:

Address:

Name:

Address:

Name:

Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV19951055144

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐


4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Stanton McComb

Print Name of Authorized Person

Date

5/24/20

Board Use Only

Date Processed: _____

Amount:

500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATIONState of Incorporation: VirginiaParent Company if any: see attached, ultimate parent McKesson CorporationCorporation Name: McKesson Medical-Surgical Inc.Mailing Address: 6651 Gate ParkwayCity: Jacksonville State: FL Zip: 32256Telephone: 904.332.4179 Fax: 904.332.3349Contact Person: Elaine Stutman

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 7.7.1994Registration number issued: 2417015Stock Exchange: NYSE

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV19951055144

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions.*

In 2013, **McKesson** entered into a consent order with the Virginia Board of Pharmacy based on the discovery of McKesson product in a non-McKesson warehouse that did not have proper security or temperate controls. Without McKesson's knowledge, an independent courier had placed McKesson customer returns in a warehouse used by the courier. After a default on the lease, McKesson was informed that its product was in the warehouse, but when McKesson attempted to retrieve the product, the owner of the warehouse denied entry. The Virginia Board was informed of the issue and ultimately held McKesson responsible for the courier's activity. A \$4,000 penalty was assessed against McKesson's Landover, Maryland distribution center (this facility closed as of May 31, 2012).

In 2014 **McKesson** disclosed to the Michigan Board of Pharmacy final agency orders from Colorado, Georgia and Oklahoma that were issued between 2009 and 2012. , The Michigan Board of Pharmacy subsequently filed a complaint alleging that it is a violation of Michigan pharmacy law for a licensee to be the subject of administrative action in another state and asked McKesson to prove compliance with the agency orders in Colorado, Georgia, and Oklahoma. McKesson promptly supplied proof of compliance to the Michigan Board of Pharmacy. The Michigan Board of Pharmacy determined that McKesson had accepted responsibility in Colorado, Georgia, and Oklahoma and taken corrective measures to prevent re-occurrences of the issues that gave rise to those agency orders and the matter was resolved via consent order, pursuant to which McKesson accepted a reprimand and a fine.

In 2014, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning its Landover, Maryland distribution center (the “Landover DC”) that had closed in May 2012. The Final Consent Order resolved allegations that, from January 2008 – November 2009, McKesson’s Landover DC purchased approximately \$2.95 million of prescription drugs/devices from a wholesale distributor that was not licensed in Maryland. McKesson paid a \$30,000 fine in November 2014.

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson’s Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant

additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In April 2016 the **McKesson Medical-Surgical Inc.** Clear Brook, VA facility, which is a wholly-owned subsidiary of McKesson Corporation, was fined by the California Board of Pharmacy for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In September 2016, **McKesson Medical Surgical, Inc.** entered into a Consent Agreement for a \$2,750 fine with the Louisiana Board of Drug and Device concerning its St. Rose, Louisiana distribution center (the "St. Rose DC"). McKesson Medical Surgical, Inc agreed that it failed to maintain copies of current licenses for customers that are shipped or sold drugs or devices, or, if customer licenses are maintained offsite, by failing to maintain at the licensed distribution location a list of customer names, addresses, license numbers, and license expiration dates for all customers that are shipped or sold drugs or devices.

In 2016 **McKesson Packaging Services, a business unit of McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that McKesson Packaging Services failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since February 2, 2016 fully licensed. McKesson paid a \$500 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Washington Court House, OH distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since August 6, 2014 fully licensed. McKesson paid \$400 fine. The fine is related to a non-disciplinary action.

In 2016 **McKesson Medical-Surgical Inc.** a wholly-owned subsidiary of McKesson Corporation was fined by the California Board of Pharmacy at its Clear Brook, VA location for failure to report a new Designated Representative within 30 days of change. McKesson paid \$200 fine. The fine is related to a non-disciplinary action.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland

facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018 May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017 fully licensed. McKesson paid \$1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On November 7, 2018, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Denver, Colorado distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid November 29, 2018. The Board released McKesson Medical-Surgical Inc. from the terms and conditions of the December 6, 2018, Stipulation and Final Agency Order and restored the Registration to unencumbered status.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On March 1, 2019, the Ohio Board of Pharmacy sent a Notice of Opportunity for Hearing to the **McKesson Medical-Surgical Inc.** distribution center in Urbancrest, OH, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The allegations relate to an investigation that McKesson Medical-Surgical Inc. shipped dangerous drugs to an unlicensed site in September 2017. A monetary penalty of \$4,5000 was imposed and paid on March 27, 2019.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and

Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees.

On July 31, 2019 **McKesson Medical-Surgical Inc.** received a citation from the California Board of Pharmacy regarding its Urbancrest, OH location for failure to report a new Designated Representative within 30 days of change. No fine was assessed.

On August 29, 2019 **McKesson** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("**McKesson St. Louis**").

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of \$1,150.00.

On January 7, 2020 **McKesson** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

On January 14, 2020 **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of \$1,000 was imposed and paid on January 14, 2020.

On February 20, 2020, in response to the DEA Settlement, **McKesson** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 29, 2020 the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of \$1,150 was imposed and paid in June 2020.

Pending Actions

The Georgia Board of Pharmacy issued a proposed consent order and **McKesson Corporation** is responding but have not finalized any agreement with the state.

The Delaware Board of Pharmacy issued a proposed consent order and **McKesson Corporation** is responding but have not finalized any agreement with the state.

The Illinois Department of Financial and Professional Regulation informed **McKesson Corporation** that the state would be seeking disciplinary action against Illinois licensed facilities. Please note that for the above-referenced pending actions, no final action has been taken and all relate directly to reciprocal discipline related to the DEA Settlement Agreement.

Top 4 Suppliers

1	26891 B. BRAUN MEDICAL INC	824 12TH AVENUE	BETHLEHEM PA
2	26593 MCKESSON CORPORATION	2975 EVERGREEN DRIVE	DULUTH GA
3	22702 AMERICAN REGENT LABS, INC.	ONE LUITPOLD DRIVE	SHIRLEY NY
4	27122 BRISTOL MYERS SQUIBB COMPANY	777 SCUDDERS MILL ROAD	PLAINSBORO NJ

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended March 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 1-13252

MCKESSON

McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

94-3207296

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

6555 State Hwy 161,

Irving, TX 75039

(Address of principal executive offices, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<i>(Title of each class)</i>	<i>(Trading Symbol)</i>	<i>(Name of each exchange on which registered)</i>
Common stock, \$0.01 par value	MCK	New York Stock Exchange
0.625% Notes due 2021	MCK21A	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

☒

Accelerated filer

☐

Non-accelerated filer

☐

Smaller reporting company

☐

Emerging growth company

☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2019, was approximately \$25 billion.

Number of shares of common stock outstanding on April 30, 2020: 161,853,218

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

SUBSIDIARIES OF THE REGISTRANT

There is no parent of the Company. The following is a listing of the significant subsidiaries of the Company.

	JURISDICTION OF ORGANIZATION
ClarusONE Sourcing Services LLP	United Kingdom
McKesson Europe AG	Germany
McKesson International Bermuda IP5A Limited	Bermuda
McKesson Medical-Surgical Inc.	United States
McKesson Medical-Surgical Supply Chain Services LLC	United States
McKesson Sourcing Services Inc.	United States
McKesson Specialty Care Distribution LLC	United States
McKesson Strategic Services Limited	United Kingdom
McKesson UK Finance I Limited	United Kingdom
McKesson US Finance Corporation	United States
Northstar Healthcare Holdings Unlimited Company	Ireland
US Oncology Holdings, Inc.	United States

BRADFORD PITTMAN

1 Forest Home Drive, Fort Mill, SC

C: -

.com

PROFESSIONAL SUMMARY

SKILLS

- Cost reduction strategies
- Project planning and development
- Budgeting and forecasting
- Merger and Acquisitions
- Quality assurance and control
- Logistics management
- Risk management
- Vendor sourcing
- Human resources management
- Employee relations
- Project development and life cycle
- Work flow planning
- Contract negotiation
- Unsurpassed work ethic
- Advanced training in Microsoft Office Tools

WORK HISTORY

Distribution Center Leader, 06/2015 to Current

McKesson Medical-Surgical, Inc. – Rock Hill, SC

- Manage all aspects of a newly constructed 300,080 square foot distribution center for the purpose of order fulfillment and distribution of pharmaceuticals and medical surgical supplies to extended and primary care sites.
- Manage capital funding requests of up to \$28 million from project approval to project closeout.
- Supervise a team of 4 distribution center managers and 210 personnel.
- Prepare and manage budgets, forecasts and primary P&L responsibility for \$241 million in revenue.
- Coordinate business activities with 6 Sales Managers and 76 Account Managers
- Lead corporate initiatives such as labor management programs, certified cold chain process, packing standardization, compliant waste disposal and pharmaceutical credit compliance.
- Reduced employee turnover significantly in comparison to previous DC implementations through building an employee on boarding program, setting them up for success and building a great culture.

Distribution Center Leader, 12/2014 to 06/2015

McKesson Medical Surgical, Inc. – Charlotte, NC

- Managed 2 Distribution Centers in North Carolina. A 65,000 square foot primary care site in Charlotte, NC employing 84 personnel and a 50,000 square foot extended care site in Raleigh, NC employing 35 personnel.
- Established budgets and held primary responsibility for \$123 million in revenue.
- Coordinated business activities with 4 Sales Leaders and 48 Account Managers.
- Established operational objectives, work plans and delegated assignments to subordinate managers.
- Helped earn the company 96% customer satisfaction ratings through process improvements to order fulfillment and transportation.
- Led the process for closing both distribution centers as part of an integration strategy and new construction of the Rock Hill, SC site.

Operations Leader I, 06/2009 to 12/2014

PSS World Medical, Inc. – Charlotte, NC

- Managed a 65,000 square foot primary care distribution center employing 84 personnel.
- Established budgets and held primary P&L responsibility for \$93 million in revenue.
- Coordinated business activities with 3 Sales Leaders and 40 Account Managers.
- Managed order fulfillment activities, distribution, compliance and customer accounts receivable.

- Led the distribution center from the least performing operation to the top performing within 2 years of assuming control.
- Reduced accounts receivable from 15% over 60 to less than 2% through process improvement, and most importantly working with our customers and account managers without a loss in revenue.

Operations and Compliance Leader, 01/1998 to 06/2009

Southern Anesthesia and Surgical – Columbia, SC

- Managed a 55,000 square foot distribution and office site serving the Oral and Maxillofacial industry employing 65 personnel.
- Established budgets and held primary P&L responsibility for \$55 million in revenue.
- Supervised a team of 4 leaders responsible for compliance, procurement, order fulfillment and customer service.
- Developed and ensured compliance to DEA regulations regarding the sale and distribution of controlled pharmaceuticals.
- Established tracking and compliance to PDMA regulations regarding distribution of pharmaceuticals and pedigree.
- Selected, purchased and implemented the JDE OneWorld ERP system significantly improving the operation.
- Assisted the owner with the sale of Southern Anesthesia to PSS World Medical.

Procurement/Key Account Sales/Inventory Control/Systems Administrator, 02/1994 to 01/1998

Southern Anesthesia and Surgical – Columbia, SC

- Held numerous positions in a private fast growing medical supply company serving the Oral and Maxillofacial market.
- Increased company profit by reducing operating expenses and improving buy side margins.

EDUCATION

Bachelor of Science: Business Administration - Management, 1996

University of South Carolina - Columbia, SC

MBA: Business Administration - Management, 2004

University of South Carolina - Columbia, SC

ACCOMPLISHMENTS

- Generated \$8 million in first-year profit growth by developing and leading a companywide initiative to promote customer sales from branded to our private brand offering at PSS World Medical.
- Improved profitability at Southern Anesthesia by \$4 million through vendor contract negotiations.
- Developed a working relationship with the DEA, FDA and other entities throughout my career, passing all inspections with no recommendations or improvement action items.
- Developed controlled pharmaceutical suspicious order tracking system meeting and exceeding DEA requirements.
- Implemented and led Lean Processes for PSS World Medical for the Charlotte distribution center.
- Nominated 5 times for the most prestigious award in PSS World Medical and Mckesson Medical Surgical. The Eagle Award is voted on by peers and senior leadership. I received the award 2012, 2014 and 2015.
- Nominated and served on the Operations Excellence Team for PSS World Medical and Mckesson for 7 years.

CERTIFICATIONS

Certified Designated Representative – State of California – EXC19849

Certified Designated Representative – State of Florida – 88:10890

Certified Designated Representative – State of South Carolina, Arizona, Tennessee, Virginia

PRC 1039971

PERMIT NO. 15689
DATE ISSUED: 07/01/2020

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy
Non-Dispensing Drug Outlet Permit

2020-2021

Expires 06/30/2021

MCKESSON MEDICAL-SURGICAL, INC.
Permit Holder: BRADFORD PITTMAN
885 PARAGON WAY
ROCK HILL SC 29730


Eric Strauss, Chairman


J. Addison Livingston, Vice Chairman

[Print this page](#)**South Carolina Board of Pharmacy****McKESSON MEDICAL-SURGICAL, INC.**

885 PARAGON WAY
ROCK HILL, SC 29730

License number: 15689**License type:** Non-Dispensing Drug Outlet**Status:** Active**First Issue Date:** 03/12/2015**Expiration:** 06/30/2021[File a Complaint against this licensee](#)

No disciplinary action taken by the Board. This certifies that the above licensee is in good standing.

Board Public Action History:[View Orders](#)[View Other License for this Person](#)

No Orders Found

NABP ACCREDITED

DRUG DISTRIBUTOR

McKesson Medical-Surgical Inc.

located at

885 Paragon Way, Rock Hill, SC 29730

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.



Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary



06/03/2019 - 06/02/2022

Period of Accreditation

Verified
6/25/20
VMS

Commonwealth of Virginia



State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.



Signed and Sealed at Richmond on this Date:

April 22, 2020

Joel H. Peck

Joel H. Peck, Clerk of the Commission

Officer Listing

Title	Name	Address	Phone	DOB
President; Director	Stanton J. McComb	Mayland Drive, Suite Richmond, VA		
VP & Treasurer; Director	Timothy Skansi	Mayland Drive, Suite Richmond, VA		
VP & Secretary; Director	Michele Lau	Post Street San Francisco, CA		

Ownership Information

McKesson Medical-Surgical Inc. (Federal ID 94-2640465), located at 885 Paragon Way, Rock Hill, SC 29730 is 100% owned by

McKesson Medical-Surgical Inc., (Federal ID 94-2640465), 9954 Mayland Drive Suite 4000, Richmond, VA 23233 which is 100% owned by

McKesson Medical-Surgical Holdings Inc., (Federal ID 13-3734754), 9954 Mayland Drive Suite 4000, Richmond, VA 23233 which is 100% owned by

McKesson Medical-Surgical Top Holdings Inc., (Federal ID 59-2280364), 6651 Gate Parkway Jacksonville, FL 32256 which is 100% owned by:

McKesson Corporation, (Federal ID 94-3207296), 6535 N. State Highway 161, Irving, TX 75039— a publicly held company

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: McKesson Specialty Distribution LLC

Physical Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: Pending Fax Number: Pending

Toll Free Number: Pending

E-mail: mckessonlicensing@mckesson.com Website: www.mckesson.com

Facility Manager: Coleman Harris

Professional qualifications and experience of facility manager: See Attached Resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers
☒ Other: Health Departments & Clinics

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☒ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: New facility - no purchases yet.

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20041313052

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐


4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau

9/2/20

Print Name of Authorized Person

Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: McKesson CorporationCorporation Name: McKesson Specialty Distribution LLCMailing Address: 6535-6555 State Hwy 161City: Irving State: TX Zip: 75039Telephone: 972-446-4800 Fax: _____Contact Person: Maria Spencer

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 7/7/1994Registration number issued: 2417015Stock Exchange: NYSE - MCK

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV19951055144

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

McKesson Specialty Distribution LLC

FEIN: 20-1858098

Delaware Limited Liability Company incorporated on 11/04/2004.

Parent Company:

McKesson Corporation

6535 N. State Highway 161, Irving, TX 75039

FEIN: 94-3207296

Corporate Officers

Kirk Kaminsky, President

North State Highway 161, Irving, TX 75039

SSN:

DOB:

Todd Baldanzi, Vice President and Treasurer

North State Highway 161, Irving, TX 75039

SSN:

DOB:

Michele Lau, Vice President and Secretary

Post Street, San Francisco, CA 94104

SSN:

DOB:

Application Contact:

Beatrix Erdei, Sr. Manager, Compliance and Regulatory Affairs

Phone: 415-983-9247

Email: mckessonlicensing@mckesson.com

6651 Gate Parkway, Regulatory Affairs/McKesson, Jacksonville, FL 32256

Description of Operation

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2020

OR

☐

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 1-13252**McKESSON****McKESSON CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3207296

(I.R.S. Employer Identification No.)

6555 State Hwy 161,Irving, TX 75039

(Address of principal executive offices, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)
Common stock, \$0.01 par value	MCK	New York Stock Exchange
0.625% Notes due 2021	MCK21A	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: NoneIndicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer☒

Accelerated filer

☐

Non-accelerated filer

☐

Smaller reporting company

☐

Emerging growth company

☐If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2019, was approximately \$25 billion.

Number of shares of common stock outstanding on April 30, 2020: 161,853,218

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

State Of Delaware

Entity Details

9/2/2020 12:50:36PM

File Number: 3877194

Incorporation Date / Formation Date: 11/4/2004

Entity Name: MCKESSON SPECIALTY DISTRIBUTION LLC

Entity Kind: Limited Liability Company

Entity Type: General

Residency: Domestic

State: DELAWARE

Status: Good Standing

Status Date: 11/4/2004

Registered Agent Information

Name: CORPORATION SERVICE COMPANY

Address: 251 LITTLE FALLS DRIVE

City: WILMINGTON

Country:

State: DE

Postal Code: 19808

Phone: 302-636-5401

Attachment

Home State License

The applicant is applying for the resident state license. We will provide this license as soon as we receive them.

- **Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.**

McKesson Corporation and its subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.*

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson's Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In January 2017, **McKesson** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In February 2017, in response to California Board of Pharmacy fine **McKesson Specialty Distribution LLC** was fined by the Florida Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics for failing to operate in compliance with applicable state law. McKesson paid the \$1,500 fine. The fine is related to a non-disciplinary action.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** (Lakeland distribution center) entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution

centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making

deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees.

On August 29, 2019 **McKesson** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of \$1,150.00.

On January 7, 2020 **McKesson** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

On February 20, 2020, in response to the DEA Settlement, **McKesson** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

COLEMAN B. HARRIS

m • (719)

Linkedin.com/in/colemanharris

OPERATIONS AND DISTRIBUTION MANAGEMENT PROFESSIONAL

Supply Chain Management • Distribution Center Operations • Leadership • Process Improvement

Accomplished leader with over 12 years of managerial and operations experience that drives results through a culture of high performance, continuous learning and team-oriented leadership. Proven ability to effectively prioritize operations and conduct strategic planning and forecasting. Directed significant programs, creating innovative supply chain solutions and systems improvement. Demonstrated success developing training programs and mentoring team members for continuous growth and future advancement.

- Proven leader of teams exceeding 100 employees within the military and corporate America
- Recognized as an Exceptional Performance Leader by a Fortune #8 company
- Successfully managed customer relations with over 1600 pharmacy accounts and \$160M in on-site inventory
- Bronze Star recipient for exceptional meritorious service in support of Operation Enduring Freedom

EXPERIENCE

MCKESSON CORPORATION,

2017—Present

Logistics Manager, National Redistribution Center (NOV2019 – Present)

Lead a Logistics Team with 6 direct reports responsible for the on-time movement of 200+ weekly high-value truck loads to 26 forward distribution centers across the United States. Manage strong carrier portfolio that exceeds 98.5% on-time delivery. Actively manage transportation costs and carrier scorecards to drive superior performance.

Key Achievements:

- Streamlined transportation lanes that resulted in \$1.4M in savings for the year, within 60 days in role.
- Created automated tools that consolidated reporting that led to significant labor optimization within team.
- Developed innovative carrier scorecard and dynamic cost analysis tools resulting in an increase in visibility and carrier performance.

MCKESSON CORPORATION, McCalla, AL

2017—Present

Distribution Center Inventory Manager (MAY2017 – NOV2019)

Led a pharmaceutical inventory control team with 11 direct reports essential to the execution of five distribution center functions: quality control, reverse logistics, regulatory, warehouse optimization and customer service.

Key Achievements:

- Selected as an Exceptional Performance Leader FY19 due to high leader engagement, exceeding performance metrics and demonstrating leadership potential two levels above current role
- Awarded Top Performing Distribution Center 2019 and achieved record breaking performance by reducing inventory loss below .005% of \$160M for 18 months consecutive
- Exceeded critical performance metrics in FY19: Cost Per Line by 5% resulting in \$400k savings, Inventory Control by 243% resulting in \$45k savings and Safety Index improved by 25% YOY

LOVES TRAVEL STOPS, McCalla, AL

2016—2017

Operations Manager (MAY2016 – MAY2017)

Managed high volume retail facility and supported the development of operational programs, budget trend analysis and accountable for profit and loss. Led internal operations to include sales, inventory, customer service and maintenance.

Key Achievements:

- Selected for promotion to GM after 10 months for outstanding leadership and achieving performance goals
- Decreased facilities turnover rate from 225% to under 120% within 6 months through quality recruiting practices and high leader engagement
- Decreased loss by 20% by collaborating with team leadership and streamlining inventory management practices

Coleman B. Harris - Page 2

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• [Linkedin.com/in/colemanharris](https://www.linkedin.com/in/colemanharris)**UNITED STATES ARMY, Fort Carson, CO**

2008—2016

Company Commander (SEP2014 – MAY2016)

Led 99-person company cross-functionally and synchronized logistics for 577-person organization. Managed four logistics programs simultaneously to include food service, transportation, supply and maintenance.

Key Achievements:

- Earned Meritorious Service Medal for the development and launch of logistics model that optimized performance and program efficiency; ranked #1 of 6 units at the National Training Center
- Created optimal supply discipline program; reduced shortages by 570%, from \$1.2 million to \$210,000
- Managed 297 vehicles, largest combat fleet out of 6 units in 4,000-person Brigade; exceeded 90% readiness

UNITED STATES ARMY, Fort Carson, CO

2008—2016

Logistics Development Officer (OCT2012 – SEP2014)

Developed and integrated creative solutions for the training, fielding, maintenance, and logistics programs of the Afghan National Army and Regional Logistics Support Command while deployed to Afghanistan.

Key Achievements:

- Earned Bronze Star for developing and spearheading innovative training program resulting in a 35% increase in Afghan Army maintenance operational readiness
- Generated comprehensive progress reviews to measure growth and develop improvement plans for the Afghanistan National Army; reviews impacted regional and national Ministry of Defense policies

UNITED STATES ARMY, Fort Riley, KS

2008—2016

Logistics Plans Officer (JUN2011 – OCT2012)

Provided, directed and synchronized timely and accurate logistics support to 3,700 Soldiers, 110 army aviation aircraft and over 500 motorized vehicles for Brigade Global Response Force mission.

Key Achievements:

- Earned Army Commendation for producing combat ready force capable of deploying within 48 hours worldwide
- Received additional Army Commendation Medal for creating response team initiative and training program, resulting in the recovery of downed aircraft in combat area

UNITED STATES ARMY, Fort Riley, KS

2008—2016

Senior Transportation Officer (JAN2011 – JUN2011)

Led team providing logistics and transportation support for over 4,100 Soldiers employing 550 vehicles and 233 aircraft in Iraq. Managed airfield control team at Taji Airbase to ensure safe boarding and departure of personnel and cargo.

Key Achievements:

- Led and coordinated flights that moved 3,550 Soldiers and 233 aircraft from Iraq to US with no incidents
- Directed and synchronized Army and Air Force ground and aviation assets; resulted in successful execution of 51 high priority missions across Iraq that delivered critical aviation assets essential to 95% readiness rate

UNITED STATES ARMY, Fort Riley, KS

2008—2016

Brigade Adjutant (MAR2010 – JAN2011)

Planned and synchronized protocol and logistics for Brigade Commander, distinguished visitors and VIPs for 3,700-person Brigade in Iraq for 12 months. Manage Brigade commander's schedule and enable battlefield site visits.

Key Achievements:

- Selected through special appointment by senior commander; rated top 1% of 98 lieutenants in Brigade
- Earned Army Commendation Medal for exceptionally meritorious service during combat operations in Iraq

EDUCATION AND CREDENTIALS**UNIVERSITY OF ARKANSAS, Fayetteville, AR**

December 2007

Bachelor of Arts, Music

4WW

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: McKesson Specialty Distribution LLC

Physical Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: Pending Fax Number: Pending

Toll Free Number: Pending

E-mail: mckessonlicensing@mckesson.com Website: www.mckesson.com

Facility Manager: Neil Chabot

Professional qualifications and experience of facility manager: See Attached Resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers
☒ Other: Health Departments & Clinics

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☒ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☒ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA?
(If yes, provide a copy of your FDA registration)

Yes ☐ No ☒

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: New facility - no purchases yet.

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20041313052

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐


4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michele Lau
Print Name of Authorized Person

9/2/20
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: McKesson CorporationCorporation Name: McKesson Specialty Distribution LLCMailing Address: 6535-6555 State Hwy 161City: Irving State: TX Zip: 75039Telephone: 972-446-4800 Fax: _____Contact Person: Maria Spencer

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 7/7/1994Registration number issued: 2417015Stock Exchange: NYSE - MCK

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV19951055144

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 1-13252

McKESSON

McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3207296

(I.R.S. Employer Identification No.)

6555 State Hwy 161,

Irving, TX 75039

(Address of principal executive office, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)
Common stock, \$0.01 par value	MCK	New York Stock Exchange
0.625% Notes due 2021	MCK21A	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

☒

Accelerated filer

☐

Non-accelerated filer

☐

Smaller reporting company

☐

Emerging growth company

☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2019, was approximately \$25 billion.

Number of shares of common stock outstanding on April 30, 2020: 161,853,218

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

McKesson Specialty Distribution LLC

FEIN: 20-1858098

Delaware Limited Liability Company incorporated on 11/04/2004.

Parent Company:

McKesson Corporation

6535 N. State Highway 161, Irving, TX 75039

FEIN: 94-3207296

Corporate Officers

Kirk Kaminsky, President

5 North State Highway 161, Irving, TX 75039

SSN:

DOB:

Todd Baldanzi, Vice President and Treasurer

North State Highway 161, Irving, TX 75039

SSN:

DOB:

Michele Lau, Vice President and Secretary

1000 Post Street, San Francisco, CA 94104

SSN:

DOB:

Application Contact:

Beatrix Erdei, Sr. Manager, Compliance and Regulatory Affairs

Phone: 415-983-9247

Email: mckessonlicensing@mckesson.com

6651 Gate Parkway, Regulatory Affairs/McKesson, Jacksonville, FL 32256

Description of Operation

Attachment

Home State License

The applicant is applying for the resident state license. We will provide this license as soon as we receive them.

State Of Delaware

Entity Details

9/2/2020 12:50:36PM

File Number: 3877194

Incorporation Date / Formation Date: 11/4/2004

Entity Name: MCKESSON SPECIALTY DISTRIBUTION LLC

Entity Kind: Limited Liability Company

Entity Type: General

Residency: Domestic

State: DELAWARE

Status: Good Standing

Status Date: 11/4/2004

Registered Agent Information

Name: CORPORATION SERVICE COMPANY

Address: 251 LITTLE FALLS DRIVE

City: WILMINGTON

Country:

State: DE

Postal Code: 19808

Phone: 302-636-5401

- **Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.**

McKesson Corporation and its subsidiaries (hereinafter “McKesson”) delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 97 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. *The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.*

In 2015, **McKesson** entered into a Final Consent Order with the Maryland Board of Pharmacy concerning Landover DC. The Final Consent Order resolved allegations that, from January 2009 – December 2009, McKesson’s Landover DC purchased approximately \$2.5 million of prescription drugs/devices from an unlicensed wholesale distributor. Since the period when the alleged violations occurred, McKesson has made numerous enhancements and significant additional investments in its compliance program related to the acquisition and distribution of pharmaceutical drug products. McKesson paid a \$15,000 fine in June 2015.

In January 2017, **McKesson** entered into an agreement (the “DEA Settlement”) with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson’s practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay \$150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers’ DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson’s contract with the Department of Veterans Affairs.

In February 2017, in response to California Board of Pharmacy fine **McKesson Specialty Distribution LLC** was fined by the Florida Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics for failing to operate in compliance with applicable state law. McKesson paid the \$1,500 fine. The fine is related to a non-disciplinary action.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson's** Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In September 2017, in response to the DEA Settlement, the Colorado State Board of Pharmacy placed the wholesaler registration of **McKesson's** distribution center in Aurora, Colorado (14500 39th Ave) on probation. McKesson also agreed to pay a fine of \$45,000, with an additional surcharge of 15%, totaling \$51,750. No other suspensions or fines were issued.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board \$250.00 for administrative costs. No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson's** distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of \$2,000.00. No other suspensions or fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In February 2018, in response to the DEA Settlement, the Florida Department of Business & Professional Regulation and **McKesson Corporation** (Lakeland distribution center) entered in a Settlement Agreement as disposition of an alleged violation of Section 499.0121(10), Florida Statutes (2008-2017), by operating not in compliance with applicable federal laws and regulations. McKesson also agreed to pay a settlement amount of \$10,000.00. No other suspensions or fines were issued.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation's** distribution

centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson's** distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

On May 31, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On December 17, 2018, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019 **McKesson Corporation** entered into a settlement for a payment of \$10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making

deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 10, 2019, in response to the DEA Settlement, **McKesson** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars (\$15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On July 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reprimand with **McKesson** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reprimand, agreed to pay \$4,000 in investigative fees.

On August 29, 2019 **McKesson** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

On August 29, 2019 **McKesson** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of \$1,150.00.

On January 7, 2020 **McKesson** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and that butalbital products continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019.

On February 20, 2020, in response to the DEA Settlement, **McKesson** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

NEIL T. CHABOT

Fallen Timbers Ln ~ Collierville TN ~ 919-

~ neil.chabot@mckesson.com

MANAGEMENT PROFESSIONAL

Demonstrated areas of expertise include:

- | | | |
|---------------------------------|-----------------------|----------------------|
| * Business Profitability | * P&L Performance | * Expense Management |
| * Sales Force Management | * Six Sigma Blackbelt | * cGMP Compliance |
| * DEA Security and distribution | * Team Development | * FDA Compliance |

PROFESSIONAL EXPERIENCE

SR. DIRECTOR OF OPERATIONS

2020 – Present

McKesson Specialty Distribution Services

Responsible for 3PL Rx product distribution in an ambient, refrigerated and freezer environment.

- Responsible for team of 75+ for Receiving, Shipping, and Distribution activities
- Assemble SOPs for safe shipment of refrigerated and frozen Rx products
- Oversea complete plant management and physical site security

SR. DIRECTOR OF OPERATIONS

2018 - 2020

DIRECTOR of OPERATIONS

2005 - 2018

McKesson Packaging Services - RxPak ~ Concord, NC-Memphis TN

Responsible for all aspects of SKY branded NDC pharmaceutical packaging operation which includes DEA controlled substances Class II-V.

- Oversee complete plant management and physical site security.
- Responsible for an operational team of 52 while managing operations, receiving, shipping, and technical support.
- Responsible for all operational and capital budget development, adherence, and expenditure control.
- Direct and manage all raw material purchasing, finished goods production, and inventory management/distribution.

BUSINESS PROCESS RE-DESIGN MANAGER

2002 to 2005

McKesson Corporation ~ San Francisco, CA

McKesson trained six sigma Greenbelt and **Blackbelt** working on financial projects in Richmond Medical-Surgical corporate office. Two baseline projects completed on accounts payable process functions. **Rigorous adherence to six sigma core values and methodology, extensive analytical and methodical process redesigns.**

- Six Sigma liaison to McK Packaging in Concord, NC performing various process improvements centered on improved production efficiencies and SAP utilization and planning.
- Completed additional McK CEUs in Project Management, Kaizen, and Lean Six Sigma.
- 1.0MM annual savings within Medical-Surgical division back office project.

EDUCATION

New Hampshire Technical College, Nashua, NH
AAS, Machine Tool Processes – 1983
Journeyman Tool & Die Maker

4XX

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☒ Partnership – Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Safe chain solutions dba SC wholesale

Physical Address: 1812 W. Sunset Blvd #34

City: St. George State: Utah Zip Code: 84770

Telephone Number: 855-437-5727 Fax Number: 855-614-4118

Toll Free Number: _____

E-mail: compliance@safchain.com Website: www.safchain.com

Facility Manager: Jon C. Bennett

Professional qualifications and experience of facility manager: please see separate page attached.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☒

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Capital Wholesale Drugs
Address: 873 Williams Ave. Grandview Heights, OH 43212.

Name: Anda, Inc
Address: 2915 Weston Rd. Weston, FL 33331

Name: TopRx LLC
Address: 2950 Brother Blvd. Bartlett, TN 38133

Name: Richie Pharmacal
Address: 119 State Avenue Glasgow, KY 42141

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?

Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?

Yes ☐ No ☒


5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?

Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Charles Boyd
Print Name of Authorized Person

1-7-2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership:

General _____

Limited ☒

List names of 4 largest partners and percentage of ownership:

Name: Charles Boyd %: 50Name: Patrick Boyd %: 50

Name: _____ %: _____

Name: _____ %: _____

Partnership Name: Safe Chain SolutionsMailing Address: 822 Chesapeake DriveCity, State Zip Code: Cambridge, MD 21613Telephone Number: 855-437-5727 Fax Number: 855-614-4118Contact Person: Abbie Divilio / Kelsy Jones compliance@safechain.com

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a partnership

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

JON BENNETT

1/7/2020

OPERATIONS MANAGER – UTAH WAREHOUSE

* Designated Rep *

My professional qualifications and experience include 36 years in Pharmaceutical Sales and Sales Management, 32 years of which were with Merck Pharmaceuticals. Much of that time I was responsible for managing and procuring pharmaceuticals both prescription and over-the-counter types.

During the past 12 months as Operations Manager at Safe Chain Solutions in Utah, I have been actively involved receiving, packing, shipping and the general maintenance of inventory. This has been done while adhering to strict state and federal regulations and guidelines. Below is a list of daily duties conducted as the Operations Manager:

1. Manage day to day delivery receipts
2. Check and confirm NDC, LOT and Expiration dates
3. Enter receipts into our ERP system
4. Possess a thorough understanding of our shipping system
5. Manage day to day outbound shipping
6. Carefully pack outbound shipments
7. Maintain a clean and organized warehouse
8. Keep sufficient quantities of packing supplies on hand
9. Maintain proficiency in our software's
10. Hire and train warehouse workers to grow with the company
11. Maintain compliance with all Federal and UT State regulations in regard to purchasing and sale of pharmaceuticals.

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

**Safe Chain Solutions, LLC. dba SC
Wholesale**

EFFECTIVE **01/24/2019** EXPIRATION **09/30/2021**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

11126931-1710 Pharmacy - Class C

Wholesaler
Distributor

SIGNATURE OF HOLDER

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

SAFE CHAIN SOLUTIONS, LLC. DBA SC
WHOLESALE
1812 W SUNSET BLVD STE 34
SAINT GEORGE UT 84770

Please visit our web site at
www.dopl.utah.gov should you have any
questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: 01/24/2019

EXPIRATION DATE: 09/30/2021


ISSUED TO: Safe Chain Solutions, LLC. dba SC Wholesale
1812 W Sunset Blvd Ste 34
Saint George UT 84770

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

11126931-1710 Pharmacy - Class C

Wholesaler
Distributor

SIGNATURE OF HOLDER





SafeChain Solutions

SAFE CHAIN SOLUTIONS OFFICER INFORMATION

Charles Boyd – President

Calves Acre Lane
Easton, MD 21601

[@safechain.com](#)

SSN

DC

50% Ownership

Patrick Boyd – Managing Partner

Waverly Road
Easton, MD 21601

[@safechain.com](#)

SSN

DOB

50% Ownership

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SAFE CHAIN SOLUTIONS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTY-FIRST DAY OF AUGUST, A.D. 2020.



4848635 8300

SR# 20206969053

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBULLOCK", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 203552687

Date: 08-31-20

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SAFE CHAIN SOLUTIONS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF OCTOBER, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SAFE CHAIN SOLUTIONS LLC" WAS FORMED ON THE FIFTEENTH DAY OF JULY, A.D. 2010.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



4848635 8300

SR# 20197476877

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBULLOCK", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 203867324

Date: 10-25-19

RENEWAL VERIFICATION CERTIFICATE

This is to certify that Bond No. LPM7644231 issued by FIDELITY AND DEPOSIT COMPANY OF MARYLAND, written on behalf of Safe Chain Solutions, LLC as Principal, in favor of Nevada State Board of Pharmacy, as Obligee, the amount of \$100,000, covers an indefinite term which began on March 26, 2015, and ends with the cancellation of said bond; that said bond is now in full force and effect and will continue in full force and effect until cancelled.

Anniversary Premium Period: March 26, 2020 through March 26, 2021

Signed, sealed and dated this 11 day of January, 2020.

FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: Laura Scholze
Laura Scholze, Attorney-in-Fact

LPM7644231

Bond Number

Nevada State Board of Pharmacy

Obligee

**ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by **Robert D. Murray, Vice President**, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint Laura Scholze, its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings**, and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

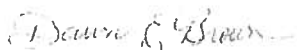
IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND, this 11th day of January, A.D. 2020.



ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND



By: Robert D. Murray
Vice President



By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 11th day of January, A.D. 2020, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President** and **Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, depose and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.





Constance A. Dunn, Notary Public
My Commission Expires: July 9, 2023

EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8, Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify or revoke any such appointment or authority at any time."

CERTIFICATE

I, the undersigned, Vice President, of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 11th day of January, 2020.



Brian M. Hodges

By: Brian M. Hodges
Vice President

TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
www.reportsfclaims@zurichna.com
800-626-4577



SafeChain Solutions



Safe Chain Solutions, LLC dab SC Wholesale

1812 W Sunset Blvd. Suite 34

St. George, UT 84770

Employee List:

Jon Bennett, Designated Representative

Collin Christensen, Warehouse Manager

STATE OF MARYLAND
Department of Assessments and Taxation

I, MICHAEL L. HIGGS OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES, OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT SAFE CHAIN SOLUTIONS LLC (Z14124358), REGISTERED MAY 19, 2011, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF DELAWARE, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS SEPTEMBER 24, 2019.



Michael L. Higgs
Director



301 West Preston Street, Baltimore, Maryland 21201
Telephone Baltimore Metro (410) 767-1340 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: W45orfM2dEmCiKBJqa2PmA
To verify the Authentication Code, visit <http://dat.maryland.gov/verify>

STATE OF MARYLAND
Department of Assessments and Taxation

I, MICHAEL L. HIGGS OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES, OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT SAFE CHAIN SOLUTIONS LLC (Z14124358), REGISTERED MAY 19, 2011, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF DELAWARE, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS AUGUST 27, 2020.



Michael L. Higgs
Director



301 West Preston Street, Baltimore, Maryland 21201
Telephone Baltimore Metro (410) 767-1340 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: m9Ks1tAcB0Ct23MKV6dl_A
To verify the Authentication Code, visit <http://dat.maryland.gov/verify>

RENEWAL VERIFICATION CERTIFICATE

This is to certify that Bond No. LPM7644231 issued by FIDELITY AND DEPOSIT COMPANY OF MARYLAND, written on behalf of Safe Chain Solutions, LLC as Principal, in favor of Nevada State Board of Pharmacy, as Obligee, the amount of \$100,000, covers an indefinite term which began on March 26, 2015, and ends with the cancellation of said bond; that said bond is now in full force and effect and will continue in full force and effect until cancelled.

Anniversary Premium Period: March 26, 2019 through March 26, 2020

Signed, sealed and dated this 31 day of July, 2019.

FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: Laura Scholze
Laura Scholze, Attorney-in-Fact

**ZURICH AMERICAN INSURANCE COMPANY
 COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
 FIDELITY AND DEPOSIT COMPANY OF MARYLAND
 POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Maryland, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Maryland (herein collectively called the "Companies"), by **GERALD F. HALEY, Vice President**, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint **Thomas A. WHIPPLE, Douglas J. DIXON and Laura SCHOLZE**, all of Timonium, Maryland, **EACH** its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings**, and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND, this 8th day of December, A.D. 2014.

ATTEST:

**ZURICH AMERICAN INSURANCE COMPANY
 COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
 FIDELITY AND DEPOSIT COMPANY OF MARYLAND**



By: _____

Secretary
Michael McKibben

Gerald F. Haley

Vice President
Gerald F. Haley

State of Maryland
 County of Baltimore

On this 8th day of December, A.D. 2014, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **GERALD F. HALEY, Vice President**, and **MICHAEL MCKIBBEN, Secretary**, of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, depose and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Constance A. Dunn

Constance A. Dunn, Notary Public
 My Commission Expires: July 14, 2015



4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

- ☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.
- ☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b
☒ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Renown Regional Medical Center dba Renown Pharmacy

Physical Address: 75 Pringle Way

City: Reno State: Zip Code: 89502 Telephone:

775-982-7737 Fax: 775-982-7738 Toll Free Number: n/a

E-mail: john.gagliardi@renown.org

Website:

Managing Pharmacist: John Gagliardi License Number: 6199

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral
☐ ☒ Parenteral (outpatient)
☒ ☐ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding
☒ ☐ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

Retail location

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

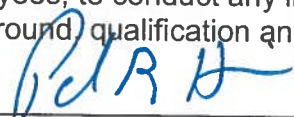
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Paul Harris, Chief Legal Officer

Print Name of Authorized Person

Date

8/27/20

Board Use Only

Date Processed: _____

Amount:

500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: NevadaParent Company if any: Renown HealthMailing Address: W. LibertyCity: Reno State: NV Zip: 89502Telephone: 775-982-5722 Fax: 775-982-4742Contact Person: Paul Harris, Chief Legal Officer

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Addressb) N/A
Name Business Addressc) N/A
Name Business Addressd) N/A
Name Business Address2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 8 am 5:30 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Paul Harris

Responsible Person of Renown Regional Medical Center dba Renown Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Paul Harris, Chief Legal Officer

Print Name of Authorized Person

8/27/20

Date

Managing Pharmacist

 Pharmacist Name: John Gagliardi

 License #: 6199

 Pharmacy Name: Renown Pharmacy, 75 Pringle Way

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

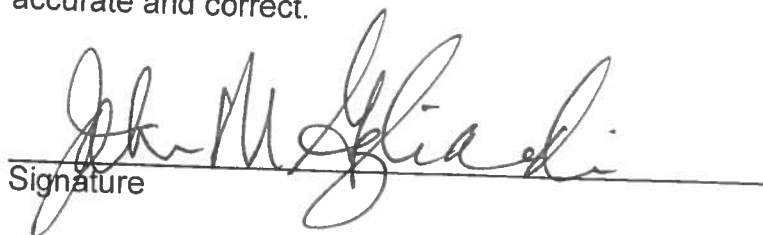
If you marked YES to any of the numbered questions above, please include the following information

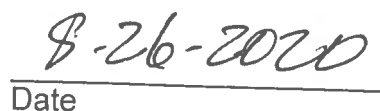
Board Administrative Action:	State: _____	Date: _____	Case #: _____
And/or Criminal Action:	State: _____	Date: _____	Case #: _____
	County: _____	Court: _____	

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

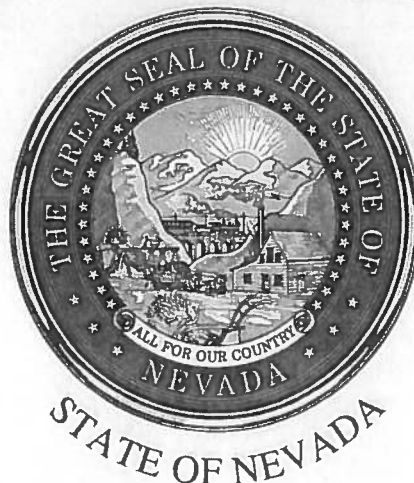

 Signature


 Date

List of Officers and Directors

Last	First	Position
Cooney	Kimberly	Secretary/Director
Dermody	Tammy	Director
Deveny	(Thomas) Cliff	Director
Devia	Alvaro	Director
DeVolld	James	Chair/Director
Fennell	Harvey	Director
Johnson	Steve	Director
Knobel	Mark	Director
Kramer	Adam	Vice Chair/Director
Matteoni	Christi	Director
McKenzie	Todd	Treasurer/Director
Mora	Marc	Director
Olsen	Joanne	Director
Peterson	Michael	Director
Resnik	Jeff	Director
Slonim	Anthony	President/Director
Smith	Blake	Director

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational documents on file in this office for
RENOWN REGIONAL MEDICAL CENTER

Organizational Documents on File	Filing Date
----------------------------------	-------------

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, RENOWN REGIONAL MEDICAL CENTER, as a corporation duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 07/29/1985, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my
hand and affixed the Great Seal of State, at my
office on 08/24/2020

Barbara K. Cegavske

Certificate Number: B202008241026217

You may verify this certificate
online at <http://www.nvsos.gov>

BARBARA K. CEGAVSKE
Secretary of State

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

813

Date 8-26-2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for RETAIL PHARMACY
RENOWN PHARMACY Nature of Pharmacy or Wholesaler
Name and Address of Business for Which Designated Representative is Requested 75 PRINGLE WAY - RENO, NV 89502

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name GAGLIARDI First Name JOHN Middle Name MICHAEL
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)
Present Residence Address-Street or RFD GLEN EAGLES DR. City RENO State/Zip NV 89523
LOCUST ST. Dates 5/2011-PRESENT City RENO State/Zip NV 89502
Present Business Address RETAIL PHARMACY SUPERVISOR Dates 5/2011-PRESENT City _____ State/Zip _____
Present Position with the Pharmacy or Wholesaler
Phone: _____
Residence _____
Business 775-982-5281
Date of Birth _____ Place of Birth (City, County, State) GRASSVALLEY, NEVADA, CALIFORNIA
Age 69 Social Security Number or ITIN _____ Sex M
Color of Eyes HAZEL Color of Hair BLACK Complexion OLIVE Weight 245 Build STOCKY Height 5'10"

Scars, tattoos or distinguishing marks and/or characteristics NONE

Are you a citizen of the United States? ☒ Yes ☐ No ☐ If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

Page 1

A. **Current Marriage** DECEMBER 15, 1973 NEVADA CITY, NEVADA, CALIF.
 Spouse's full name (Maiden) ANN ERNESTINA SPARK ^{Date} 12/15/73 ^{City, County and State} NEVADA CITY, NV
 Date of Birth [REDACTED] Place of Birth BERKELEY, CA
 Resident address [REDACTED] GLEN EAGLES DR. RENO, NV 89523
 Street City State Zip
 Telephone: Residence [REDACTED] Business N/A
 Spouse's employer N/A Occupation RETIRED
 Address of employer [REDACTED]
 Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
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N/A

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
------	--------	------	-------	-----	-----------

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
CHRISTINA M. SCHELLER	[REDACTED]	LAS VEGAS, NV	WHITTAKER OAKS, LI RENO, NV 89523
ERICA L. ORME	[REDACTED]	SACRAMENTO, CA	PEAVINE CREEK R RENO, NV 89523
JOHN M. GAGLIARDI, II	[REDACTED]	GRASS VALLEY, CA	PROVENCE, CT. RENO, NV 89523

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

[Signature]

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father ARTHUR J. GAGLIARDI	[REDACTED]	ALEXANDER ST. NEVADA CITY, CA	DECEASED
Mother INEZ M. AUSTI	[REDACTED]	SAME	DECEASED
Father-in-Law ALVIN B. SPARNHAWK	[REDACTED]	15528 RIDGE ROAD NEVADA CITY, CA	DECEASED
Mother-in-Law ALIDA D. OLDENBOURG	[REDACTED]	SAME	DECEASED

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
ROBERT J. GAGLIARDI	[REDACTED]	MORRISTOWN RD MODESTO, CA 95356	RETIRED
Spouse CAROLANN CANTANZARI	[REDACTED]	SAME	RETIRED
JANIS M. GAGLIARDI	[REDACTED]	HUNTER GLENDR. RENO, NV 89523	RETIRED
Spouse DOUGLAS P. PEACOCK	[REDACTED]	SAME	RETIRED
JOSEPH P. GAGLIARDI	[REDACTED]	SUTTER ST FOLSOM, CA 95680	ADMINISTRATOR
Spouse MAUREEN FLYNN GAGLIARDI	[REDACTED]	SAME	TEACHER

Spouse _____

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School NEVADA CITY ELEMENTARY	NEVADA CITY, CA	1956-1965	Yes <input checked="" type="radio"/> No <input type="radio"/>
High School NEVADA UNION HIGH SCHOOL	GRASS VALLEY, CA	1965-1969	Yes <input checked="" type="radio"/> No <input type="radio"/>
College IDAHO STATE UNIVERSITY	POCATELLO, ID.	1969-1971	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other UNIVERSITY OF UTAH	SALT LAKE CITY, UT	1971-1974	Yes <input checked="" type="radio"/> No <input type="radio"/>

Type of degree obtained, if any BS PHARMACY

College or university where obtained UNIVERSITY OF UTAH

Applicant's initial 

A. Have you ever served in any armed forces?

Yes

No

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes

No

County NEVADA State CA Date registered 12/1966

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
------	--------------	--------	----------	------

Applicant's initial

[Signature]

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
 Yes ☒ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
---	------------	--------------------------	------------------------	------------------

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
 Yes ☒ No ☒ If yes, complete the following:

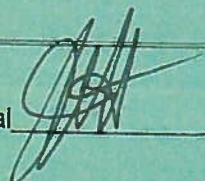
Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
----------------	----------------	--

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
6/2005-Present	[REDACTED] GLENEAGLES DR	RENO	NV
6/2004-6/2005	? MTN. VISTA DR.	RENO,	NV
6/2003-6/2004	? MTN VISTA DR	RENO,	NV
6/2001-6/2003	? MORGAN RANCH ESTATES	GRASS VALLEY	CA
8/1995-6/2001	10747 BANNER LAVA CAP	NEVADA CITY	CA

Applicant's initial



A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

5/2011 -	RENO PHARMACY - 21 LOCUST ST. - RENO 89502	18000+
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
RETAIL PHARMACY SUPERVISOR		ADAM POLATH
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial



List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
RETIRED Name: RON DARRY	Home: GLEN EAGLES DR.	RENO, NV	89523			15
RETIRED Name: LEIGHTON BRUMBLE	Home: S. McCARRAN BLVD	RENO, NV	89502			5
RETIRED Name: SUSAN ORME	Home: SANDY CT.	TROUTDALE, OR	97060			17
RETIRED Name: JOHN GALLEGOS	Home: BROOKDALE CT.	ALBUQUERQUE, N.M.	87113			50
RETIRED Name: PATTI SPENCER	Home: CHAPEL ST.	GAASS VALLEY, CA	95945			
RETIRED Name: [REDACTED]	Home: [REDACTED]	[REDACTED]	[REDACTED]			

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☒

If yes, state type, where and years held

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

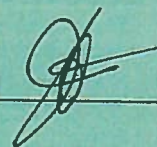
GAGLIARDI'S PHARMACY 715 ZION ST NEVADA CITY, CA 3/81-3/1997

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

Applicant's initial



14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability?
 Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry?
 Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances?
 Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler)
 Yes ☐ No ☒

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry?
 Yes ☐ No ☒

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler?

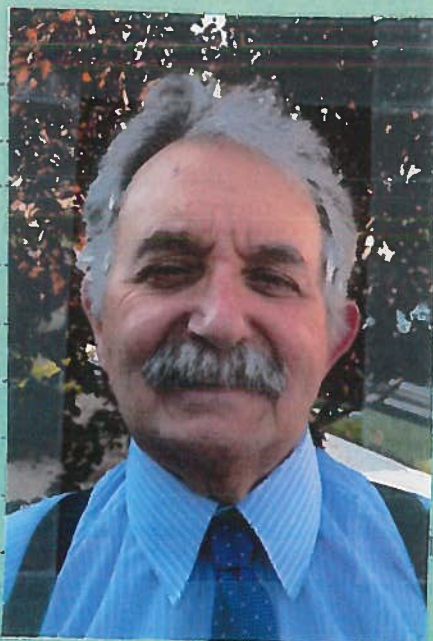
Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler?

Yes ☒ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours?

Yes ☒ No ☐



ATTACH PHOTOGRAPH

TAKEN WITHIN LAST

30 DAYS HERE

Date of photograph

8-26-2020

Applicant's initial

[Handwritten signature]

COUNTY OF Washoe

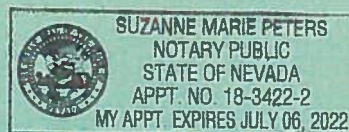
I, JOHN MICHAEL GAGLIARDI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

John Michael Gagliardi
Original Signature of Applicant

Subscribed and Sworn to before me this 27th day of

August, 2020
Suzanne M. Peters
Notary Public



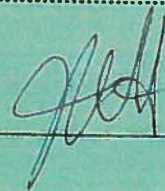
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Applicant's initial

JMG

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Applicant's initial



4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b

☐ Partnership - Pages 1,2,6,10,11a&b

☒ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b

☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Affordable Excellence Surgery Center

Physical Address: 6120 S. Fort Apache Rd, Ste. 200

City: Las Vegas NV State: NV Zip Code: 89148 Telephone: _____

702 948 8894 Fax: 702-948-8956 Toll Free Number: _____

E-mail: Mike C @ 215sc.com

Website: _____

Managing Pharmacist: Mary Grear License Number: 10687

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☐ Retail
☐ ☐ Hospital (# beds _____)
☐ ☐ Internet
☐ ☐ Nuclear
☒ ☐ Ambulatory Surgery Center
☐ ☐ Community
☐ ☐ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☐ Off-site Cognitive Services
☒ ☐ Parenteral
☐ ☐ Parenteral (outpatient)
☐ ☐ Outpatient/Discharge
☐ ☐ Mail Service
☐ ☐ Long Term Care
☐ ☐ Sterile Compounding
☐ ☐ Non Sterile Compounding
☐ ☐ Mail Service Sterile Compounding
☐ ☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

MA Chesek

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mike Chesek

Print Name of Authorized Person

7/29/20
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: Nevada

Parent Company if any: _____

Mailing Address: 6120 S. Fort Apache Rd, Ste 200City: Las Vegas State: NV Zip: 89148Telephone: 702-948-8894 Fax: 702-948-8956Contact Person: Mike Cheseck

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Jeremy Lipshutz 6120 S. Fort Apache Rd, Ste 100 Las Vegas ^{NV} 89148
(Name) Business Address

CS17864 ✓

b) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address2) Provide the number of shares issued by the corporation. 13) What was the price paid per share? \$

List any physician shareholders and percentage of ownership.

Name: Jeremy Lipshutz %: 100

Name: _____ %: _____

Hours of Operation for the pharmacy:

^{Thursday}
 Monday thru Friday 8 am 5 pm Saturday _____ am _____ pm
 Sunday _____ am _____ pm 24 Hours _____

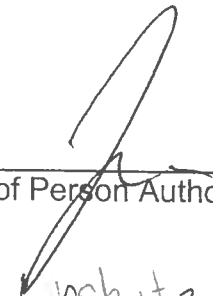
A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20281694749

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Jeremy Lipshutz
Responsible Person of Affordable Excellence Surgery Center
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Jeremy Lipshutz
Print Name of Authorized Person

7/29/20
Date

Managing Pharmacist

Pharmacist Name: Mary Grear, RPh License #: 10687

Pharmacy Name: Affordable Excellence Surgery Center

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action:	State: <u>NV</u>	Date: <u>2002</u>	Case #: <u>02-036-R245</u>
And/or Criminal Action:	State: _____	Date: _____	Case #: _____
	County: _____	Court: _____	

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Mary Green, RPh
 Signature

7/29/2020
 Date

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date 8/9/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Ambulatory Surgery Center
Affordable Excellence Surgery Center Nature of Pharmacy or Wholesaler
6120 S Fort Apache Rd, Ste 200 Name and Address of Business for Which Designated Representative Is Requested
Las Vegas NV
89148
 If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name Lipshutz First Name Jeremy Middle Name Marc

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Candlestick Ave Henderson NV 89052
 Present Residence Address-Street or RFD City State/Zip

9/2015 - present
 Dates

6120 S. Fort Apache Rd #200 Las Vegas, NV 89148
 Present Business Address City State/Zip

2014 - present
 Dates

Medical Director - Surgery Center Phone:
 Residence

Business 702-948-8894

Date of Birth Place of Birth (City, County, State)

Boston, Suffolk, MA

Age 47 Social Security Number Sex Male

Color of Eyes Hazel Color of Hair Brown Complexion White Weight 450lbs Build Heavy Height 6'0"

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No

If naturalized, certificate No N/A Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial J

MARITAL INFORMATION-Continued

A. **Current Marriage** 11/12/2000 Novi, Oakland MI
 Date City, County and State
 Spouse's full name (Maiden) Renee Debra (Miller) Lipshutz
 Date of Birth Southfield, MI Place of Birth
 Resident address Candlestick Ave Henderson NV 89052
 Street City State Zip
 Telephone: Resider. 702-250-8266 Business
 Spouse's employer Lipshutz & Wilk Medical Group, LLP Occupation Marketing
 Address of employer 6120 S. Fort Apache Rd #100 Las Vegas NV 89148
 Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
----------------	-------------------------	---------------------------	------------------	-----------------------

N/A

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
------	--------	------	-------	-----	-----------

N/A

3. **FAMILY INFORMATION:**A. **Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Parker Lipshutz		Royal Oak, MI	Candlestick Ave Henderson, NV 89052
Maxwell Lipshutz		Cleveland, OH	"
Ryder Lipshutz		CommerceTwp, MI	"

B. **Child Support Information:**

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

Page 2

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father			
Nelson Lipshutz		Rodliff Rd, Woburn, MA 02468	Consultant
Mother			
Sallee (Horowitz) Lipshutz		"	Executive
Father-in-Law			
Stuart Fishman		Mountain City St, Henderson, NV 89052	Retired
Mother-in-Law			
Dena (Goroff) Fishman		"	Retired

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Abigail (Lipshutz) Schildcrout		LaSalle, Huntington Woods, MI	Physician
Spouse			
Douglas Schildcrout		LaSalle " 48070	Engineer
Rebecca (Lipshutz) Peak		Adams St, Westborough, MA	Physician
Spouse			
Brian Peak		" 01581	Entrepreneur

Spouse _____

Spouse _____

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Ainger Elementary	Woburn, MA	1982-1985	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	Newton South High School	Newton, MA	1987-1991	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College	Grinnell College	Grinnell, IA	1991-1995	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
University	Johns Hopkins U. Public Health	Baltimore, MD	1996-1998	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	Wayne State U. School of Medicine	Detroit, MI	1998-2003	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	UNLV-William S. Boyd School of Law	Las Vegas, NV	2015-2019	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any MD, JD, MHSCollege or university where obtained Wayne State U. SOM, UNLV-Boyd School of Law, Johns Hopkins UApplicant's initial AL

5 MILITARY INFORMATION:

833

A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch N/A Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☒ No ☐

County Middlesex State MA Date registered 1991

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
<u>N/A</u>					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? N/A city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? N/A city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
<u>N/A</u>				

Applicant's initial _____

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Defendant	8/31/2015	Eighth Judicial District - NV A-NV-701103-B	Las Vegas, Clark, NV	Dismissed with Prejudice 7/12/2016
Defendant	Under Seal	US District Court - NV 2:19-cv-1871-KJD-VCF	Las Vegas, Clark, NV	Pending

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☒ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
Barch Enterprises, LLC-Series I	LLC-Corporation	2015
Lipshutz + Wills Medical Group LLP	LLP - Partnership	2019
Jeremy M. Lipshutz, MD, Ltd	S-Corporation	2019

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
9/2015 - present	2284 Candlestick Ave	Henderson	NV
11/2011 - 9/2015	502 Beneficial Pl	Henderson	NV
2/2010 - 11/2011	1355 Quiet River Ave	Henderson	NV
3/2009 - 2/2010	1363 Quiet River Ave	Henderson	NV
9/2005 - 3/2009	West Blenheim Oaks Dr	West Blenheim	MI
6/2003 - 9/2005	Fenwick Rd	University Hts	OH
6/1999 - 6/2003	Main St	Royal Oak	MI
6/1998 - 6/1999		Troy	MI
3/1980 - 6/1999	24 Rockliff Rd	Newton (Waban)	MA

Applicant's initial _____

8. EMPLOYMENT:

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A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year <i>11/2011 - present</i>	Name/Mailing Address of Employer/Business <i>Lipshutz White Medical Group, LLP 61205 Fort</i>	Number of Employed Hours <i>1700</i>
Title <i>Physician</i>	Description of Duties <i>Medical Practice as a doctor</i>	Name of Supervisor <i>Self</i>
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial



9. CHARACTER REFERENCES:

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List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Scott Averbach</u>	Ho	<u>RiverSpry</u>	<u>Henderson, NV</u>	<u>89012</u>		<u>11</u>
Employer	Business					
Name <u>Lisa Averbach</u>	Ho	<u>RiverSpry</u>	<u>Henderson, NV</u>	<u>89012</u>		<u>11</u>
Employer	Business					
Name <u>Rajiv Khamankar</u>	Home					<u>5</u>
Employer	Business					
Name <u>Allen Gossen</u>	Home					<u>30</u>
Employer	Business					
Name <u>Stephanie Lerner</u>	Home					<u>10</u>
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

Medical license MI 2005-present; Medical License NV 2009-present;
Lawyer, State Bar of Nevada 2019 - present

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
 If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

N/A

Applicant's initial

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14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☐ No ☒

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

N/A

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? *Surgery Center* Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? *Surgery Center* Yes ☐ No ☒

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? *Owner / Medical Director*
Sometimes - will not always be present when open. Yes ☒ No ☐



Date of photograph 8/19/20

Applicant's initial [Signature]

COUNTY OF Clark

I, Jeremy Lipshutz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

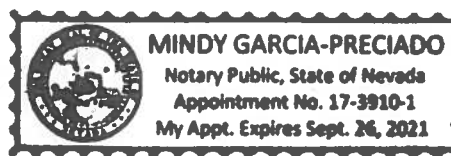
I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 19 day of August, 2020

Notary Public

(seal)



Applicant's initial

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Affordable Excellence Surgery Center, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 01/20/2020, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/31/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200731968684

You may verify this certificate
online at <http://www.nvsos.gov>



BARBARA K. CEGAVSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
 (775) 684-5708
 Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Affordable Excellence Surgery Center, LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: Read instructions before completing and returning this form.

Please indicate the entity type (check only one):

- ☐ Corporation
- ☐ This corporation is publicly traded, the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☒ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of	Business Number
<i>Barbara K. Cegavske</i>	E4272552020-4
Secretary of State	Filing Number
State Of Nevada	20200427256
	Filed On
	01/20/2020 12:49:50 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is \$200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee.
 Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C § 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit \$200.00 for the state business license.

- ☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. §501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required.
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****



BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE <u>MANAGING MEMBER</u> :			
Jeremy M. Lipshutz, MD, Ltd.		USA	
Name		Country	
6120 South Fort Apache Road, Suite 200		Las Vegas	NV 89148
Address		City	State Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X Jeremy M. Lipshutz, MD, Ltd.

Signature of Officer, Manager, Managing
Member, General Partner, Managing Partner,
Trustee, Member, Owner of Business,
Partner or Authorized Signer FORM WILL BE RETURNED IF

UNSIGNED

Managing Member

Title

01/17/2020

Date

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b

☐ Partnership - Pages 1,2,6,10,11a&b

☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b

☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Desert Orthopaedic Pain Center

Physical Address: 8205 West Warm Springs Rd. #130 Las Vegas

City: Las Vegas

State: NV Zip Code: 89113

Telephone: _____

Fax: 702-735-7921

Toll Free Number: 702-735-7355

E-mail: ernie.elliott@doclv.com

Website: _____

Managing Pharmacist: Mary O'neal

License Number: 10687

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☒ ☐ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☒ ☒ Parenteral
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☐ ☒ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.


Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Eric Elliott
Print Name of Authorized Person

2/20/2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General _____ Limited X

List names of 4 largest partners and percentage of ownership:

Name: Troy Watson %: 5.11
 Name: Michael Miao %: 5.11
 Name: Andrew Kim %: 5.11
 Name: Paraminder Kaur %: 5.11

Partnership Name: Institute of Orthopaedic Surgery LLC

Mailing Address: 5-Deseret Fnd Rd.

City, State Zip Code: Las Vegas NV 89121

Telephone Number: _____ Fax Number: 702-735-7921

Contact Person: Ernie Elliott

List any physician shareholders and percentage of ownership.

Name: Troy Watson %: 5.11
 Name: Michael Miao %: 5.11
 Name: Andrew Kim %: 5.11

Hours of Operation for the pharmacy:

Monday thru Friday 7 am 5 pm Saturday _____ am _____ pm
 Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Ernie Elliott

Responsible Person of Desert Orthopaedic Pain Center

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Ernie Elliott

Print Name of Authorized Person

8/20/2020

Date

Managing Pharmacist

Pharmacist Name: Mary Grear, RPh License #: 10687

Pharmacy Name: Desert Orthopaedic Pain Center

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action:	State: <u>AZ</u>	Date: <u>4/2002</u>	Case #: <u>02-036-RPHS</u>
And/or Criminal Action:	State: _____	Date: _____	Case #: _____
County	_____	Court: _____	

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Mary Greer, RPh
Signature

8/24/2020
Date

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date

8/20/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Business Pharmacy License

Desert Orthopaedic Center Pain Center, 8205 W. Warm Springs Rd. Ste #130, Las Vegas, NV 89113
 Nature of Pharmacy or Wholesaler
INSTITUTE OF ORTHOPAEDIC SURGERY, LLC
 Name and Address of Business for Which Designated Representative Is Requested
 If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Miao Michael
 Last Name First Name Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

9 Wade Hampton Trail Henderson NV 89052
 Present Residence Address-Street or RFD City State/Zip

E. Desert Inn Rd. Las Vegas NV 89121
 Present Business Address City State/Zip

Present Position with the Pharmacy or Wholesaler
 Phone: Residenc
 Business 702-731-1616

Los Angeles, CA
 Date of Birth Place of Birth (City, County, State)

57 M
 Age Social Security number or ITIN Sex

Brown Black Tan 210 Broad 5'11"
 Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? ☒ Yes ☐ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

Honolulu, HI

City, County and State
SS# or IT

Honolulu, HI

Wade Hampton Trail

Henderson

NV

89052

Business N/A

N/A

Occupation N/A

Street

City

State

Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
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List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
------	--------	------	-------	-----	-----------

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Tyler		Fontana, CA	Wade Hampton Trail Henderson, NV 89052

Jared Las Vegas, NV Wade Hampton Trail Henderson, NV 89052

Rylan Henderson, NV Made Hampton Trail Henderson, NV 89052

B. Child Support Information:

Please mark the appropriate response:

- ✓ ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initials

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Deceased			
Father			
Deceased			
Mother			
Deceased			
Father-in-Law			
Myrna Woo Hoang Hu		Hawane Pl Honolulu, HI	N/A
Mother-in-Law			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Deborah Miao		N Granada Ave Alhambra, CA 91801	Retired
Spouse			
Spouse			
Diana Miao		Brentwood Ave San Francisco, CA 94127	Dental Hygienist
Michael Eng			Bartending
Spouse			
Pamela Miao		Dormouse San Diego, CA 92129	School Admin.
Spouse			

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School Delevan Drive Elementary	Los Angeles, CA	1968-77	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
High School Flintridge Prep	Los Angeles, CA	1977-80	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
College Harvard University	MA	1980-1984	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Other University of Southern California	CA	1986-1991	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Type of degree obtained, if any Medical DoctorateCollege or university where obtained University of Southern California

Applicant's initial

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces?

Yes ☐ **No** ☐

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☐ No ☐County Los Angeles, CA State CA Date registered 1981**6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)**

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ **No** ☐ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ **No** ☐

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ **No** ☐

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☐

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ **No** ☐ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ **No** ☐ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ **No** ☐ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial 

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

☒ Yes ☐ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Defendant	1998		Fontana, Los Angeles, CA	Settled 5/20/99
Defendant	2001		Fontana, Los Angeles, CA	2002
Defendant	1998		Fontana, Los Angeles, CA	2001
Defendant	1998		Fontana, Los Angeles, CA	Dismissed 1999

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
9/2001-current	Wade Hampton Trail	Henderson	NV 89052
5/2000-9/2001	93 Fountain Head Circle	Henderson	NV 89052
8/1997-5/2000	7426 Butterfield Pl.	Rancho Cucumunga	CA 91730
8/1996-8/1997	3718 Columa Dorado Dr. #B106	San Diego	CA 92124
6/1991-8/1996	5600 Munhall Rd.	Pittsburgh	PA 15217

Applicant's initial



8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

6/2000	Desert Orthopaedic Center 2800 E. Desert Inn Rd. #100, Las Vegas, NV 89121	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
MD/Partner	Ortho Surgery/Sports Med	Michael Pendleton
Title	Description of Duties	Name of Supervisor
8/1997-5/2000	So, California Permanente Medical Group 9985 Sierra Ave, Fontana, CA 92335	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
MD	Ortho Surgery/Sports Med	David Anderson, MD
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.



Applicant's initial _____

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Connie M.</u>	<u>Home</u>	<u>Green Valley Pkwy Henderson, NV 89074</u>				20
Employer <u>N/A</u>	Business					
Name <u>Jennifer Kwok</u>	<u>Home</u>	<u>Aragon Canyon St. Las Vegas, NV 89135</u>				20
Employer <u>N/A</u>	Business					
Name <u>Kelly Tourek</u>	<u>Home</u>	<u>Desert Highlands Dr. Henderson, NV 89052</u>				10
Employer <u>N/A</u>	Business					
Name <u>Dawn Soong</u>	<u>Home</u>	<u>Newfort Isle Ct. Las Vegas, NV 89117</u>				18
Employer <u>N/A</u>	Business					
Name <u>Michelle Chir</u>	<u>Home</u>	<u>7ia Savona Henderson, NV 89052</u>				
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

☒ Yes ☐ No

If yes, state type, where and years held

MD HI 2000-current

MD CA 1996-Current

MD NV 2000-current

MD PA 1991-1996

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐
- If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No ☐

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☒ No ☐

If yes to the above, state where, when and for what reason:

Applicant's initial



14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☐ No ☒

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☒ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☒ No ☐



Date of photograph _____

Applicant's initial Qi

ss.

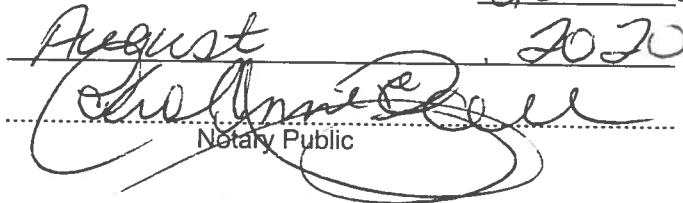
COUNTY OF Clark

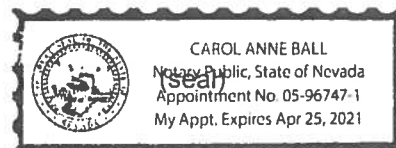
I, Michael Miao, MD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.


Original Signature of Applicant

Subscribed and Sworn to before me this 20th day of

August, 2020

Notary Public



Applicant's initial MM

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date

8/26/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Business Pharmacy License

Nature of Pharmacy or Wholesaler

Desert Orthopaedic Center Pain Center, 8205 W. Warm Springs Rd. Ste #130, Las Vegas, NV 89113

Name and Address of Business for Which Designated Representative Is Requested

INSTITUTE OF ORTHOPAEDIC SURGERY, LLC

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Kim Andrew B
Last Name First Name Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Plaza De Rafael Las Vegas NV 89102
Present Residence Address-Street or RFD City State/Zip

2800 E. Desert Inn Rd. #100 Las Vegas NV 89121
Present Business Address City State/Zip

Provider Partner Dates 1/9/2017
Present Position with the Pharmacy or Wholesaler

Phone:
Residence

Business 702-731-1616

Chicago, IL
Date of Birth Place of Birth (City, County, State)

42 Male
Age Sex

Brown Grey Medium 245 6'1"
Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics

Are you a citizen of the United States? ☒ Yes ☐ No If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

A

A. Current Marriage 03/26/2013

Spouse's full name (Maiden) Glenda Docatre Date 03/26/2013 City, County and State Chicago, IL
 SS# or ITIN

Date of Birth Place of Birth Chicago, IL

Resident address Plaza De Rafael Las Vegas NV 89102
 Street City State Zip

Telephone: Residenc Business N/A

Spouse's employer N/A Occupation Registered Nurse

Address of employer
 Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:**A. Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Elijah		Las Vegas	Plaza De Rafael Las Vegas, NV 89102
Luke		Las Vegas	Plaza De Rafael Las Vegas, NV 89102

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Byung Chul Kim Father		N. Knox Skokie, IL 60076	Retired
In Sub Kim Mother		N. Knox Skokie, IL 60076	Retired
Roland Docatre Father-in-Law		1 Buckhorn Island Ave, Las Vegas, NV 89113	Retired
Lucy Docatre Mother-in-Law		Buckhorn Island Ave, Las Vegas, NV 89113	Registered Nurse

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Cynthia Kim Spouse		Lafin St Chicago, IL 60607	Teacher
Spouse			
Spouse			
Spouse			

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School Devonshire	Skokie, IL	1985-1989	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School Niles North	Skokie, IL	1992-1996	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University of Illinois at Urbana	Champagne, IL	1996-2000	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other NOVA Southeastern University	Florida	2002-2006	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any DOCollege or university where obtained NOVA Southeastern University

Applicant's initial

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces?

Yes ☐ No ☒

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☐ No ☒

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☒ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☒ No ☐ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☒ No ☐

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☒ No ☐

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☒ No ☐

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☒ No ☐ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☒ No ☐ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☒ No ☐ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial _____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☒ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
2015-present	Plaza De Rafael	Las Vegas	NV
2013-2015	349 Falcons Fire	Las Vegas	NV
2011-2013	1601 Trineo Ct	Las Vegas	NV
2010-2011	1540 S. Centreca	Los Angeles	CA
2007-2010	2626 North Blvd	Houston	TX
2006-2007	9020 N. Knox	Skokie	IL
2003-2006	9411 Evergreen Pl	Davie	FL
2002-2003	2876 S. University Dr.	Davie	FL
2000-2002	9020 N. Knox	Skokie	IL
1996-2000	University of Illinois Campus	Urbana	IL
1980-1996	9020 N. Knox	Skokie	IL

Applicant's initial



8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

12/2016-Present	Desert Orthopaedic Center 2800 E. Desert Inn Rd. #100, Las Vegas, NV 89121	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
DO/Partner	Pain Management	Michael Pendleton
Title	Description of Duties	Name of Supervisor
10/2011-12/2016	Southern Nevada Pain Center 6950 W. Desert Inn Rd.#110 Las Vegas, NV 89117	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
DO	Pain Management	
Title	Description of Duties	Name of Supervisor
7/2010-6/2011	UCLA, UCLA VA Campus	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Fellow	Fellowship Training	Quyah Pham, MD
Title	Description of Duties	Name of Supervisor
7/2007-7/2010	University of Texas-Houston	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Resident	Residency Training	Gerard Francisco, MD
Title	Description of Duties	Name of Supervisor
7/2006-6/2007	Advocate Lutheran General	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Intern	Internship Training	Gary Solomon, MD
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial



9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Adam Boester	Hom	Sul Ross St.	Houston, TX	77098		18
Employer	Business					
Name Mazen Hamameh	Hom	Whitefield St.	Dearborn Heights, MI	48127		18
Employer Premier Pediatrics	Business					
Name Tom Kim	Hom	Lurking Ave	Deerfield, IL	60115		30
Employer District 219	Business					
Name Khuram Khan	Hom	Watercrest Circle	East Parkland, FL	33076		18
Employer Prestige Anesthesia	Business					
Name Daniel D. Lee, MD	Hom	Hawk Ridge Dr.	Las Vegas, NV	89135		9
Employer Desert Orthopaedic Center	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

☒ Yes ☐ No

If yes, state type, where and years held

NV 2011-Current

CA 2010-Current

AZ 2014-Current

TX 2008-Current

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No
- If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☒ No

If yes to the above, state where, when and for what reason:

Applicant's initial



14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☒ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☒ No ☒

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☒ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☒ No ☒

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☒ No ☒

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☒ No ☒

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☒ No ☒

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☒ No ☒



Date of photograph _____

Applicant's initial _____

ss.

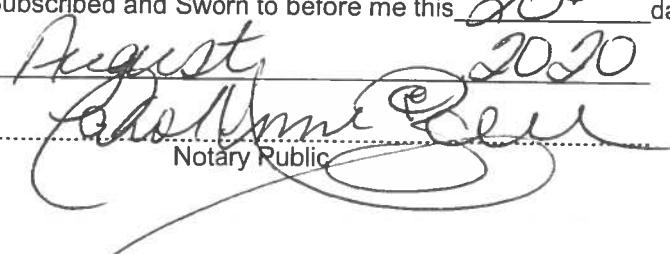
COUNTY OF Clark

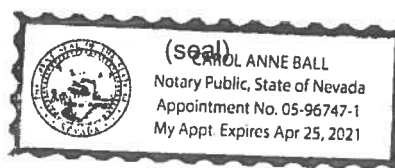
I, Andrew Kim, DO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.


.....
Original Signature of Applicant

Subscribed and Sworn to before me this 20th day of

August
2020

.....
Notary Public



Applicant's initial A

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date

8/2/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Business Pharmacy License

Nature of Pharmacy or Wholesaler

Desert Orthopaedic Center Pain Center, 8205 W. Warm Springs Rd. Ste #130, Las Vegas, NV 89113

Name and Address of Business for Which Designated Representative Is Requested

If applicable, Name Under Which It Is Now Operated

INSTITUTE OF ORTHOPAEDIC SURGERY, LLC

1. PERSONAL INFORMATION:

Kang Parminder S
Last Name First Name Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Enchanted View St. Las Vegas NV/89149
Present Residence Address-Street or RFD City State/Zip

2800 E. Desert Inn Rd. #100 Las Vegas NV/89121
Present Business Address City State/Zip

Dates
Present Position with the Pharmacy or Wholesaler
Phone: Residence
Business 702-731-1616

Date of Birth Place of Birth (City, County, State)

41 Male
Age Social Security Number or ITIN Sex

Brown Black Medium 218 Medium 5'10"
Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics Left Chest Tatoo (Khunda)

Are you a citizen of the United States? ☒ Yes ☐ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

MARITAL INFORMATION-Continued

A. Current Marriage 11/30/2018 Las Vegas, Clark, NV

Spouse's full name (Maiden) Tamara Vannah Las Vegas, Clark, NV
Date City, County and State
SS# or ITIN

Date of Birth Place of Birth Las Vegas, NV

Resident address: Enchanted View St. Las Vegas NV 89149
Street City State Zip

Telephone: Residence Business

Spouse's employer Vannah & Vannah Occupation Attorney

Address of employer 400 S. 7th St. Las Vegas NV 891010
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
Gurpreet Singh	12/18/2012	Houston, TX	Divorce	Flagstaff, AZ

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
Gurpreet Singh	Deceased				

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Sukhamani Kang		Flagstaff, AZ	Enchanted View St. Las Vegas, NV 89149

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Bolden Kang Father		Emory Oak Dr. Las Vegas, NV 89138	Retired
Gurmeet Ghuman Mother		Emory Oak Dr. Las Vegas, NV 89138	Homemaker
Robert Vannah Father-in-Law		Congressional Court, Las Vegas, NV 89113	Attorney
Marsha Dorny Mother-in-Law		Congressional Court, Las Vegas, NV 89113	Homemaker

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Tajinder Kang Spouse		Emory Oak Dr. Las Vegas, NV 89138	Medical Student
Vimni Kang Spouse		Corby St. Omaha, NE 68116	Doctor
Awinder Singh		Corby St. Omaha, NE 68116	Doctor

Spouse _____

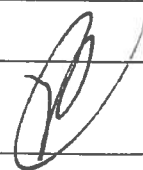
Spouse _____

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School Brinley Middle School	Las Vegas, NV	1991-1993	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
High School Clark High School	Las Vegas, NV	1993-1997	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
College University of California at Berkeley	Berkeley, CA	1997-2001	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Other State University of New York Downstate Medical Center	Brooklyn, NY	2001-2005	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Type of degree obtained, if any Medical DoctorateCollege or university where obtained State University of New York Downstate Medical Center

Applicant's initial



5 MILITARY INFORMATION:

870

A. Have you ever served in any armed forces?

Yes ☐ ☒ No ☐

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

☒ Yes ☐ No ☐

County Clark State Nevada Date registered 6/1997

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) ☒ Yes ☐ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
11/25/2009	30	Misdemeanor Assault	Houston, TX	Sealed 5/19/2011	Houston Police Dept.

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ ☒ No ☐ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ ☒ No ☐

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ ☒ No ☐

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☐

F. Have you ever had a civil or criminal record expunged or sealed by a court order? ☒ Yes ☐ No ☐
If yes, when? 10/21/2014 city, county and state Houston, Morris County, TX

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ ☒ No ☐
If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ ☒ No ☐
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

☒ Yes☐ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Defendant	10/30/2018	A-18-782012-C	Las Vegas, Clark, NV	Pending-10/1/2017

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

☒ Yes☐ No

If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
8/2017-Present	Enchanted View St.	Las Vegas	NV
8/2011-8/2017	9191 Dutch Oven Ct.	Las Vegas	NV
7/2010-8/2011	530 North Union Blvd. Apt 201	St. Louis	MO
7/2005-7/2010	1330 Old Spanish Trail	Houston	TX
8/2001-6/2005	825 New York Ave.	Brooklyn	NY
8/1997-8/2001	2498 Piedmont Ave	Berkeley	CA
6/1990-7/1997	4613 Stacey Ave.	Las Vegas	NV

Applicant's initial

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

May 2012	Desert Orthopaedic Center 2800 E. Desert Inn Rd. #100, Las Vegas, NV 89121	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Provider/Partner	Ortho Consults/Surgery/Admin	Michael Pendleton
Title	Description of Duties	Name of Supervisor
8/2010	Washington University in St. Louis 6605 Euclid Ave, St. Louis, MO 63110	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Fellow	Specialized Training in Joint replacement	
Title	Description of Duties	Name of Supervisor
7/2005	Baylor College of Medicine Baylor Plaza, Houston, TX 77030	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Resident	Training in Orthopaedics	John Marymont
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial



9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Jaswinder Grover	Home	Smoke Ranch Rd.,	Las Vegas, NV	89128		8
Employer NV Spine Clinic	Business					8
Name Ed McDougal	Home	3loomington Dr.	Las Vegas, NV	89134		7
Employer Smith & Nephew	Business					
Name Mario Dauhs	Home					8
Employer	Business					
Name Thomas Alfreda	Home	W. Horizon Ridge Pkwy,	Henderson, NV	89052		7
Employer Self-employed	Business	Primary Care Physician				
Name Amanda Graham	Home	ampart St. 100,	Las Vegas, NV	89145		6
Employer Self	Business	Interventional Pain				

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

☒ Yes ☐ No

If yes, state type, where and years held

MD Nevada-2012-present

MD MO 2010-2012

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐
- If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No ☐

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☒ No ☐

If yes to the above, state where, when and for what reason:

Applicant's initial



14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☐ No ☒

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☒ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☒ No ☐



Date of photograph _____

Applicant's initial _____

SS.

COUNTY OF Clark

I, Parminder S. Kang, MD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.


Original Signature of ApplicantSubscribed and Sworn to before me this 20th day of
Notary PublicApplicant's initial 

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date

8/20/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Business Pharmacy License

Nature of Pharmacy or Wholesaler

Desert Orthopaedic Center Pain Center, 8205 W. Warm Springs Rd. Ste #130, Las Vegas, NV 89113

Name and Address of Business for Which Designated Representative Is Requested

Institute of Orthopaedic Surgery, LLC

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Watson

Troy

S.

Last Name

First Name

Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Kittansett Loop

Henderson

NV 89052

Present Residence Address-Street or RFD

City

State/Zip

2800 E. Desert Inn Rd. #100

Dates

Las Vegas

NV 89121

Present Business Address

City

State/Zip

Physician/Partner

Dates 6/1/2000-Present

Present Position with the Pharmacy or Wholesaler

Phone:

Residence 7C

Business 702-731-1616

Date of Birth

Los Angeles, CA

Place of Birth (City, County, State)

54

Age

Social Security Number or ITIN

Male

Sex

Green

Brown

165

5'9"

Color of Eyes

Color of Hair

Complexion

Weight

Build

Height

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? ☒ Yes ☐ No ☐ If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

TRW

A. Current Marriage 8/24/1996Los Angeles, CASpouse's full name (Maiden) Judith Batliner WatsonDate _____
City, County and State
SS# or ITIN _____Date of Birth _____ Place of Birth Los Angeles, CAResident address Kittansett Loop Henderson NV 89052
Street City State Zip

Telephone: Resider _____ Business _____

Spouse's employer N/A Occupation _____Address of employer _____
Street City State Zip**B. Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:**A. Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Skyler		Charlotte, NC	Kittansett Loop, Henderson, NV 89052
Clayton		Charlotte, NC	Kittansett Loop, Henderson, NV 89052
Chloe		Las Vegas, NV	Kittansett Loop, Henderson, NV 89052

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial JSW

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Father			
--------	--	--	--

Deceased			
----------	--	--	--

Mother			
--------	--	--	--

Harriette Watson		Mission Viejo, CA	Retired Teacher
------------------	--	-------------------	-----------------

Father-in-Law			
---------------	--	--	--

Mother-in-Law			
---------------	--	--	--

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Brooks Watson		Austin, TX	Retired
---------------	--	------------	---------

Spouse			
--------	--	--	--

Shawn Watson		Conneticut	Restaurant Owner
--------------	--	------------	------------------

Spouse			
--------	--	--	--

Spouse			
--------	--	--	--

Spouse			
--------	--	--	--

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate	
Grammar School			Yes <input type="checkbox"/>	No <input type="checkbox"/>
High School	Capistrano Valley High School	CA	1980-1983	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College	University of Southern California	CA	8/1983-12/1987	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	Georgetown University	Washington D.C.	8/1990-5/1994	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Medical DoctorateCollege or university where obtained Georgetown University, Washington D.C.

Applicant's initial



5 MILITARY INFORMATION:

A. Have you ever served in any armed forces?

Yes ☐ No ☒

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☐ No ☒

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☒ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☒ No ☐ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☒ No ☐

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☒ No ☐

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☒ No ☐

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☒ No ☐ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☒ No ☐ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☒ No ☐ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial

TSY

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☐ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:


Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
	Kittansett Loop	Henderson	NV
	9 Clear Crossing Trail	Henderson	NV

Applicant's initial



8. EMPLOYMENT:

881

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

6/2000	Desert Orthopaedic Center 2800 E. Desert Inn Rd. #100, Las Vegas, NV 89121	N/A
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
MD	Ortho Foot/Ankle Consults/Surgeries/Admin	Michael Pendleton
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial

TSW

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Jim Wade</u>	<u>Home</u>	<u>St. Rosemary Henderson NV</u>				<u>5</u>
Employer <u>Arthur</u>	<u>Business</u>	<u>89052</u>				
Name <u>Shawn Parsons</u>	<u>Home</u>	<u>Madison Park Minneapolis MN</u>				<u>3</u>
Employer <u>Medtronic</u>	<u>Business</u>					
Name <u>D. Lee</u>	<u>Home</u>	<u>DESERT INN Las Vegas NV</u>				<u>5</u>
Employer <u>Doc</u>	<u>Business</u>					
Name <u>T. Watson</u>	<u>Home</u>	<u>DESERT INN Las Vegas NV</u>				<u>5</u>
Employer <u>Doc</u>	<u>Business</u>					
Name <u>M. Miao</u>	<u>Home</u>	<u>DESERT INN Las Vegas NV</u>				<u>5</u>
Employer <u>Doc</u>	<u>Business</u>					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

☒ Yes ☐ No

If yes, state type, where and years held

NC 1999-2000

GA 1997-1997

LA 1995-2000

NV 2000-Current

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☒ No

If yes to the above, state where, when and for what reason:

Applicant's initial

Tsu

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☒ No ☐

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☒ No ☐

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☒ No ☐

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☒ No ☐

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☒ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☒ No ☐



Date of photograph _____

Applicant's initial _____

TSW

ss.

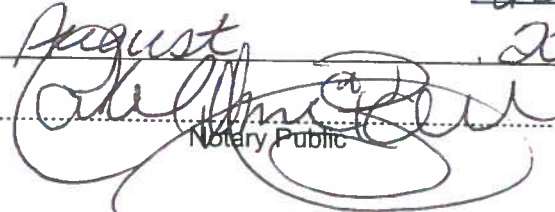
COUNTY OF Clark

I, Troy S. Watson, MD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.


Original Signature of Applicant

Subscribed and Sworn to before me this 20th day of

August, 2020

Notary Public



Applicant's initial TW

Baldauf	5.11%	-
Bassewitz	5.11%	-
Dunn	5.11%	-
Fontes	5.11%	-
Fouse	5.11%	-
Hanson	5.11%	-
Huff	5.11%	-
Kang	5.11%	-
Kim	5.11%	-
Lee, D	5.11%	-
Lee, M	5.11%	-
Miao	5.11%	-
Nevins	3.83%	-
Park	4.26%	-
Perry	5.11%	-
Raissi	5.11%	-
Stewart	5.11%	-
Tingey	5.11%	-
Watson	5.11%	-
Winder	5.11%	-
TOTAL	<u>100.00%</u>	<u>-</u>

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.
☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b
☒ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: First Specialty Surgery Center
Physical Address: 6120 S. Fort Apache Rd, Ste. 200
City: Las Vegas NV State: Zip Code: 89148 Telephone: 702-948-8891
Fax: 702-948-8956 Toll Free Number: _____
E-mail: Mike C @ 215sc.com

Website: _____

Managing Pharmacist: Mary Grear License Number: 10687

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☐ Retail
☐ ☐ Hospital (# beds _____)
☐ ☐ Internet
☐ ☐ Nuclear
☒ ☐ Ambulatory Surgery Center
☐ ☐ Community
☐ ☐ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☐ Off-site Cognitive Services
☒ ☒ Parenteral
☐ ☐ Parenteral (outpatient)
☐ ☐ Outpatient/Discharge
☐ ☐ Mail Service
☐ ☐ Long Term Care
☐ ☐ Sterile Compounding
☐ ☐ Non Sterile Compounding
☐ ☐ Mail Service Sterile Compounding
☐ ☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Michael
Original Signature of Person Authorized to Submit Application, no copies or stamps

Mike Chesak
Print Name of Authorized Person

7/29/20
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: Nevada

Parent Company if any: _____

Mailing Address: 6120 S. Fort Apache Rd, Ste 200City: Las Vegas State: NV Zip: 89148Telephone: 702-948-8894 Fax: 702-948-8956Contact Person: Mike CheseK

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Jeremy Lipshutz 6120 S. Fort Apache Rd, Ste 100 Las Vegas NV 89148
Name Business Address

CS17864

b) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address2) Provide the number of shares issued by the corporation. 13) What was the price paid per share? \$

List any physician shareholders and percentage of ownership.

Name: Jeremy Lipshutz %: 100

Name: _____ %: _____

Hours of Operation for the pharmacy:

Thursday
 Monday thru Friday 8 am 5 pm Saturday _____ am _____ pm
 Sunday _____ am _____ pm 24 Hours _____

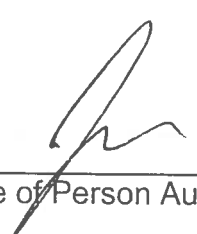
A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV 20201694751

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Jeremy Lipshutz
Responsible Person of First Specialty Surgery Center
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Jeremy Lipshutz
Print Name of Authorized Person

7/29/20
Date

Managing Pharmacist

Pharmacist Name: Mary Gnear, RPh License #: 10687

Pharmacy Name: First Specialty Surgery Center, LLC

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action:	State: <u>WV</u>	Date: <u>2002</u>	Case #: <u>02-036 RPA-S</u>
And/or Criminal Action:	State: _____	Date: _____	Case #: _____
County	_____	Court: _____	

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Mary Green RPh
Signature

7/24/2020
Date

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date 8/9/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for First Specialty Surgery Center
6120 S. Fort Apache Rd Ste. 200 Las Vegas NV 89148
 Name and Address of Business for Which Designated Representative Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name Lipshutz First Name Jeremy Middle Name Marc

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Candlestick Ave Henderson NV 89052
 Present Residence Address-Street or RFD City State/Zip

6120 S. Fort Apache Rd #200 2014-present
 Present Business Address City Las Vegas, NV State/Zip 89148

Present Position with the Pharmacy or Wholesaler Medical Director - Surgery Center
 Phone Residence 702-948-8894
 Business

Date of Birth 47 Place of Birth (City, County, State) Boston, Suffolk, MA

Age 47 Social Security Number 1 Sex Male

Color of Eyes Hazel Color of Hair Brown Complexion White Weight 450lbs Build Heavy Height 6'0"

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No.

If naturalized, certificate No. N/A Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

MARITAL INFORMATION-Continued

A. **Current Marriage** 11/12/2000 Novi, Oakland MI
Date City, County and State
 Spouse's full name (Maiden) Renee Debra (Miller) Lipshutz
No.
 Date of Birth Place of Birth Southfield, MI
 Resident address Candlestick Ave Henderson NV 89052
Street City State Zip
 Telephone: Residence Business 702-250-8266
 Spouse's employer Lipshutz & Wilk Medical Group, LLP Occupation Marketing
 Address of employer 6120 S. Fort Apache Rd #100 Las Vegas NV 89148
Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
<u>N/A</u>				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
<u>N/A</u>					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
<u>Parker Lipshutz</u>	<u>1.1.11</u>	<u>Royal Oak, MI</u>	<u>Candlestick Ave Henderson, NV 89052</u>
<u>Maxwell Lipshutz</u>	<u>1.1.11</u>	<u>Cleveland, OH</u>	<u>"</u>
<u>Ryder Lipshutz</u>	<u>1.1.11</u>	<u>CommerceTwp, MI</u>	<u>"</u>

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father			
<u>Nelson Lipshutz</u>		<u>Radcliff Rd, Woburn, MA 02468</u>	<u>Consultant</u>
Mother			
<u>Sallee (Horowitz) Lipshutz</u>		<u>"</u>	<u>Executive</u>
Father-in-Law			
<u>Stuart Fishman</u>		<u>Mountain City St, Henderson, NV 89052</u>	<u>Retired</u>
Mother-in-Law			
<u>Dena (Gorsoff) Fishman</u>		<u>"</u>	<u>Retired</u>

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
<u>Abigail (Lipshutz) Schildcrout</u>		<u>LaSalle, Huntington Woods, MI</u>	<u>Physician</u>
Spouse			
<u>Douglas Schildcrout</u>		<u>LaSalle " 48070</u>	<u>Engineer</u>
<u>Rebecca (Lipshutz) Peak</u>		<u>Adams St, Westborough, MA</u>	<u>Physician</u>
Spouse			
<u>Brian Peak</u>		<u>" 01581</u>	<u>Entrepreneur</u>

Spouse _____

Spouse _____

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	<u>Ainger Elementary</u>	<u>Woburn, MA</u>	<u>1982-1985</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	<u>Newton South High School</u>	<u>Newton, MA</u>	<u>1987-1991</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College	<u>Grinnell College</u>	<u>Grinnell, IA</u>	<u>1991-1995</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
University	<u>Johns Hopkins U. Public Health</u>	<u>Baltimore, MD</u>	<u>1996-1998</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	<u>Wayne State U. School of Medicine</u>	<u>Detroit, MI</u>	<u>1998-2003</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	<u>UNLV-William S. Boyd School of Law</u>	<u>Las Vegas, NV</u>	<u>2015-2019</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any MD, JD, MHSCollege or university where obtained Wayne State U. SOM, UNLV-Boyd School of Law, Johns HopkinsApplicant's initial L

5 MILITARY INFORMATION:

- A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch N/A Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

- B. Have you registered for the draft? Yes ☒ No ☐

County Middlesex State MA Date registered 1991

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

- A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

N/A

- B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.
- C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒
- D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒
- E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒
- F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? N/A city, county and state _____
- G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? MA city, county and state _____
- H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
------	--------------	--------	----------	------

N/A

Applicant's initial _____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Defendant	8/31/2015	Eight Judicial District - NV A-M-701103-B	Las Vegas, Clark, NV	Dismissed with Prejudice 7/12/20
Defendant	Under Seal	US District Court - NV 2:19-cv-1871-KJD-VCF	Las Vegas, Clark, NV	Pending

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☒ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
Bardar Enterprises, LLC-Series I	LLC-Corporation	2015
Lipshutz + Wills Medical Group LLP	LLP-Partnership	2019
Jeremy M. Lipshutz, MD, Ltd	S-Corporation	2019

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
9/2015 - present	Candlestick Ave	Henderson	NV
11/2011 - 9/2015	502 Beneficial Pl	Henderson	NV
2/2010 - 11/2011	1355 Quiet River Ave	Henderson	NV
3/2009 - 2/2010	1363 Quiet River Ave	Henderson	NV
9/2005 - 3/2009	West Bloomfield Oaks Dr	West Bloomfield	MI
6/2003 - 9/2005	Fenwick Rd	University Hts	OH
6/1999 - 6/2003	Main St	Royal Oak	MI
6/1998 - 6/1999		Troy	MI
3/1980 - 6/1999	24 Rockliff Rd	Newton (Woburn)	MA

Applicant's initial

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year <i>11/2011 - present</i>	Name/Mailing Address of Employer/Business <i>Lipshutz/H/15 Medical Group LLP 61205 Fort</i>	Number of Employed Hours <i>1700</i>
Title <i>Physician</i>	Description of Duties <i>Medical Practice as a doctor</i>	Name of Supervisor <i>Self</i>
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Scott Auerbach</u>	Hc	<u>RiverSpay Henderson, NV</u>	<u>89012</u>			<u>11</u>
Employer	Business					
Name <u>Lisa Auerbach</u>	Home	<u>RiverSpay Henderson, NV</u>	<u>89012</u>			<u>11</u>
Employer	Business					
Name <u>Rajiv Khamankar</u>	Home					<u>5</u>
Employer	Business					
Name <u>Allen Gessen</u>	Home					<u>30</u>
Employer	Business					
Name <u>Stephanie Lerner</u>	Home					<u>10</u>
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

Medical License MI 2005-present; Medical License NV 2009-present;
Lawyer, State Bar of Nevada 2019-present

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
 If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

N/A

Applicant's initial

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒
15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒
17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☐ No ☒
18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

N/A

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? *Surgery Center* Yes ☒ No ☐
20. Will you be employed fulltime with the pharmacy or wholesaler? *Surgery Center* Yes ☐ No ☒
Owner / Medical Director
21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? *Sometimes - will not always be present when open.* Yes ☒ No ☐



Date of photograph 8/19/20

Applicant's initial *[Signature]*

STATE OF Nevada

SS.

COUNTY OF Clark

I, Jeremy Lipschutz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 19 day of

August, 2020
Mindy Garcia-Preciado
 Notary Public

(seal)



Applicant's initial

Page 9

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **First Specialty Surgery Center, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 01/20/2020, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/31/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200731968672

You may verify this certificate
online at <http://www.nvsos.gov>



BARBARA K. CEGAVSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
 (775) 684-5708
 Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

First Specialty Surgery Center, LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: Read instructions before completing and returning this form.

Please indicate the entity type (check only one):

- ☐ Corporation
- ☐ This corporation is publicly traded, the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☒ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of <i>Barbara K. Cegavske</i>	Business Number E4272612020-5
Secretary of State State Of Nevada	Filing Number 20200427262
	Filed On 01/20/2020 12:50:08 PM
	Number of Pages 2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is \$200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee.
 Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C § 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit \$200.00 for the state business license.

- ☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. §501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required.
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****



BARBARA K. CEGAVSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
 (775) 684-5708
 Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE MANAGING MEMBER:

Jeremy M. Lipshutz, MD, Ltd.

Name

USA

Country

6120 South Fort Apache Road, Suite 200

Address

Las Vegas

City

NV

State

89148

Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X **Patrick N. Chapin**

**Signature of Officer, Manager, Managing
 Member, General Partner, Managing Partner,
 Trustee, Member, Owner of Business,
 Partner or Authorized Signer** FORM WILL BE RETURNED IF
 UNSIGNED

Organizer

Title

01/15/2020

Date

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206-- Reno, NV 89521 -- (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.
☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☒ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Signature Surgery Center

Physical Address: 6930 S. Cimarron Rd Suite 100

City: Las Vegas NV State: NV Zip Code: 89113 Telephone: _____

702 780 4222 Fax: * Toll Free Number: _____

E-mail: * _____

Website: * _____

Managing Pharmacist: Mary Grear License Number: 10687

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☒ ☐ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☐ Off-site Cognitive Services
☒ ☐ Parenteral
☐ ☐ Parenteral (outpatient)
☐ ☐ Outpatient/Discharge
☐ ☐ Mail Service
☐ ☐ Long Term Care
☐ ☐ Sterile Compounding
☐ ☐ Non Sterile Compounding
☐ ☐ Mail Service Sterile Compounding
☐ ☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.


Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Himanshu Shah
Print Name of Authorized Person

8/13/20
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Himansu Shah ✓ CS11151
 Business Name: Signature Surgery Center, LLC
 Current Business Address: 6930 S Cimarron Rd Suite 100
 City: Las Vegas State: NV Zip Code: 89113
 Telephone: 702-780-4222 Fax: 702-684-5503

List any physician shareholders and percentage of ownership.

Name: _____ %: _____
 Name: _____ %: _____
 Name: _____ %: _____
 Name: _____ %: _____

Hours of Operation for the pharmacy:

* Monday thru Friday 8 am 4 pm Saturday _____ am _____ pm
 Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Himansu Shah

Responsible Person of Signature Surgery Center

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Himansu Shah
Print Name of Authorized Person

8/20/20
Date

Managing Pharmacist

 Pharmacist Name: Mary Greer, RPh

 License #: 10687

 Pharmacy Name: Signature Surgery Center

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action:	State: <u>NV</u>	Date: <u>4/2002</u>	Case #: <u>020362P15</u>
And/or Criminal Action:	State: _____	Date: _____	Case #: _____
	County: _____	Court: _____	

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Mary Green RPL
 Signature

8/20/2020
 Date

**APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada**

912

Date 8/20/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Signature Surgery Center
6930 S. Cimarron St. Suite 100 Las Vegas NV 89113
Nature of Pharmacy or Wholesaler
Name and Address of Business for Which Designated Representative Is Requested
If applicable, Name Under Which It is Now Operated

1. PERSONAL INFORMATION:

SHAH Himansu RAMESH
Last Name First Name Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

FOOTHILLS Village Dr HENDERSON NV 89012
Present Residence Address-Street or RFD City State/Zip

6930 S. Cimarron Rd 08/20 Las Vegas NV 89113
Present Business Address Dates City State/Zip

Present Position with the Pharmacy or Wholesaler Phone: Residence

KARAMSAD, GUJARAT, INDIA
Date of Birth Place of Birth (City, County, State) Business

53 M
Age Social Security Number or ITIN Sex

Brown Black/gray Brown 152lbs medium 5' 5 1/2"
Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics Right Eyebrow Scar

Are you a citizen of the United States? ☒ Yes ☐ No If alien, registration No

If naturalized, certificate N Date 3/13/1987

Place Newark, NJ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial HS

A. **Current Marriage** 12/3/1994 Baroda, Gujarat, India
Date City, County and State
 Spouse's full name (Maiden) Lopa Dilip Kumar SHAH SS# or ITIN
 Date of Birth _____ Place of Birth Baroda, India
 Resident address Foothills Village Dr Henderson NV 89012
Street City State Zip
 Telephone: Residence _____ Business 702-492-4810
 Spouse's employer SOUTHWEST Medical Associates Occupation Physician
 Address of employer 2845 SIENNA HEIGHTS AVE Henderson NV 89052
Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
AMAR SHAH		LIVINGSTON NJ	Foothills Village Dr. Henderson NV 89012
RUSHIL SHAH		Langhorne PA	Foothills Village Dr Henderson NV 89012

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial HS

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father			
RAMESH SHAH	Deceased	
Mother			
Ansuya SHAH	8 Frey Rd Hillsborough NJ 08844	Retired
Father-in-Law			
Dilatkumar SHAH	Deceased	
Mother-in-Law			
ILA SHAH	Deceased	

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Hemangini Shah (sister)		Winchester Lane Homdel NJ 07733	Physician
Spouse			
CHIRAG SHAH (B-in Law)		Winchester Lane Homdel NJ 07733	Physician
PRASANT SHAH (Brother)		Frey Rd Hillsborough NJ 08844	Computer Engineer
Spouse			
Jolly SHAH (S-in Law)		Frey Rd Hillsborough NJ 08844	Pharmacy Tech
Spouse			
Spouse			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	DEMA REST	Hoboken NJ	09/79-06/81	<input checked="" type="radio"/> Yes <input type="radio"/> No
High School	Hoboken High School	Hoboken NJ	09/81-06/85	<input checked="" type="radio"/> Yes <input type="radio"/> No
College University	STEVENS Institute of Tech.	Hoboken NJ	08/85-05/89	<input checked="" type="radio"/> Yes <input type="radio"/> No
Other	UMDNJ-NSM	Newark NJ	08/89-05/93	<input checked="" type="radio"/> Yes <input type="radio"/> No

Type of degree obtained, if any ① B.S. ② M.D.

College or university where obtained STEVENS Institute of Technology UMDNJ-NSM Newark

Applicant's initial HD

5 MILITARY INFORMATION:

915

A. Have you ever served in any armed forces?

Yes

No

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes No If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes

No

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes No If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes No If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes No

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes No

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes No

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes No If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes No If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes No If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial

HS

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Jushn Biel vs SHAH	11/20/2009	DC Clark County NV A-580455 Dept #10	Las Vegas, Clark NV	12/31/2013 Dismissed w/ prejudice
Wilson vs SHAH	3/17/20	DC Clark County NV A-200-812466-C	Las Vegas, NV	Pending

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☒ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
01/1995 - 06/1997	Baldwin Dr.	New Providence	NJ 07974
07/1997 - 06/2000	4334 Burling St	Flushing NY	11355
07/2000 - 06/2002	2201 Tremont St	Philadelphia PA	19115
07/2002 - 08/2003	2541 Citrus Garden Circle	Henderson NV	89052
09/2003 - 02/2013	2508 Skippers Cove Ave	Henderson NV	89052
03/2013 - Present	Foot Hills Village Dr	Henderson NV	89012

Applicant's initial

JB

8. EMPLOYMENT:

917

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

07-2002-10-2003	UNSom 1707 W. Charleston Blvd NV 89102	Full time
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Physician	Plastic Surgeon	Dr. Zamboni
Title	Description of Duties	Name of Supervisor
11/2003-10-2018	VA Medical Center 6900 N. Pecos Rd N. Las Vegas NV 89086	Full time
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Physician	Plastic Surgeon	Dr. Losano
Title	Description of Duties	Name of Supervisor
11/2008-Present	Himanx Shah MD, PLLC	Full time
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Physician	Plastic Surgeon	Self Employed
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial HS

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Dr. Sudhir Khemkar</u> Home		Josephine Dr.	NV	89044		10 years
Employer <u>Dr. Sudhir Khemkar</u> MD LLC Business		291 Josephine Dr.	NV	89044		
Name <u>RAMESH SRINIVASAN</u> Home		Ping Dr.	NV	89074		15 years
Employer <u>Agilysys Inc</u> Business		6775 South Edmond St Suite 280	Las Vegas	NV 89118	702-875-4898	
Name <u>Dr. Bipin Sand</u> Home		Regents gate Tr.	Henderson	NV 89012		11 years
Employer <u>Valley Health Physio Alliance</u> Business		825 N. Gibson Rd. Suite 201	Henderson	NV 89074	702-492-1162	
Name <u>Dr. Vikas Sayal</u> Home		Mallard Creek	Henderson	NV 89052		5 1/2 years
Employer <u>Pulmonary Group LLC</u> Business		2904 W Horizon Pkwy Suite 100	Henderson	NV 89052	780-0300	
Name <u>Madhukar Sathnur</u> Home		Via Cadoma	Henderson	NV 89052		5.5 years
Employer <u>Agilysys Inc</u> Business		6775 S. Edmond St Suite 100	Las Vegas	NV 89118	702-759-4845	

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor

Doctor

Accountant

Yes

No

Lawyer

Contractor

Pilot

Race horse/race dog owner

Real estate broker or salesman

Sports promoter

Securities dealer

Barber/Cosmetologist

Trainer or manager

Insurance

Gaming

Educator

If yes, state type, where and years held

New York, Pennsylvania, Nevada, Arizona

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☒
- If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No ☒

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☒ No ☒

If yes to the above, state where, when and for what reason:

Applicant's initial

HS

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability?

Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry?

Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances?

Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler)

Yes ☐ No ☒

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry?

Yes ☐ No ☒

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler?

Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler?

Yes ☐ No ☒

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours?

Yes ☒ No ☐



Date of photograph 8/20/20

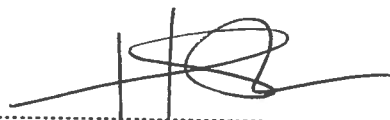
Applicant's initial HS

ss.

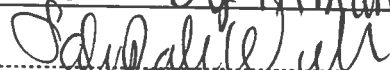
COUNTY OF CLARK

I, Himansu SHAH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

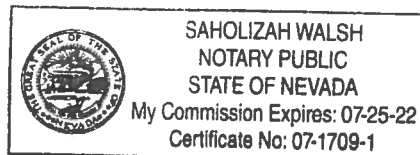
I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.



Original Signature of Applicant

Subscribed and Sworn to before me this 20 day of August2020 by Himansu Shah

Notary Public



(seal)

Applicant's initial HS

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE
WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Signature Surgery Center LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 04/22/2019, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/20/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202008201019501

You may verify this certificate
online at <http://www.nvsos.gov>

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.
☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b
☒ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Ultimate Specialty Surgery Center
Physical Address: 6120 S. Fort Apache Rd, Ste. 200 Las Vegas NV 89148
City: Las Vegas State: Zip Code: 89148 Telephone:
702-948-8894 Fax: 702-948-8956 Toll Free Number:
E-mail: Mikec@215sc.com

Website:

Managing Pharmacist: Mary Greas License Number: 10687

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☐ Retail
☐ ☐ Hospital (# beds _____)
☐ ☐ Internet
☐ ☐ Nuclear
☒ ☐ Ambulatory Surgery Center
☐ ☐ Community
☐ ☐ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☒ ☐ Off-site Cognitive Services
☒ ☒ Parenteral
☐ ☐ Parenteral (outpatient)
☐ ☐ Outpatient/Discharge
☐ ☐ Mail Service
☐ ☐ Long Term Care
☐ ☐ Sterile Compounding
☐ ☐ Non Sterile Compounding
☐ ☐ Mail Service Sterile Compounding
☐ ☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Mike CheseK

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mike CheseK
Print Name of Authorized Person

7/29/20
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: Nevada

Parent Company if any: _____

Mailing Address: 6120 S. Fort Apache Rd, Ste. 200City: Las Vegas State: NV Zip: 89148Telephone: 702-948-8894 Fax: 702-948-8956Contact Person: Mike Cheseck

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Jeremy Lipshutz 6120 S. Fort Apache Rd, Ste 100 Las Vegas NV 89148
Name Business Address CS17864b) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address2) Provide the number of shares issued by the corporation. 13) What was the price paid per share? 0

List any physician shareholders and percentage of ownership.

Name: Jeremy Lipshutz %: 100

Name: _____ %: _____

Hours of Operation for the pharmacy:

Thursday
 Monday thru Friday 8 am 5 pm Saturday _____ am _____ pm
 Sunday _____ am _____ pm 24 Hours _____


A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20201694148

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Jeremy Lipshutz
Responsible Person of Ultimate Specialty Surgery Center
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Jeremy Lipshutz
Print Name of Authorized Person

7/29/20
Date

Managing Pharmacist

Pharmacist Name: Mary Green, RPh License #: 10687

Pharmacy Name: Ultimate Specialty Surgery Center, LLC

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: NU Date: 2002 Case #: 02-036-RPH-S
 And/or Criminal Action: State: _____ Date: _____ Case #: _____
 County: _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Mary Green RPh
 Signature

7/29/2020
 Date

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date 8/9/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Ambulatory Surgery Center
Ultimate Specialty Surgery Center Nature of Pharmacy or Wholesaler
 Name and Address of Business for Which Designated Representative Is Requested 6120 S. Fort Apache Rd, Ste 200 Las Vegas NV 89148
 If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name Lipshutz First Name Jeremy Middle Name Marc

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Candlestick Ave Henderson NV 89052
 Present Residence Address-Street or RFD City State/Zip
9/2015-present Dates

6120 S. Fort Apache Rd #200 Las Vegas, NV 89148
 Present Business Address City State/Zip
2014-present Dates

Present Position with the Pharmacy or Wholesaler Medical Director - Surgery Center Phone: 702-948-8894
 Resident Business

Date of Birth 47 Place of Birth (City, County, State) Boston, Suffolk, MA

Age 47 Social Security Number Sex Male

Color of Eyes Hazel Color of Hair Brown Complexion White Weight 450lbs Build Heavy Height 6'0"

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No

If naturalized, certificate No N/A Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial [Signature]

MARITAL INFORMATION-Continued

A. **Current Marriage** 11/12/2000 Novi, Oakland MI
 Date City, County and State
 Spouse's full name (Maiden) Renee Debra (Miller) Lipshutz
 Date of Birth _____ Place of Birth Southfield, MI
 Resident address Candlestick Ave Henderson NV 89052
 Street City State Zip
 Telephone: Residence 702-250-8266 Business 702-250-8266
 Spouse's employer Lipshutz & Wilb Medical Group, LLP Occupation Marketing
 Address of employer 6120 S. Fort Apache Rd #100 Las Vegas NV 89148
 Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
<u>N/A</u>				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
<u>N/A</u>					

3. **FAMILY INFORMATION:**A. **Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
<u>Parker Lipshutz</u>	<u>1.1.11</u>	<u>Royal Oak, MI</u>	<u>Candlestick Ave Henderson, NV 89052</u>
<u>Maxwell Lipshutz</u>	<u>1.1.11</u>	<u>Cleveland, OH</u>	<u>"</u>
<u>Ryder Lipshutz</u>	<u>1.1.11</u>	<u>Commerce Twp, MI</u>	<u>"</u>

B. **Child Support Information:**

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial _____

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father <u>Nelson Lipshutz</u>		<u>... iardiff Rd, Woburn, MA 02468</u>	<u>Consultant</u>
Mother <u>Sallee (Horovitz) Lipshutz</u>		<u>"</u>	<u>Executive</u>
Father-in-Law <u>Stuart Fishman</u>		<u>Mountain City St, Henderson, NV 89052</u>	<u>Retired</u>
Mother-in-Law <u>Dena (Goroff) Fishman</u>		<u>"</u>	<u>Retired</u>

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
<u>Abigail (Lipshutz) Schilder</u>		<u>LaSalle, Huntington Woods, MI</u>	<u>Physician</u>
Spouse <u>Douglas Schilder</u>		<u>LaSalle " 48070</u>	<u>Engineer</u>
<u>Rebecca (Lipshutz) Peak</u>		<u>Adams St, Westborough, MA</u>	<u>Physician</u>
Spouse <u>Brian Peak</u>		<u>" 01581</u>	<u>Entrepreneur</u>

Spouse _____

Spouse _____

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School <u>Ainger Elementary</u>	<u>Woburn, MA</u>	<u>1980-1985</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School <u>Newton South High School</u>	<u>Newton, MA</u>	<u>1987-1991</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College <u>Grinnell College</u>	<u>Grinnell, IA</u>	<u>1991-1995</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
University <u>Johns Hopkins U. Public Health</u>	<u>Baltimore, MD</u>	<u>1996-1998</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<u>Wayne State U. School of Medicine</u>	<u>Detroit, MI</u>	<u>1998-2003</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other <u>UNLV-William S. Boyd School of Law</u>	<u>Las Vegas, NV</u>	<u>2015-2019</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any MD, JD, MHSCollege or university where obtained Wayne State U. SOM, UNLV-Boyd School of Law, Johns Hopkins U.Applicant's initial L

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch N/A Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☒ No ☐

County Middlesex State MA Date registered 1991

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

N/A

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? N/A city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? N/A city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
------	--------------	--------	----------	------

N/A

Applicant's initial _____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Defendant	8/31/2015	Eighth Judicial District - NV A-14-701103-B	Las Vegas, Clark, NV	Dismissed with Prejudice 7/17/20
Defendant	Under Seal	US District - NV 2:19-cv-1871-JSD-VCF	Las Vegas, Clark, NV	Pending

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☒ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
Barbar Enterprises, LLC-Series I	LLC-Corporation	2015
Lipshutz & Wills Medical Group LLP	LLP-Partnership	2019
Jeremy M. Lipshutz, MD, Ltd	S-Corporation	2019

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
9/2015 - present	Candlestick Ave	Henderson	NV
11/2011 - 9/2015	502 Beneficial Pl	Henderson	NV
2/2010 - 11/2011	1355 Quiet River Ave	Henderson	NV
3/2009 - 2/2010	1363 Quiet River Ave	Henderson	NV
9/2005 - 3/2009	West Blenheim Oaks Dr	West Blenheim	MI
6/2003 - 9/2005	Fenwick Rd	University Hts	OH
6/1999 - 6/2003	Main St	Royal Oak	MI
6/1998 - 6/1999		Troy	MI
3/1980 - 6/1999	24 Rockliffe Rd	Newton (Waban)	MA

Applicant's initial _____

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
11/2011 - present	Lipshutz/Hill's Medical Group LLP 61205 Fort	1700
Title	Description of Duties	Name of Supervisor
Physician	Medical Practice as a doctor	Self
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Scott Auerbach</u>	Home	<u>RiverSpray Henderson, NV</u>	<u>89012</u>			<u>11</u>
Employer	Business					
Name <u>Lisa Auerbach</u>	Home	<u>RiverSpray Henderson, NV</u>	<u>89012</u>			<u>11</u>
Employer	Business					
Name <u>Rajiv Khamankar</u>	Home					<u>5</u>
Employer	Business					
Name <u>Allen Gessen</u>	Home					<u>30</u>
Employer	Business					
Name <u>Stephanie Lerner</u>	Home					<u>10</u>
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

Medical License MI 2005-present; Medical License NV 2009-present;
Lawyer, State Bar of Nevada 2019-present

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
 If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

N/A

Applicant's initial

Page 7

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒
15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒
17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☐ No ☒
18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

N/A

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? *Surgery Center* Yes ☒ No ☐
20. Will you be employed fulltime with the pharmacy or wholesaler? *Surgery Center* Yes ☐ No ☒
Owner / Medical Director
21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? *Sometimes - will not always be present when open.* Yes ☒ No ☐



Date of photograph

8/19/20

Applicant's initial

Page 8

STATE OF Nevada

ss.

COUNTY OF Clark

I, Jeremy Lipshutz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

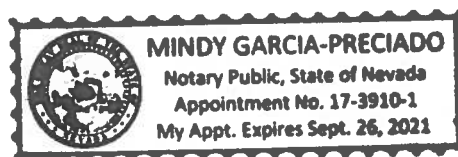
I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 19 day of

August, 2020
Mindy Garcia-Preciado
 Notary Public

(seal)



Applicant's initial jl Page 9

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Ultimate Specialty Surgery Center, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 01/20/2020, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/31/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200731968681

You may verify this certificate
online at <http://www.nvsos.gov>



BARBARA K. CEGAVSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
 (775) 684-5708
 Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Ultimate Specialty Surgery Center, LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: Read instructions before completing and returning this form.

Please indicate the entity type (check only one):

- ☐ Corporation
- ☐ This corporation is publicly traded, the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☒ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of	Business Number
<i>Barbara K. Cegavske</i>	E4272522020-7
Secretary of State	Filing Number
State Of Nevada	20200427253
	Filed On
	01/20/2020 12:49:31 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is \$200.00. Those claiming exemption under 501(c) designation must indicate by checking box below.

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee.
 Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C § 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit \$200.00 for the state business license.

- ☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. § 501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required.
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****



BARBARA K. CEGAVSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
 (775) 684-5708
 Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE MANAGING MEMBER:

Jeremy M. Lipshutz, MD, Ltd.

Name

USA

Country

6120 South Fort Apache Road, Suite 200

Address

Las Vegas

City

NV

State

89148

Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X **Jeremy M. Lipshutz, MD, Ltd.**

**Signature of Officer, Manager, Managing
 Member, General Partner, Managing Partner,
 Trustee, Member, Owner of Business,
 Partner or Authorized Signer** FORM WILL BE RETURNED IF

UNSIGNED

Managing Member

Title

01/17/2020

Date

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH 03609)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership. ADDRESS CHANGE
☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: All city Pharmacy LLC
Physical Address: 821 N Lamb Blvd STE 5
City: Las Vegas State: NV Zip Code: 89110 Telephone: 702 834 7704
(702) 834-7704 Fax: 702 834-7705 Toll Free Number: _____
E-mail: hrc allcitypharmacy.com
Website: www.allcitypharmacy.com
Managing Pharmacist: Janice Rose License Number: 13727

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

☒ ☐ Retail

☐ ☐ Hospital (# beds _____)

☐ ☐ Internet

☐ ☐ Nuclear

☐ ☐ Ambulatory Surgery Center

☐ ☐ Community

☐ ☐ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

☐ ☐ Off-site Cognitive Services

☐ ☐ Parenteral

☐ ☐ Parenteral (outpatient)

☐ ☐ Outpatient/Discharge

☐ ☐ Mail Service

☐ ☐ Long Term Care

☐ ☐ Sterile Compounding

☐ ☐ Non Sterile Compounding

☐ ☐ Mail Service Sterile Compounding

☐ ☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Janice Rose

Original Signature of Person Authorized to Submit Application, no copies or stamps

Janice Rose

9-24-20

Print Name of Authorized Person

Date

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: NEVADA

Parent Company if any: _____

Mailing Address: 821 N. LAUB BLVD STE 5City: LAS VEGAS State: NV Zip: 89110Telephone: (702) 834-7704 Fax: (702) 834-7705Contact Person: ERICA VITAL ESPINOSA

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Addressb) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 9 am 6 pm Saturday _____ am _____ pm
Sunday _____ am _____ pm 24 Hours CLOSEDA Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20161161525

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Garen Garakhanyan
 Business Name: All City Pharmacy LLC
 Current Business Address: 821 N. Lamb Blvd STE 5
 City: Las Vegas State: NV Zip Code: 89110
 Telephone: (702) 834-7704 Fax: (702) 834-7705

List any physician shareholders and percentage of ownership.

Name: N/A %: _____
 Name: _____ %: _____
 Name: _____ %: _____
 Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday _____ am _____ pm
 Sunday _____ am _____ pm 24 Hours CLOSED
CLOSED

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV 20161161525

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Janice ROSE
Responsible Person of ALL CITY pharmacy LLC
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Janice Rose
Original Signature of Person Authorized to Submit Application, no copies or stamps

Janice Rose
Print Name of Authorized Person

9-24-20
Date

Managing Pharmacist

Pharmacist Name:

Janice ROSE

License #:

13727

Pharmacy Name:

All City Pharmacy LLC

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If you marked YES to any of the numbered questions above, please include the following information		
Board Administrative Action:	State: _____	Date: _____ Case #: _____
And/or Criminal Action:	State: _____	Date: _____ Case #: _____
County	_____	Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.



 Signature

9-24-20

 Date

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **ALL CITY PHARMACY L.L.C.**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 03/16/2016, and is in good standing in this state.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation document and no amendments on file in this office as of the date of this certificate.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/21/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202009211089753

You may verify this certificate
online at <http://www.nvsos.gov>

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**MONEY
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19-145338543

A 736097 D 092120
T 1144 10
191453385430 L 029979

\$

NOT GOOD OVER \$500

PAY EXACTLY

PAY TO THE
ORDER OF

NEVADA STATE BOARD OF PHARMACY

821 N LAMBDA BLVD 89410

LIC # PH03609

PURCHASER'S SIGNATURE

PURCHASER BY SIGNING YOU AGREE TO THE TERMS ON THE REVERSE SIDE

⑆102100400⑆ 40191453385430⑆

MONEY ORDER RECEIPT - NON NEGOTIABLE

A 736097 D 092120 T 1144 10 L 029979 191453385430 L 029979

Payable to:
RETAIN THIS MONEY ORDER RECEIPT. IT MUST BE INCLUDED WITH ALL REFUND REQUESTS. BE SURE TO READ IMPORTANT INFORMATION BELOW AND ON BACK. For your own records, it is recommended that you make a photocopy of the completed Money Order before providing it to the receiver.

PURCHASE AGREEMENT: You the purchaser agree that Western Union Financial Services Inc. (WUFSI) need not stop payment on, or replace, or refund a lost or stolen WUFSI Money Order unless: (1) you fill in the face of the Money Order at the time of purchase, and (2) you report the loss or theft to Western Union Financial Services Inc. in writing immediately, and (3) You provide WUFSI with this original Money Order receipt issued by Western Union Financial Services Inc., Englewood, Colorado. For customer service, call 1-800-999-0660.

* 19145338543 *



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Nevada State Board of Pharmacy

For licensing inquiries please send an email to, pharmacy@pharmacy.nv.gov (mailto:pharmacy@pharmacy.nv.gov).

For current information on [disciplinary actions taken against licensees](#), please send an email to shunting@pharmacy.nv.gov (mailto:shunting@pharmacy.nv.gov).

VERIFY LICENSE

Last Name	First Name	License#	City	State	Country	Discipline	Action
Rose	Janice	13727	HENDERSON	NV	United States	None	

License Number : 13727

Name : Rose, Janice

License Type : Pharmacist

License Status : Active

License Date : 07/28/1997

Discipline :

Expiration Date : 10/31/2021



ENTITY INFORMATION**ENTITY INFORMATION****Entity Name:**

ALL CITY PHARMACY L.L.C.

Entity Number:

E0124232016-8

Entity Type:

Domestic Limited-Liability Company (86)

Entity Status:

Active

Formation Date:

03/16/2016

NV Business ID:

NV20161161525

Termination Date:

Perpetual

Annual Report Due Date:

3/31/2021

Series LLC:☐**Restricted LLC:**☐**REGISTERED AGENT INFORMATION**

Name of Individual or Legal Entity:

ELEN ZAKARYAN

Status:

Active

CRA Agent Entity Type:**Registered Agent Type:**

Non-Commercial Registered Agent

NV Business ID:**Office or Position:****Jurisdiction:****Street Address:**

821 N. LAMB BLVD, LAS VEGAS, NV, 89110, USA

Mailing Address:

821 N. LAMB BLVD, LAS VEGAS, NV, 89110

Individual with Authority to Act:**Fictitious Website or Domain Name:****OFFICER INFORMATION**☐ **VIEW HISTORICAL DATA**

Title	Name	Address	Last Updated	Status
Managing Member	GAREN GARAKHANYAN	821 NORTH LAMB BLVD SUITE 4, LAS VEGAS, NV, 89110, USA	03/15/2019	Active
Managing Member	GAREN GARAKHANYAN	821 NORTH LAMB BLVD SUITE 4, LAS VEGAS, NV, 89110, USA	03/15/2019	Active

Page 1 of 1, records 1 to 2 of 2

[Filing History](#)[Name History](#)[Mergers/Conversions](#)

ENTITY INFORMATION**ENTITY INFORMATION****Entity Name:**

ALL CITY PLAZA, LLC

Entity Number:

E0378002015-6

Entity Type:

Domestic Limited-Liability Company (86)

Entity Status:

Active

Formation Date:

08/06/2015

NV Business ID:

NV20151470702

Termination Date:

Perpetual

Annual Report Due Date:

8/31/2021

Series LLC:**Restricted LLC:****REGISTERED AGENT INFORMATION**

Name of Individual or Legal Entity:

ANGELA FURNCHYAN

Status:

Active

CRA Agent Entity Type:**Registered Agent Type:**

Commercial Registered Agent

NV Business ID:**Office or Position:****Jurisdiction:****Street Address:**

3446 W HACIENDA AVE, LAS VEGAS, NV, 89118, USA

Mailing Address:**Individual with Authority to Act:**

SARKIS FURNCHYAN

Fictitious Website or Domain Name:**OFFICER INFORMATION**☐ **VIEW HISTORICAL DATA**

Title	Name	Address	Last Updated	Status
Managing Member	SARKIS FURNCHYAN	3446 W HACIENDA AVE, LAS VEGAS, NV, 89118, USA	08/30/2018	Active
Managing Member	JANET FURNCHYAN	3446 W HACIENDA AVE, LAS VEGAS, NV, 89118, USA	08/30/2018	Active

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5

MATRIX GUIDELINE FOR DISCIPLINARY ACTIONS

	1st Action	2nd Action	3rd Action
Non ingested error	Letter	Letter	Hearing
No counseling	\$750.00	Counseling CE + \$1000.00	Hearing
Attorney Fees and Costs	Actual	Actual	Actual
Ingested no potential harm	\$500.00	\$1000.00	Hearing
Ingested with potential harm or adverse outcomes	\$1000.00	Hearing	Hearing
Ingested with negative outcome or patient discomfort.			
No institution intervention	Hearing	Hearing	Hearing
Ingested with significant negative health circumstance.			
With institution admit	Hearing	Hearing	Hearing
Ingested with death related to inappropriate drug therapy	Hearing	Hearing	Hearing

The investigative committee will review each case individually and may recommend a board hearing, particularly with mitigating circumstances such as inappropriate technician involvement or pharmacist malfeasance.

In certain cases with ingested errors and significant negative health circumstances requiring institutional care, the investigative committee recommendation will be a board hearing.

In all death cases resulting from inappropriate drug therapy a board hearing will occur.

Attorney fees and costs may be added in contested disciplinary actions requiring extensive attorney preparation and presentation and are not described in the above matrix.

The board has directed that ownership may be charged in disciplinary cases. In non-ingested errors copies of admonition letters will be sent to management. Accumulative actions for ownership monitoring will be based upon a 3 year period. All actions including non-ingested errors will be given a case number and monitored.

The Board has the authority to fine from \$0.00 to \$10,000 for each Cause of Action.

Updated May 2019

ANNUAL DISCIPLINE CASES			
Reporting Period: January 2020 – September 2020			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
PTs DS and MY created fraudulent prescriptions and diverted controlled substances from their employing pharmacy.	N/A	Pharmaceutical technician registrations revoked.	N/A
RPH SS failed to maintain Schedule II perpetual inventories and complete invoices for the purchase of controlled substances.	N/A	Voluntary surrender of Nevada pharmacist registration; \$750 administrative fee.	\$3,000 fine; \$750 administrative fee.
Wholesaler WP failed to comply with the requirements of NRS 639.500.	N/A	N/A	Wholesaler license suspended; suspension stayed pending receipt, review and verification of the required background check materials.
AN failed to timely renew his CS registration and wrote 33 prescriptions without a valid registration.	N/A	Letter of reprimand; \$5,000 fine; \$950 administrative fee.	N/A
RPH failed to identify a misbranding error.	N/A	\$250 fine; \$250 administrative fee; two additional CEs on error prevention.	\$3,000 fine; \$250 administrative fee.
RPH DC failed to comply with the 2/12/19 Board Order; failed to timely renew his pharmacist registration and engaged in the practice of pharmacy without a valid registration.	N/A	RPH registration revoked.	N/A
Wholesaler SWS failed to comply with the requirements of NRS 639.500.	N/A	N/A	Wholesaler surrendered license.
KH failed to timely renew her CS registration and wrote 263 prescriptions without a valid registration.	N/A	Letter of reprimand; \$5,000 fine; \$950 administrative fee.	N/A
RPH ST verified the data and final product as correct when it was not and dispensed losartan potassium 25mg tablets rather than the 50 mg. tablets prescribed. ST failed to provide adequate counseling.	N/A	Letter of reprimand; \$1,000 fine; \$1,000 attorney's fees and costs; 2 additional CEs on error prevention.	WG shall pay a \$1,000 fine; \$1,000 attorney's fees and costs.
MDs RB-R and AB pre-signed controlled substance prescriptions that were issued to patients while Respondents were travelling overseas. Respondents allowed APRN DC-L to prescribe controlled substances	N/A	Each respondent shall receive a letter of reprimand; \$5,000 fine; \$2,000 attorney's fees and costs.	N/A

ANNUAL DISCIPLINE CASES			
Reporting Period: January 2020 – September 2020			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
and dangerous drugs prior to being licensed to do so.			
RPH JA failed to maintain perpetual inventories, biennial inventories, records of controlled substance purchases; aided or abetted a person not licensed to practice pharmacy; failed to properly store expired drugs; failure to properly label prescription drugs; continued to practice pharmacy even as his behavior rendered him incompetent, unskillful and negligent. RPH JA and PT FA engaged in unlawful dispensing and sales. PT FA practiced as a registered pharmacist without registration.	N/A	JA voluntarily surrendered pharmacist registration; may not work for any facility licensed by the Board unless he petitions and is granted reinstatement by the Board; if he applies for reinstatement, he shall appear before the Board and he shall successfully complete an evaluation of his competence to practice pharmacy. FA voluntarily surrendered technician registration. She may not work for any facility licensed by the Board unless she petitions and is granted reinstatement by the Board. Respondents are jointly liable and shall pay \$2,500 fine; \$3,000 attorney fees and costs.	DT voluntarily surrendered pharmacy license and may not operate in any capacity unless it has petitioned the Board and is granted reinstatement.
PT JW's application for registration approved subject to the requirement that he enroll in PRN for one year. JW was terminated from PRN due to lack of attendance.	N/A	Revocation	N/A
APRN SJ, unlawfully prescribed controlled substances/dangerous drugs under Dr. AQ's name and credentials.	N/A	Public reprimand, \$1000 fine, \$950 in attorney's fees and costs.	N/A
Rx WM responsible for the actions of personnel in their employ in which two unauthorized refills were dispensed.	N/A	N/A	\$1000 fine, \$1000 attorney's fees and costs.
RPH PL diverted drugs from his employing pharmacy.	N/A	Revocation	N/A
Dr. VW wrote multiple prescriptions for controlled substances from June 2009 to the present while her license to practice medicine in Nevada was inactive. Dr. VW	N/A	\$14,000 fine, \$1,962.87 attorney's fees and costs.	N/A

ANNUAL DISCIPLINE CASES			
Reporting Period: January 2020 – September 2020			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
falsely represented to the Board that she held an active and current Nevada license with the NSBME on her CS renewal applications for the years 2010, 2012, 2014, 2016, and 2018. June 2020, the Board served Dr. VW with an order to cease and desist prescribing controlled substances for Nevada patients; Dr.VW surrendered her DEA which operated as an immediate suspension of her CS registration.			

5A

FILED

FEB 13 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JOSHUA AIGHOBAHI, RPH,
Certificate of Registration No. 18747,KATHERINE KUEHL, RPH,
Certificate of Registration No. 11172,FELICIA AIGHOBAHI, PT,
Certificate of Registration No. PT17660, andDIVINE TOUCH SERVICES PHARMACY,
Pharmacy License No. PH03411,

Respondents.

Case Nos. 19-035-RPH-A-S
19-035-RPH-B-S
19-035-PT-S
19-035-PH-SNOTICE OF INTENDED ACTION
AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Joshua Aighobahi, R.Ph., Certificate of Registration No. 18747, and Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172 (Kuehl), were pharmacists registered by the Board, Respondent Felicia Aighobahi, Certificate of Registration No. PT17660, was a pharmaceutical technician registered by the Board, and Respondent Divine Touch Services Pharmacy, License No. PH03411 (Divine Touch), was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

II.

Joshua Aighobahi owns and operates Divine Touch; he was the managing pharmacist of Divine Touch and the only registered pharmacist employed in the pharmacy until approximately October 31, 2019.

III.

Felicia Aighobahi is Joshua Aighobahi's wife and employed as a pharmaceutical technician by Divine Touch.

IV.

Throughout 2019, Felicia Aighobahi performed functions that are limited by law to a registered pharmacist and attributed the performance of those functions to Joshua Aighobahi.

V.

During annual inspections of Divine Touch on or about September 7, 2017, September 8, 2018, and September 23, 2019, Board staff observed that Joshua Aighobahi failed to conduct a proper biennial inventory of the pharmacy.

VI.

During the September 23, 2019, annual inspection Board staff observed that Joshua Aighobahi exhibited behavior that rendered him incapable of safely and competently practicing pharmacy, that he failed to maintain an accurate perpetual inventory of schedule II-controlled substances, and that he failed to maintain DEA 222 forms.

VII.

On or about October 10, 2019, Board staff conducted a joint inspection of Divine Touch with the Drug Enforcement Administration (DEA). During the DEA audit of controlled substances at Divine Touch, both Board staff and DEA investigators observed that Joshua

Aighobahi exhibited behavior that rendered him incapable of complying with the audit and/or of safely and competently practicing pharmacy.

VIII.

On or about October 21, 2019, Joshua Aighobahi represented to Board staff that he would voluntarily cease operation of Divine Touch until he either successfully completed an evaluation of his competence to practice pharmacy pursuant to NRS 639.2445 or, alternatively, placed a managing pharmacist approved by Board staff in charge of the pharmacy pursuant to NRS 639.220(1).

IX.

On or about October 31, 2019, Joshua Aighobahi represented to Board staff through his legal counsel that he had employed Kuehl as the managing pharmacist for Divine Touch and had ceased practicing pharmacy.

X.

On or about January 9, 2020, Board staff conducted an inspection of Divine Touch and observed that Joshua Aighobahi continued to practice pharmacy even as his behavior continued to render him incapable of safely and competently practicing pharmacy, that Kuehl as the new managing pharmacist failed to properly conduct an initial inventory of the pharmacy, and that prescription labels did not include the expiration date for the medication.

XI.

During the inspections of Divine Touch on or about September 23, 2019, October 10, 2019, and January 9, 2020, Board staff observed that the pharmacy had possession of expired controlled substances and dangerous drugs for dispensing that were not properly segregated.

XII.

On or about January 21, 2020, Kuehl represented to Board staff that Joshua Aighobahi continued to practice pharmacy and perform certain functions reserved for a managing pharmacist.

APPLICABLE LAW

XIII.

NRS 453.246 Recordkeeping and inventory requirements for registrants. Persons registered to dispense controlled substances pursuant to the provisions of NRS 453.011 to 453.552, inclusive, shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law and with any additional regulations the Board issues.

XIV.

NRS 453.251 Order forms. Controlled substances listed in schedules I and II may be distributed by a registrant or licensed pharmacy to another registrant or licensed pharmacy only pursuant to an order form and may be received by a registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed in compliance with this section.

XV.

NRS 453.326 Unlawful acts relating to recordkeeping, inspections and knowingly keeping or maintaining a place where controlled substances are unlawfully used, kept or sold; penalty.

1. It is unlawful for a person:

(a) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under the provisions of NRS 453.011 to 453.552, inclusive;

....

XVI.

NRS 453.236 Suspension, revocation of registration; seizure, placement under seal of controlled substance owned or possessed by registrant; notification of Drug Enforcement Administration and Division concerning suspension, revocation or forfeiture; registrant prohibited from employing person whose pharmacist's certificate was suspended or revoked.

1. The Board may suspend or revoke a registration pursuant to NRS 453.231 to dispense a controlled substance upon a finding that the registrant has:

....

(d) Committed an act that would render registration under NRS 453.231 inconsistent with the public interest as determined pursuant to that section.

XVII.

NRS 639.100(1)(a) states in relevant part: "It is unlawful for any person to sell or dispense, or permit to be . . . sold or dispensed, any drug, . . . unless the person . . . [i]s a registered pharmacist. *See also* 21 U.S.C. § 841(a).

XVIII.

NRS 639.210 Grounds for suspension or revocation of certificate, license, registration or permit or denial of application. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant:

1. Is not of good moral character;

....

4. Is guilty of unprofessional conduct or conduct contrary to the public interest;

....

9. Has willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of this chapter;

....

11. Has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs;

12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit;

....

15. Has, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of this chapter or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision;

....

17. Has failed to maintain and make available to a state or federal officer any records in accordance with the provisions of this chapter or chapter 453 or 454 of NRS;

XIX.

NRS 639.2445 Physical or mental examination of holder of certificate believed to be incompetent; competency hearing; probation for use of alcohol or drugs.

1. Whenever the Board believes that a holder of a certificate is or has become incompetent to practice pharmacy by reason of any physical or mental injury, illness or disability or by reason of chronic or excessive use of alcohol or drugs, the Board may order that the holder of the certificate submit to a physical or psychiatric examination, or both, at the expense of the Board.

2. The Board shall designate a physician or a psychiatrist or both, as the case may be, to conduct the examination or examinations of the holder of the certificate and furnish the Board and the holder of the certificate with a report of the findings. If the holder of the certificate is dissatisfied with the findings, the holder of the certificate may obtain an independent examination and report at his or her own expense, not later than 10 days following receipt of the initial report.

3. Upon receipt of the findings the Board shall conduct a hearing to determine whether the holder of the certificate is competent to practice pharmacy. Except as provided in subsection 4, if the Board finds that the holder of the certificate is not competent to practice pharmacy, it shall order an immediate suspension of his

or her right to practice pharmacy, and the suspension remains in effect until the Board determines that a certificate may be reinstated.

4. The Board may place on probation a holder of a certificate who is not competent to practice pharmacy by reason of chronic or excessive use of alcohol or drugs if the holder of the certificate voluntarily enters and completes a program of treatment approved by the Board and complies with any other conditions imposed by the Board.

XX.

NRS 639.282 Unlawful possession or sale of certain pharmaceutical preparations, drugs or chemicals; destruction.

1. Except as otherwise provided . . . it is unlawful for any person to have in his or her possession, or under his or her control, for the purpose of resale, or to sell or offer to sell or dispense or give away, any pharmaceutical preparation, drug or chemical which:

. . . .

(d) Is no longer safe or effective for use, as indicated by the expiration date appearing on its label; or

XXI.

NAC 453.475 Initial and biennial inventory of controlled substances by new managing pharmacist.

1. A pharmacist who is hired or promoted to manage a pharmacy pursuant to the provisions of NRS 639.220 shall:

(a) Within 48 hours after first reporting for duty as the managing pharmacist, conduct an inventory of the controlled substances of the pharmacy with the pharmacist who preceded him or her as the managing pharmacist. The pharmacists shall sign the inventory.

(b) After the date on which the inventory required pursuant to paragraph (a) was taken, conduct an inventory of the controlled substances of the pharmacy at least once every 2 years during the course of his or her employment as managing pharmacist at the pharmacy. The managing pharmacist may conduct the biennial inventory on any date which is within 2 years of the date on which the previous biennial inventory was conducted.

2. An inventory required by subsection 1 must be:

(a) Conducted according to the method prescribed by the provisions of 21 C.F.R. Part 1304; and

(b) Placed in the records of the controlled substances of the pharmacy.

XXII.

NAC 639.050 Storage and destruction of certain controlled substances.

....

2. Each practitioner or pharmacy shall physically separate each controlled substance which is outdated, damaged, deteriorated, misbranded or adulterated from the balance of its stock medications.

XXIII.

NAC 639.473 Procurement and storage of drugs.

1. The managing pharmacist of a pharmacy is responsible for the procurement and storage of drugs in that pharmacy.

....

3. Outdated drugs must be removed from stock and identified and maintained separately from other stock until disposal.

XXIV.

NAC 639.482 Maintenance and availability of records.

1. Each record required to be kept pursuant to NAC 639.483 to 639.489, inclusive, must be kept by a pharmacy for at least 2 years after the date of the record.

2. Records maintained by a pharmacy must be made available for inspection and copying upon the request of the Board, its representatives, or another authorized local, state or federal law enforcement agency.

XXV.

NAC 639.485 Maintenance of records for controlled substances.

1. A pharmacy shall maintain records for controlled substances:

- (a) In a readily retrievable manner.

- (b) In a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy.

2. A pharmacy shall maintain a perpetual inventory of any controlled substance listed in schedule II.

3. Records of the distribution of controlled substances listed in schedule II, schedule III or schedule IV must include:

- (a) The name of the drug, dosage form and strength.

- (b) The name of the pharmacist distributing or authorizing the distribution of the controlled substance.

(c) The name of the authorized person receiving the controlled substance. This information may be included on the record of administration.

(d) The location to which the controlled substance is being distributed.

(e) Controlled substances returned to the pharmacy.

(f) A record of any waste of any prepared or partially administered dose of a controlled substance, which must be witnessed and cosigned by another person who is licensed to provide medical care.

XXVI.

NAC 639.487 Maintenance of additional records.

In addition to any other requirements for keeping records, a pharmacy shall maintain the following records:

1. Copy 3 of the order form of the Drug Enforcement Administration (DEA 222C), properly dated, initialed and filed, copies of each unaccepted or defective order form, and any attached statements or other documents.

2. Suppliers' invoices of controlled substances and dangerous drugs. The pharmacist or other personnel of the pharmacy shall clearly record on each invoice the actual date on which the controlled substance or dangerous drug was received.

3. Suppliers' credit memos for controlled substances and dangerous drugs.

4. The biennial inventory of controlled substances required by the Drug Enforcement Administration.

5. Any reports of theft or significant loss of controlled substances submitted to the Drug Enforcement Administration.

6. Reports of the surrender or destruction of controlled substances or dangerous drugs, or both, to an appropriate state or federal agency.

7. A register book for nonprescription drugs listed in schedule V.

XXVII.

NAC 639.510 Maintenance and storage of pharmaceutical stock.

-
2. The managing pharmacist of a pharmacy:

(a) Is responsible for, and must have knowledge and control of, the acquisition and disposition by the pharmacy of the stock of the pharmacy; and

(b) Shall ensure that the records relating to the acquisition or disposition of the stock of the pharmacy are maintained as required by law.

3. The dangerous drugs, controlled substances, chemicals, biologicals and devices kept in the stock of a pharmacy must meet all of such standards of purity and strength as established by current official compendia or as established on the appropriate labels, and must be properly stored. Any preparation which varies from such standards of purity and strength or becomes unfit for use from deterioration or other cause must not be carried in stock and must be destroyed in a manner provided by law when so ordered by an agent of the Board.

XXVIII.

NAC 639.512 Class A and B packaging: Label; expiration date; log.

....

2. Each unit dose of a controlled substance or dangerous drug packaged or repackaged by a pharmacy must contain a label which specifies:

....

(c) The expiration date; and

....

XXIX.

NAC 639.523 Physical address for delivery of drugs.

....

3. A pharmacist employed by a pharmacy shall acknowledge on every invoice that the drugs listed in the invoice were physically received by the pharmacy at the physical address to which the Board has issued the license of the pharmacy.

XXX.

NAC 639.601 Prescription drugs: Separation and disposal of certain drugs.

1. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier.

....

XXXI.

NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.

1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

-
- (h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.
 - (i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.
 - (j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.
 - (k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.
-
- (m) Failing to provide any document, data or information that is required to be made and maintained pursuant to chapters 453, 454, 585 and 639 of NRS and chapters 453, 454, 585 and 639 of NAC to a member of the Board or a member of the staff of the Board upon his or her request.

....

2. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ.

XXXII.

NAC 639.955 Imposition of fines; authority to take disciplinary action.

1. Except as otherwise provided in this section, the Board may impose a fine against a pharmacist or pharmacy pursuant to paragraph (f) of subsection 1 of NRS 639.255 according to the following schedule:

-
- (h) For failing to make or maintain a biennial inventory of controlled substances.....\$1,000.00
-

2. The Board may impose a fine for a violation listed in subsection 1 that is less than or greater than the amount set forth in that subsection for that violation after giving consideration to any aggravating and mitigating factors that relate to the violator's role in and responsibility for the conduct for which the fine is being imposed, and the unique circumstances of each case.

....

5. The Board may, as it deems appropriate, impose a fine for a violation not listed in subsection 1 that is commensurate with the severity of the violation.

6. No fine imposed by the Board will exceed \$10,000.

....

8. This section will be construed and applied so as to preserve the discretion of the Board to take any disciplinary action authorized by NRS 639.255.

XXXIII.

21 C.F.R. § 1304.11 Inventory requirements.

....

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

XXXIV.

21 C.F.R. § 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to §1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

XXXV.

21 U.S.C. § 842(a)(5) states in relevant part: "It shall be unlawful for any person . . . to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration,

order or order form, statement, invoice, or information required under this subchapter or subchapter II[.]”

FIRST CAUSE OF ACTION

Failure to Maintain Perpetual Inventories of Controlled Substances (Respondents Joshua Aighobahi and Divine Touch)

XXXVI.

By failing to maintain at least two years’ worth of perpetual inventories of schedule II-controlled substances in a readily retrievable manner, Joshua Aighobahi and Divine Touch violated NRS 453.246, NAC 639.485(1) and (2), and NAC 639.482(a) and (b), engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4), (12) and (17).

SECOND CAUSE OF ACTION

Failure to Maintain Accurate Biennial Inventories of Controlled Substances (Respondents Joshua Aighobahi and Divine Touch)

XXXVII.

By failing to maintain at least two years’ worth of biennial inventories of its controlled substances in a readily retrievable manner, Joshua Aighobahi and Divine Touch violated NRS 453.246, NAC 453.475(1)(b) and (2), NAC 639.482(a) and (b), NAC 639.487(4), NAC 639.510, 21 U.S.C. § 842(a)(5) and 21 CFR § 1304.11, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and are subject to discipline pursuant to NRS 453.236(1), NRS 639.210(4), (12) and (17).

THIRD CAUSE OF ACTION

Failure to Maintain Records of Controlled Substance Purchases (Respondents Joshua Aighobahi and Divine Touch)

XXXVIII.

By failing to maintain accurate and complete invoices for the controlled substances Divine Touch purchased and received, Joshua Aighobahi and Divine Touch violated NRS 453.246, NRS 453.251, NRS 453.326(1)(a), NAC 639.510, NAC 639.523(3), 21 U.S.C. §

842(a)(5) and 21 CFR § 1304.21, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and are subject to discipline pursuant to NRS 453.236(1), NRS 639.210(4), (11), (12) and (17).

FOURTH CAUSE OF ACTION

Fraudulent or Deceitful Practice/Practicing as a Registered Pharmacist Without Registration
(Respondent Felicia Aighobahi)

XXXIX.

By performing functions that are limited by law to a registered pharmacist and attributing the performance of those functions to Joshua Aighobahi, Felicia Aighobahi was party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct as defined in NAC 639.945(1)(h) and (k), and is subject to discipline pursuant to NRS 639.210(4).

FIFTH CAUSE OF ACTION

Fraudulent or Deceitful Practice /Aiding or Abetting a Person Not Licensed to Practice Pharmacy
(Respondent Joshua Aighobahi)

XL.

By permitting Felicia Aighobahi to perform duties that are limited by law to a registered pharmacist, Joshua Aighobahi was party to a fraudulent or deceitful practice or transaction, aided or abetted a person not licensed to practice pharmacy in the State of Nevada, engaged in unprofessional conduct as defined in NAC 639.945(1)(h) and (j), and is subject to discipline pursuant to NRS 639.210(4).

SIXTH CAUSE OF ACTION

Unlawful Dispensing and Sales
(Respondents Joshua Aighobahi and Felicia Aighobahi)

XLI.

By permitting Felicia Aighobahi to perform functions that are limited by law to a registered pharmacist and attributing the performance of those functions to Joshua Aighobahi, Joshua Aighobahi and Felicia Aighobahi violated, attempted to violate, assisted or abetted in the

violation of or conspired to violate NRS 453.331(1)(c), NRS 453.381(8), NRS 453.401(1)(a), NRS 639.100(1)(a), NRS 639.284 and/or 21 U.S.C. § 841(a), and are subject to discipline pursuant to NRS 639.210(9), (11) and (12).

SEVENTH CAUSE OF ACTION

Failure to Conduct Initial Inventory of Controlled Substances (Respondent Kuehl)

XLII.

By failing to properly conduct an initial inventory of the pharmacy as the new managing pharmacist, Kuehl violated NRS 453.246, NAC 453.475(1)(a) and (2) and NAC 639.510, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and is subject to discipline pursuant to NRS 639.210(4), (15) and (17).

EIGHTH CAUSE OF ACTION

Failure to Properly Store Expired Drugs (Respondents Joshua Aighobahi, Kuehl and Divine Touch)

XLIII.

By failing to segregate expired drugs from unexpired drugs and secure those expired drugs in an area where they could not be used to administer or fill prescriptions, Joshua Aighobahi, Kuehl and Divine Touch violated NRS 639.282(1)(d), NAC 639.050(2), NAC 639.473(1) and (3), NAC 639.510(3) and NAC 639.601(1), engaged in unprofessional conduct as defined in NAC 639.945(i), and are subject to discipline pursuant to NRS 639.210(4), (12) and (15).

NINTH CAUSE OF ACTION

Failure to Properly Label Prescription Drugs (Respondents Joshua Aighobahi, Kuehl and Divine Touch)

XLIV.

By failing to include the expiration date for medication on prescription labels, Joshua Aighobahi, Kuehl and Divine Touch violated NAC 639.512(2)(c), engaged in unprofessional

conduct as defined in NAC 639.945(i), and are subject to discipline pursuant to NRS 639.210(4), (12) and (15).

TENTH CAUSE OF ACTION

Incompetent, Unskillful and Negligent Practice of Pharmacy
(Respondent Joshua Aighobahi)

XLV.

By continuing to practice pharmacy even as his behavior rendered him incapable of safely and competently practicing pharmacy, Joshua Aighobahi performing his duties as a registered pharmacist and as the owner of Divine Touch in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct as defined in NAC 639.945(1)(i), is subject to discipline pursuant to NRS 639.210(4), and should be required to submit to a physical or psychiatric examination, or both, pursuant to NRS 639.2445.

ELVENTH CAUSE OF ACTION

Managing Pharmacist Responsibilities
(Respondents Joshua Aighobahi and Kuehl)

XLVI.

As the managing pharmacists of Divine Touch at the time of the violations alleged herein, either Joshua Aighobahi and Kuehl are responsible for those violations, including those of the pharmacy's employees, pursuant to NRS 639.220(1), NAC 639.473, NAC 639.510 and NAC 639.702, and are subject to discipline pursuant to NRS 639.210(15).

TWELVTH CAUSE OF ACTION

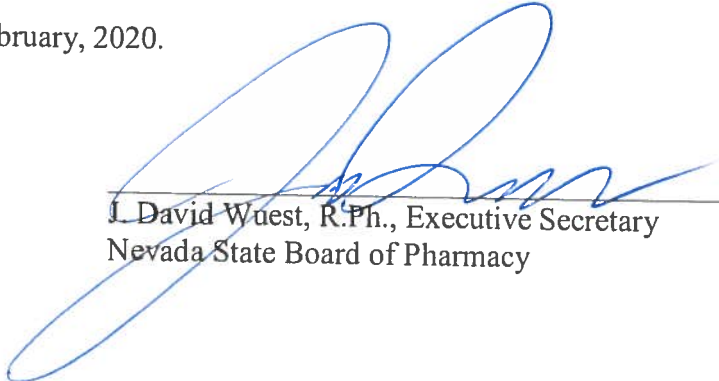
Pharmacy/Pharmacy Owner Responsibility
(Respondent Joshua Aighobahi)

XLVII.

As the owner of Divine Touch at the time of each of the violations alleged herein, Joshua Aighobahi is responsible for the violations, including those of his employees, pursuant to NRS 639.230(5) and NAC 639.945(2), and is subject to discipline pursuant to NRS 639.210(1), (4), (9) (11), (12), (15) and (17).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and/or licenses of these respondents.

DATED this 13th day of February, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-035-RPH-B-S

Petitioner,

v.

**KATHERINE KUEHL, RPH,
Certificate of Registration No. 11172,**

**STATEMENT TO
THE RESPONDENT
AND NOTICE OF HEARING**

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, March 18, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

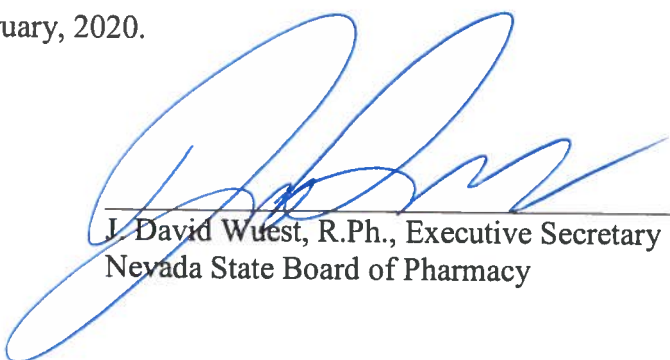
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 13th day of February, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**KATHERINE KUEHL, RPH
Certificate of Registration No. 11172,**

Respondent.

CASE NO. 19-035-RPH-B-S

**ANSWER AND NOTICE
OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ____ day of February 2020.

KATHERINE KUEHL, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of February, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Joshua Aighobahi, R.Ph.
9504 Empire Rock Street
Las Vegas, NV 89143

Katherine L. Kuehl, R.Ph.
700 North Las Vegas Blvd.
Las Vegas, NV 89101

Felicia Aighobahi, PT
2208 E. Charleston Blvd., #B
Las Vegas, NV 89104

Divine Touch Services Pharmacy
2208 E. Charleston Blvd., #B
Las Vegas, NV 89104

Persi J. Mishel, Esq.
10161 Park Run Drive, Ste. 150
Las Vegas, NV 89145



SHIRLEY HUNTING

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of March, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Katherine L. Kuehl, RPH
2000 Paradise Rd., #1205
Las Vegas, NV 89104


SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**JOSHUA AIGHOBAHI, RPH,
Certificate of Registration No. 18747,**

**KATHERINE KUEHL, RPH,
Certificate of Registration No. 11172,**

**FELICIA AIGHOBAHI, PT,
Certificate of Registration No. PT17660, and**

**DIVINE TOUCH SERVICES PHARMACY,
Pharmacy License No. PH03411,**

Respondents.

**Case Nos. 19-035-RPH-A-S
19-035-RPH-B-S
19-035-PT-S
19-035-PH-S**

**STIPULATION AND ORDER
(Respondent Katherine Kuehl)**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172 (Kuehl), **HEREBY STIPULATE AND AGREE THAT:**

1. On or about March 19, 2020, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.
2. Respondent is fully aware of her right to seek the advice of counsel in this matter prior to entering into this Stipulation.
3. Respondent is aware of her right to a hearing on the matters alleged in the Accusation, her right to reconsideration, her right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of Paragraph 7 below, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*, that:

A. By failing to properly conduct an initial inventory of the pharmacy as the new managing pharmacist, Kuehl violated NRS 453.246, NAC 453.475(1)(a) and (2) and NAC 639.510, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and is subject to discipline pursuant to NRS 639.210(4), (15) and (17);

B. By failing to segregate expired drugs from unexpired drugs and secure those expired drugs in an area where they could not be used to administer or fill prescriptions, Kuehl violated NRS 639.282(1)(d), NAC 639.050(2), NAC 639.473(1) and (3), NAC 639.510(3) and NAC 639.601(1), engaged in unprofessional conduct as defined in NAC 639.945(i), and is subject to discipline pursuant to NRS 639.210(4), (12) and (15);

C. By failing to include the expiration date for medication on prescription labels, Kuehl violated NAC 639.512(2)(c), engaged in unprofessional conduct as defined in NAC 639.945(i), and is subject to discipline pursuant to NRS 639.210(4), (12) and (15); and

D. As the managing pharmacist of Divine Touch at the time of the violations herein, Kuehl is responsible for those violations, including permitting Joshua Aighobahi to continue to practice pharmacy even as his behavior continued rendered him incapable of safely

and competently practicing pharmacy, pursuant to NRS 639.220(1), NAC 639.473, NAC 639.510 and NAC 639.702, and Kuehl is therefore subject to discipline pursuant to NRS 639.210(15).

6. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172, stipulate to the following penalties:

A. Kuehl shall receive a letter of reprimand from Board Staff regarding her duties and responsibilities as a managing pharmacist.

B. Kuehl may not be designated as and shall not work as managing pharmacist in any facility licensed by the Board for a period of one (1) year;

C. Kuehl shall complete two (2) extra hours of continuing education (CE) on pharmacy management, in addition to the CE hours she must otherwise complete to maintain her licensure;

D. Kuehl shall pay a fine of One-Thousand Dollars (\$1000.00) for the alleged violations, payable by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, in monthly installments of \$250.00 for four (4) months and due on the first date of each month commencing September 1, 2020; and

E. Kuehl shall pay Five-Hundred Dollars (\$500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte

Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2020, in Las Vegas. Respondent will appear at the meeting to answer questions from the Board members and/or staff. The Board members may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board it shall be a public record pursuant to NRS 622.330.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of October, 2020

Signed this ____ day of October, 2020

KATHERINE KUEHL, RPH,
Certificate of Registration No. 11172

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172, in Case No. 19-035-RPH-B-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ____ day of October, 2020.

Helen Park, President
Nevada State Board of Pharmacy

5B

JUL 30 2020

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY****NEVADA STATE BOARD OF PHARMACY,****Petitioner,****v.****LILY AKANA, PT****Certificates of Registration Nos. PT07926,
TD01906 and TD01907****Respondent.****CASE NO. 19-075-PT-S****NOTICE OF INTENDED ACTION
AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Lily Akana ("Akana"), Certificate of Registration No. PT07926, was a pharmacy technician registered with the Board.

2. Akana subsequently registered with the Board as a dispensing technician trainee for two dispensing practitioners and was issued Certificates of Registration Nos. TD01906 and TD01907.

FACTUAL ALLEGATIONS

3. Akana was employed by Walgreens Pharmacy #2590 ("Walgreens"), located on 6435 North Aliante Parkway, North Las Vegas, Nevada 89084, until April 2019.

4. On or about April 25, 2019, Walgreens' Asset Protection Manager ("APM") Michael Lisi ("Lisi") in the course of investigating drug shortages at Walgreens interviewed Akana and discovered that Akana was diverting drugs from Walgreens.

5. A subsequent investigation by Walgreens' loss prevention staff identified a total of at least forty-two (42) tablets diverted by Akana from either valid prescriptions dispensed to patients or directly from Walgreens' inventory, consisting of the following controlled substances:

- 17 Oxycodone tablets
- 57 Percocet tablets
- 5 Carisoprodol/Soma tablets
- 2 Clonazepam tablets
- 1 bottle of Oxycodone

6. During the investigation, Akana admitted to the unlawful diversion activity.

7. Walgreens terminated Akana on April 25, 2019.

FIRST CAUSE OF ACTION

Unlawful Acquisition of Controlled Substances

8. NRS 453.331(1)(d) states, in relevant part, that “[i]t is unlawful for a person knowingly or intentionally to . . . [a]cquire or obtain . . . possession of a controlled substance . . . by misrepresentation, fraud, forgery, deception, subterfuge or alteration.” Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(12).

9. By diverting controlled substances as alleged herein, Akana violated, or attempted to violate, NRS 453.331(1)(d) and is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION

Unlawful Possession of Controlled Substances

10. NRS 453.336(1) states, in relevant part, that “a person shall not knowingly or intentionally possess a controlled substance, unless the substance was obtained directly from, or pursuant to, a [lawful] prescription or order of a [practitioner]”. Violating, attempting to violate, any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of

pharmacy is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(12).

11. By diverting controlled substances as alleged herein, Akana violated, or attempted to violate, NRS 453.336(1) and is subject to discipline pursuant to NRS 639.210(12).

THIRD CAUSE OF ACTION **Unprofessional Conduct - Diversion**

12. “Supplying or diverting drugs . . . which are legally sold in pharmacies . . . so that unqualified persons can circumvent any law pertaining to the legal sale of such articles” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(g). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).

13. By diverting controlled substances as alleged herein, Akana engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

FOURTH CAUSE OF ACTION **Unprofessional Conduct - Deceitful Practice**

14. “Performing or in any way being a party to any fraudulent or deceitful practice or transaction” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(h). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).

15. By diverting controlled substances as alleged herein, Akana was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is subject to discipline pursuant to NRS 639.210(4).

FIFTH CAUSE OF ACTION**Violations of Federal Law**

16. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(11).

17. By diverting controlled substances as alleged herein, Akana violated, or attempted to violate, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), and 21 U.S. Code § 844, and is subject to discipline pursuant to NRS 639.210(11).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 30th day of July, 2020.



J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

LILY AKANA, PT
Certificates of Registration Nos. PT07926,
TD01906 and TD01907

Respondent.

CASE NO. 19-075-PT-S

**STATEMENT TO THE
 RESPONDENT AND
 NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. *See* NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. *See* NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this this Statement and Notice, and of the Notice of Intended Action and Accusation served within. *See* NRS 639.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. *See* NRS 622A.350.

DATED this 30th day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Lily Akana, PT
5404 LEMHI CT
NORTH LAS VEGAS, NV 89031

Charles Goodwin, Esq.
2970 W. Sahara Avenue
Las Vegas, NV 89102



SHIRLEY HUNTING

FILED

AUG 10 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

Petitioner.

CASE NO.: 19-075-PT-S

v.

ANSWER TO NOTICE OF INTENDED
ACTION AND ACCUSATION

LILY AKANA, PT

Certificate of Registration No. PT07926,
TD01906 and TD01097

Respondent.

Lily Akana, PT, ("Ms. Akana"), by and through her counsel of record MURPHY JONES APC, in answer to the Notice of Intended Action and Accusation ("Accusation") filed in the above-entitled matter before the Nevada State Board of Pharmacy ("Board"), declares:

1. That her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against her, is hereby interposed on the following grounds:

None.

2. That, in answer to the Notice of Intended Action and Accusation, Ms. Akana admits, denies and alleges as follows:

Ms. Akana has recently retained legal counsel who is conducting an independent investigation into the allegations espoused in the Accusation. Ms. Akana requests a hearing in the matter, on the merits of the case, and will provide additional information and produce relevant documentation after her legal counsel has been afforded the opportunity to adequately prepare a defense to the Accusation. With the afore referenced reservation, Ms. Akana admits and denies the allegations espoused in the Notice of Intended Action and Accusation as follows:

ANSWER

I - II.

Ms. Akana admits that the Board has jurisdiction over this matter.

II. - VII.

Ms. Akana is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph II-VII and therefore denies the same.

FIRST CAUSE OF ACTION

(Unlawful Acquisition of Controlled Substance)

Ms. Akana states that the allegations contained in paragraph VIII - IX contain legal conclusions therefore denies the same.

SECOND CAUSE OF ACTION

(Unlawful Possession of Controlled Substances)

Ms. Akana states that the allegations contained in paragraph X - XI contain legal conclusions therefore denies the same.

THIRD CAUSE OF ACTION

(Unprofessional Conduct - Diversion)

Ms. Akana states that the allegations contained in paragraph XII - XIII contain legal conclusions therefore denies the same.

FOURTH CAUSE OF ACTION

(Unprofessional Conduct - Deceitful Practice)

Ms. Akana states that the allegations contained in paragraph XIV - XV contain legal conclusions therefore denies the same.

FIFTH CAUSE OF ACTION

(Violations of Federal Law)

Ms. Akana states that the allegations contained in paragraph IV contain legal conclusions therefore denies the same.

ANSWER

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

1. Complainant fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. Complainant's causes of action are barred by applicable statute of limitations

THIRD AFFIRMATIVE DEFENSE

3. Complainant's causes of action are barred by the doctrine of unclean hands.

FOURTH AFFIRMATIVE DEFENSE

4. Complainant's causes of action are barred by the doctrine of laches.

FIFTH AFFIRMATIVE DEFENSE

5. Complainant's causes of action are barred by the doctrines of estoppel and/or waiver.

SIXTH AFFIRMATIVE DEFENSE

6. The facts not having been fully developed, Respondent further affirmatively pleads the following affirmative defenses as may be applicable in this action: accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, status of limitations, waiver, and any other matter constituting and avoidance or affirmative defense

DATED: August 10, 2020

By: 

Kevin C. Murphy, Esq.
Attorney for Respondent Lily Akana, PT

CERTIFICATE OF SERVICE

Case Name: **In the Matter of: Lily Akana, PT**

Agency Case No.: 19-075-PT-S

I declare:

I am employed in the law firm of MURPHY JONES APC, which is the office of a member of the Nevada State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter.

On August 10, 2020, I served the attached **ANSWER** via **EMAIL SERVICE** to the following person(s):

Courtney K. Lee, General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, Nevada 89521
Email: c.lee@pharmacy.nv.gov

I declare under penalty of perjury under the laws of the State of Nevada the foregoing is true and correct, and that this declaration was executed on August 10, 2020, at San Diego, California.



Kevin C. Murphy, Esq.
Declarant

5C

FILED

SEP 11 2020

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY****NEVADA STATE BOARD OF PHARMACY,****Petitioner,****v.****ASHLEY CARRIER, APRN,
Certificate of Registration No. CS27118,****Respondent.****CASE NO. 19-089-CS-S****FIRST AMENDED NOTICE OF
INTENDED ACTION
AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an amended accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Ashley Carrier, APRN ("Carrier"), held a Nevada controlled substance registration, Certificate of Registration No. CS27118, issued by the Board.

FACTUAL ALLEGATIONS

2. On April 30, 2019, Nevada Highway Patrol Trooper Rusian Shumlyakovskiy (Trooper Shumlyakovskiy) pulled Carrier's vehicle over and subsequently conducted a driving under the influence (DUI) investigation. The driver of the vehicle was Carrier.

3. In the front seat of Carrier's vehicle, Trooper Shumlyakovskiy observed a clear pill container. The contents of the pill container were identified by Nevada Poison Control as:

- 1 Xtampza (oxycodone) 13.5 mg capsule
- 5 Morphine Sulfate Extended Release 15 mg tablets
- 1 Morphine Sulfate 15 mg tablet
- 1 Alprazolam 2 mg tablet
- 77 Clonazepam 1 mg tablets

4. Carrier did not have a prescription for the controlled substances and was not able to explain to Trooper Shumlyakovskiy how she acquired the controlled substances. Additionally, Carrier did not respond to Board Staff's inquiries regarding the acquisition of the controlled substances.

5. Carrier was arrested for DUI and five counts of possession of controlled substances.

6. Carrier pled guilty to DUI and open alcohol container in vehicle. The controlled substance charges were dismissed.

7. On May 6, 2019, Carrier's Advanced Practice Registered Nurse (APRN) License No. APRN002874 with the Nevada State Board of Nursing (NSBN) was placed on inactive status pursuant to NRS632.341(3), which provides in pertinent part "the licensee may not practice nursing during the time the license is inactive."

8. Carrier wrote multiple prescriptions for controlled substances after May 6, 2019, when her NSBN License No. APRN002874 was inactive and she was prohibited from practicing.

9. On or about August 11, 2020, Board staff served Carrier with an order pursuant to NRS 639.2895(1) to immediately cease and desist prescribing controlled substances for Nevada patients.

10. On August 12, 2020, Carrier surrendered her DEA Certificate of Registration No. MC4737788 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

11. By executing the DEA Surrender for Cause, Carrier acknowledged in pertinent part the following:

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

12. On or about August 21, 2020, Board staff served Carrier with notice that her surrender of her DEA Certificate of Registration No. MC4737788 for cause operated as an immediate suspension of her Certificate of Registration No. CS27118 with the Board pursuant to NRS 639.2107.

13. Even after her APRN License No. APRN002874 was placed on inactive status, service of the cease and desist, surrender of her DEA Certificate of Registration No. MC4737788, and suspension of her Certificate of Registration No. CS27118, Carrier continues to represent herself as a licensed APRN as an employee/agent/affiliate of the Center for Wellness and the Good Samaritan, and to prescribe controlled substances, including, without limitation, alprazolam.

FIRST CAUSE OF ACTION

Unlawful Acquisition of Controlled Substances

14. NRS 453.331(1)(d) states, in relevant part, that “[i]t is unlawful for a person knowingly or intentionally to . . . [a]cquire or obtain . . . possession of a controlled substance . . . by misrepresentation, fraud, forgery, deception, subterfuge or alteration.”

15. By diverting controlled substances as alleged herein, Carrier violated, or attempted to violate, NRS 453.331(1)(d) and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

SECOND CAUSE OF ACTION

Unlawful Possession of Controlled Substances

16. NRS 453.336(1) states, in relevant part, that “a person shall not knowingly or intentionally possess a controlled substance, unless the substance was obtained directly from, or pursuant to, a [lawful] prescription or order of a [practitioner]”.

17. By diverting controlled substances as alleged herein, Carrier violated, or attempted to violate, NRS 453.336(1) and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(12).

THIRD CAUSE OF ACTION
Unprofessional Conduct - Diversion

18. “Supplying or diverting drugs . . . which are legally sold in pharmacies . . . so that unqualified persons can circumvent any law pertaining to the legal sale of such articles” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(g).

19. By diverting controlled substances as alleged herein, Carrier engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(4).

FOURTH CAUSE OF ACTION
Unprofessional Conduct – Diversion as Deceitful Practice

20. “Performing or in any way being a party to any fraudulent or deceitful practice or transaction” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(h).

21. By diverting controlled substances as alleged herein, Carrier was a party to any fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(4).

FIFTH CAUSE OF ACTION
Violations of Federal Law - Diversion

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal or state law or regulation relating to controlled substances is grounds for suspension or revocation of a controlled substances registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

23. By diverting controlled substances as alleged herein, Carrier violated, or attempted to violate, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), and 21 U.S.C. § 844, and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11).

SIXTH CAUSE OF ACTION
Unlawful Prescribing of Controlled Substances

24. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by federal and state law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 221 U.S.C. § 841(a); 21 U.S.C. § 842(a); 21 CFR § 1306.03; NRS 453.226(1); NRS 453.232; NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235; NRS 639.2813(1). An advanced practice registered nurse may only prescribe controlled substances with authorization from both the Board and the NSBN. NRS 639.2351; NAC 639.850; NAC 639.854.

25. By prescribing controlled substances without holding an active APRN license with the NSBN, Carrier violated, or attempted to violate, 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 221 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 CFR § 1306.03, NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235, NRS 639.2351, NRS 639.2813(1), NAC 639.850, and NAC 639.854, and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(11) and (12).

SEVENTH CAUSE OF ACTION
Unprofessional Conduct – Unlawful Prescribing

26. “Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(k).

27. By prescribing controlled substances without holding an active APRN license, Carrier engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(4).

EIGHTH CAUSE OF ACTION

Unprofessional Conduct – Unlawful Prescribing as Deceitful Practice

28. Falsely representing oneself as a practitioner entitled to write prescriptions for controlled substances in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.2813(1).

29. By falsely representing that she is licensed APRN entitled to write prescriptions for controlled substances in this state, Carrier was a party to any fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is subject to discipline pursuant to NRS 453.236(1) and/or NRS 639.210(4).

NINTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

30. By her actions as set forth herein, Carrier committed acts that render her registration to dispense controlled substances inconsistent with the public interest pursuant to NRS 453.231, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

TENTH CAUSE OF ACTION

Surrender of DEA Registration for Cause

31. By surrendering her DEA Certificate of Registration No. MC4737788 for cause, Carrier has admitted to failing to comply with the Federal requirements pertaining to controlled substances, has committed an act that would render her registration to dispense controlled substances inconsistent with the public interest, is no longer authorized by federal law to dispense controlled substances, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

32. By surrendering her DEA Certificate of Registration No. MC4737788 for cause, the suspension of Carrier's Certificate of Registration No. CS27118 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of September, 2020.



J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 19-089-CS-S
)	
Petitioner,)	
v.)	
)	
ASHLEY CARRIER, APRN)	STATEMENT TO THE
Certificate of Registration No. CS27118,)	RESPONDENT
)	AND NOTICE OF HEARING
	/	
Respondent.		

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

PLEASE NOTE CHANGE IN HEARING DATE

The Board has scheduled your hearing on this matter for Wednesday, October 14, 2020, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

Via Videoconference at Zoom: <https://zoom.us/j/5886256671>

or

Via Teleconference at 1 (669) 900-6833

Meeting ID: 588 625 6671

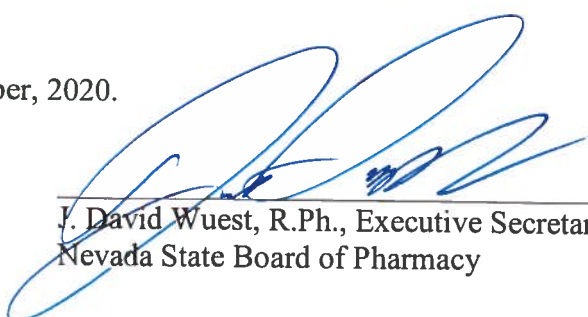
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of September, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 19-089-CS-S
)	
Petitioner,)	ANSWER AND NOTICE
v.)	OF DEFENSE
)	
ASHLEY CARRIER, APRN)	
Certificate of Registration No. CS27118,)	
Respondent.)	
	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

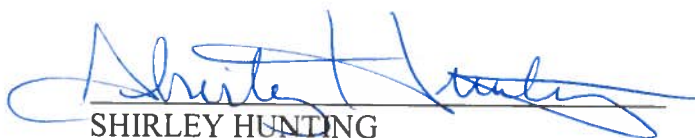
DATED this ____ day of _____, 2020.

ASHLEY CARRIER, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of September, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Ashley Carrier, APRN
5327 Caprock Canyon Ave.
Las Vegas, NV 89139



SHIRLEY HUNTING

5D

FILED**JUL 23 2020****NEVADA STATE BOARD
OF PHARMACY****BEFORE THE NEVADA STATE BOARD OF PHARMACY****NEVADA STATE BOARD OF PHARMACY,****Petitioner,****v.****THEODORE HERRERA,
Certificate of Registration No. IN04741,****Respondent.****CASE NO. 19-079-IN-S****NOTICE OF INTENDED ACTION
AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Theodore Herrera ("Herrera"), Certificate of Registration No. IN04741, was a pharmacy intern registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent Herrera was employed by Walgreens Pharmacy #5311, located on 1180 East Flamingo Road, Las Vegas, Nevada 89119, from approximately June 2018 to April 2019.

3. On or about April 19, 2019, Walgreens' Asset Protection Manager ("APM") Michael Lisi ("Lisi") was contacted by APM Serge Ahmad concerning a customer who reported a prescription for Oxycodone 15 mg was missing two (2) tablets, filled on April 18, 2019.

4. A subsequent investigation by Walgreens' loss prevention staff identified a total of at least sixty-six (66) tablets sold and diverted between June 2018 and April 2019 by Respondent Herrera. The valid prescriptions to other patients, from which Herrera diverted a portion, consisted of the following controlled substances:

- 20 Alprazolam 1mg tablets
- 10 Alprazolam 2mg tablets
- 6 Oxycodone 10mg tablets
- 10 Oxycodone 15mg tablets
- 20 Oxycodone 30mg tablets

5. During the investigation, Herrera admitted to the unlawful diversion activity.

6. Walgreens terminated Herrera on April 23, 2019.

FIRST CAUSE OF ACTION

Unlawful Acquisition of Controlled Substances

7. NRS 453.331(1)(d) states, in relevant part, that “[i]t is unlawful for a person knowingly or intentionally to . . . [a]cquire or obtain . . . possession of a controlled substance . . . by misrepresentation, fraud, forgery, deception, subterfuge or alteration.” Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(12).

8. By diverting controlled substances as alleged herein, Respondent Herrera violated, or attempted to violate, NRS 453.331(1)(d) and is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION

Unlawful Possession of Controlled Substances

9. NRS 453.336(1) states, in relevant part, that “a person shall not knowingly or intentionally possess a controlled substance, unless the substance was obtained directly from, or pursuant to, a [lawful] prescription or order of a [practitioner]”. Violating, attempting to violate,

assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(12).

10. By diverting controlled substances as alleged herein, Respondent Herrera violated, or attempted to violate, NRS 453.336(1) and is subject to discipline pursuant to NRS 639.210(12).

THIRD CAUSE OF ACTION **Unprofessional Conduct - Diversion**

11. “Supplying or diverting drugs . . . which are legally sold in pharmacies . . . so that unqualified persons can circumvent any law pertaining to the legal sale of such articles” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(g). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).

12. By diverting controlled substances as alleged herein, Respondent Herrera engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

FOURTH CAUSE OF ACTION **Unprofessional Conduct - Deceitful Practice**

13. “Performing or in any way being a party to any fraudulent or deceitful practice or transaction” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(h). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).

14. By diverting controlled substances as alleged herein, Respondent Herrera was a party to any fraudulent or deceitful practice or transaction, engaged in unprofessional conduct

and conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is subject to discipline pursuant to NRS 639.210(4).

FIFTH CAUSE OF ACTION

Violations of Federal Law

15. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(11).

16. By diverting controlled substances as alleged herein, Respondent Herrera violated, or attempted to violate, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), and 21 U.S. Code § 844, and is subject to discipline pursuant to NRS 639.210(11).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 23rd day of July, 2020.



J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

THEODORE HERRERA,
Certificate of Registration No. IN04741,

Respondent.

CASE NO. 19-079-IN-S

**STATEMENT TO THE
RESPONDENT AND
NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

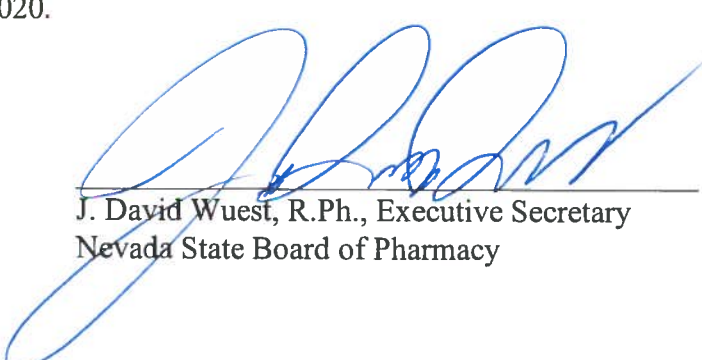
2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. *See* NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. *See* NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this this Statement and Notice, and of the Notice of Intended Action and Accusation served within. *See* NRS 639.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. *See* NRS 622A.350.

DATED this 23rd day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Theodore Herrera
2362 N. Green Valley Pkwy #P-236
Henderson, NV 89014


SHIRLEY HUNTING

RETURN OF SERVICE

STATE OF Nevada)
)
 COUNTY OF Washoe)
)
 ss.

I HEREBY certify and return that I received the within Nevada State Board of Pharmacy Notice of Intended Action and Accusation, Statement to the Respondent and Notice of Hearing, and Answer and Notice of Defense in Case 19-079-IN-S on the 29th day of July, 2020 and that I personally served the same upon Theodore Herrera, a person at least eighteen years of age, at 10559 Crystal Bay Drive, Reno, NV 89521 on the 29th day of July, 2020.

Signature

Name (print)

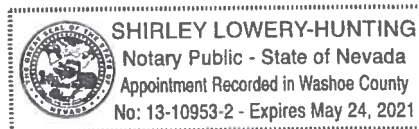
Joseph J. Depczynski

SUBSCRIBED AND SIGNED before me

this 29th day of JULY, 2020

by JOSEPH DEPCZYNSKI.

SHIRLEY LOWERY-HUNTING
 NOTARY PUBLIC



FILED**SEP 18 2020**NEVADA STATE BOARD
OF PHARMACY

Charles C. Diaz (NV Bar 3349)
Diaz & Galt, LLC.
443 Marsh Avenue
Reno, Nevada 89509
T: 775.324.6443
E: cdiaz@diazgaltlaw.com
Attorney for Plaintiff

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

CASE NO. 19 -079-IN-S

Petitioner,

v.

THEODORE HERRERA,
Certificate of Registration No. IN04741

**ANSWER TO NOTICE OF INTENDED
ACTION AND ACCUSATION**

Respondent.

Theodore Herrera, Respondent herein, by and through his attorney, Charles D. Diaz of Diaz & Galt, LLC, hereby makes the following answer to Notice of Intended Action and Accusation.

JURISDICTION

(1) Paragraph 1.- Mr. Herrera admits the allegations contained in paragraph 1.

FACTUAL ALLEGATIONS

(2) Paragraph 2.- Mr. Herrera admits that he worked at Walgreens Pharmacy #5311 located on 1180 East Flamingo Road, Las Vegas, Nevada during the months of June 2018 to April 2019 but denies the inference that he worked more than part time. Mr. Herrera was attending pharmacy school during the relevant time period. His schedule at the above referenced Walgreens Pharmacy was limited to sometimes only once a month and he did not consistently work more than one or two days a week. Mr. Herrera denies the inference that

1 this period of time was the extent of his work at this location because based on information
2 and belief Mr. Herrera worked at this Walgreens location, part time from August 2017 when
3 Pharmacy school started until April 2019, first as a pharmacy technician and then as a
4 pharmacy intern.

5
6 (3) Paragraph 3.- Mr. Herrera is without knowledge or information sufficient to form a
7 belief as to the truth of the averment stated in Paragraph 3.

8
9 (4) Paragraph 4.- Mr. Herrera admits that for several months prior to April 2019 he
10 diverted a portion of valid prescriptions to other patients (approximately tablets, and as set
11 forth in paragraph 4, but denies that he engaged in this conduct during the entire period of his
12 employment.

13
14 (5) Paragraph 5. - Mr. Herrera admits that, during the investigation of this matter, he
15 admitted to this unlawful diversion activity.

16
17 (6) Paragraph 6.- Mr. Herrera admits this averment.

18
19 **FIRST CAUSE OF ACTION**
Unlawful Acquisition of Controlled Substances

20 (7) Paragraph 7.- Mr. Herrera agrees with and admits the law as outlined in this
21 paragraph.

22 (8) Paragraph 8.- Mr. Herrera admits to diverting controlled substances amounting to
23 approximately 66 tablets and admits that this behavior is subject to discipline under NRS
24 639.210(4), but is without the experience and training to form a legal conclusion.

25
26 //

27 //

28 //

SECOND CAUSE OF ACTION
Unlawful Possession of Controlled Substances

(9) Paragraph 9.- Mr. Herrera agrees with and admits the law as outlined in this paragraph.

(10) Paragraph 10.- Mr. Herrera admits to diverting controlled substances amounting to approximately 66 tablets and admits that this behavior is subject to discipline under NRS 639.210(4), but is without the experience and training to form a legal conclusion.

THIRD CAUSE OF ACTION
Unprofessional Conduct-Diversion

(11) Paragraph 11.- Mr. Herrera agrees with and admits the law as outlined in this paragraph.

(12) Paragraph 12.- Mr. Herrera admits to diverting controlled substances amounting to approximately 66 tablets and admits that unprofessional conduct and conduct contrary to the public interest is subject to discipline but is without the experience and training to form a legal conclusion.

FOURTH CAUSE OF ACTION
Unprofessional Conduct-Deceitful Practice

(13) Paragraph 13.- Mr. Herrera agrees with and admits the law as outlined in this paragraph.

(14) Paragraph 14.- Mr. Herrera admits to diverting controlled substances amounting to approximately 66 tablets and admits that unprofessional conduct and conduct contrary to the public interest is subject to discipline but is without the experience and training to form a legal conclusion.

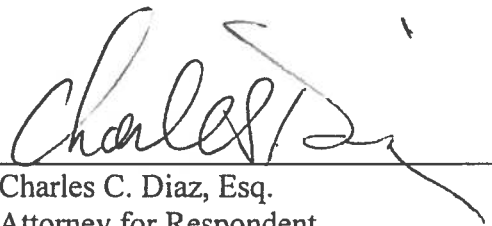
FIFTH CAUSE OF ACTION
Violations of Federal Law

(15) Paragraph 15.- Mr. Herrera agrees with and admits the law as outlined in this paragraph.

(16) Paragraph 16.- Mr. Herrera admits that he diverted controlled substances amounting to approximately 66 tablets and admits he is subject to discipline.

(17) I hereby declare, under penalty of perjury, that the foregoing Answer and all facts therein stated, are true and correct to the best of my knowledge.

DIAZ & GALT, LLC.

By 
Charles C. Diaz, Esq.
Attorney for Respondent

5E

JUL 30 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JERALD CLYDE, RPH,
Certificate of Registration No. 10310, andSMITH'S PHARMACY #366,
License No. PH01771,

Respondents.

CASE NOS. 19-061-RPH-S
19-061-PH-SNOTICE OF INTENDED ACTION
AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Jerald Clyde (Clyde), Certificate of Registration No. 10310, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #366, License No. PH01771, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Clyde was employed by Smith's #366 at the time of the events alleged herein.
3. On June 21, 2018, L.V.'s physician electronically transmitted a prescription to Smith's Pharmacy #348 for Dexilantⁱ 60 mg. delayed release capsule, quantity 90, for a 90-day supply. The prescription allowed for three (3) refills.
4. Smith's Pharmacy #348 computer system designated the prescription as no. 6759964.
5. Smith's Pharmacy #348 dispensed the initial fill of 30 Dexilant 60 mg. capsules on June 22, 2018, and dispensed a refill on July 30, 2018.

ⁱ Dexilant is a proton pump inhibitor used to treat heartburn and gastroesophageal reflux disease (GERD).

6. On September 28, 2018, Smith's Pharmacy #348 electronically transferred prescription no. 6759964 to Smith's Pharmacy #366.
7. Smith's Pharmacy #366 computer system designated the transferred prescription as no. 6027081.
8. Smith's Pharmacy #366 refilled and dispensed 30 capsules of Dexilant 60 mg. on September 28, 2018, and again on October 31, 2018.
9. On November 30, 2018, pharmaceutical technician Daniel Saucedo processed a refill of prescription no. 6027081.
10. Clyde filled the prescription. During the filling process, Clyde inadvertently selected a bottle of *Duloxetine*ⁱⁱ 60 mg. capsules rather than the *Dexilant* 60 mg. capsules as prescribed.
11. Clyde is on record as the verifying pharmacist for prescription no. 6027081. He failed to detect the medication error when he performed the final product review.
12. L.V. experienced headaches and ophthalmological issues after ingesting seven (7) doses of the mis-filled medication over a three-day period. L.V. checked the medication bottle and discovered the error.

FIRST CAUSE OF ACTION

(Respondent Clyde)

13. Unprofessional conduct includes the failure by a licensee to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). It also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). Additionally, NAC 639.252 states in relevant part:

If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, *the pharmacist supervising the pharmaceutical technician* is responsible for the filled prescription, including, but not limited to, verifying:

- (a) The selection and strength of the drug;
- (b) The dosage form; and
- (c) The labeling of the prescription.

ⁱⁱ **Duloxetine** is a selective serotonin and norepinephrine reuptake inhibitor antidepressant used to treat major depressive disorder.

NAC 639.252(2) (emphasis added.)

14. Respondent Clyde violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when he verified the scanned data and final product on prescription no. 6027081 as accurate when it was not, which resulted in Smith's dispensing *Duloxetine* 60 mg. capsules rather than the *Dexilant* 60 mg. capsules as prescribed. Clyde is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

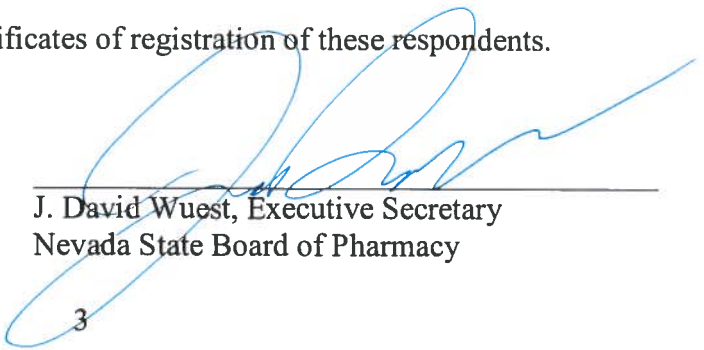
SECOND CAUSE OF ACTION
(Respondent Smith's Pharmacy #366)

15. NRS 639.230(5) provides: "Any violation of any of the provisions of this chapter [NRS Chapter 639] by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for the suspension or revocation of the license of the pharmacy by the Board." Additionally, "[t]he owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission." NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

16. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Smith's Pharmacy #366 is responsible for any violations of law by Clyde pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

Signed this 30th day of July, 2020.



J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NOS. 19-061-RPH-S

Petitioner,

v.

JERALD CLYDE, RPH
Certificate of Registration No. 10310,

Respondent.

**STATEMENT TO THE RESPONDENT
 NOTICE OF INTENDED ACTION
 AND ACCUSATION
 RIGHT TO HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

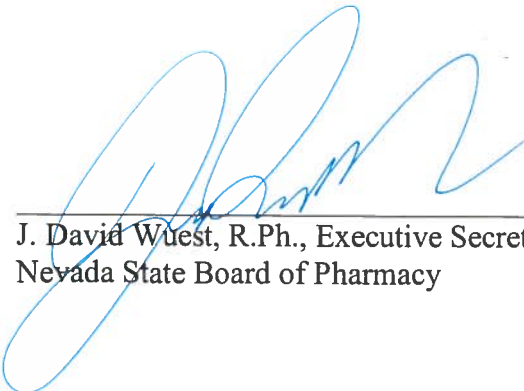
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jerald Clyde, R.Ph.
2378 Goldfire Circle
Henderson, NV 89052

Smith's Pharmacy #366
55 South Valle Verde Drive
Henderson, NV 89012



SHIRLEY HUNTING

FILED

AUG 24 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF
PHARMACY,

PETITIONER,

v.

JERALD CLYDE, RPH
Certificate of Registration No. 10310, andSMITH'S PHARMACY #366, License No.
PH01771,

RESPONDENTS.

CASE NO. 19-061-PH-S

ANSWER AND NOTICE OF DEFENSE

Respondents above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, jointly declare:

1. That this objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against them, is hereby interposed on the following grounds: (State specific objections or insert "none").

None

2. That, in answer to the Notice of Intended Action and Accusations, Respondents jointly admit, deny and allege as follows:

Respondents are currently investigating these allegations. At this time, Respondents deny the allegations.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 25th day of August, 2020.

Roger N. Morris

TYPE OR PRINT NAME



AUTHORIZED REPRESENTATIVE FOR
SMITH'S PHARMACY #366 AND
JERALD CLYDE

5F

BEFORE THE NEVADA STATE BOARD OF PHARMACY**NEVADA STATE BOARD OF PHARMACY,****CASE NOS. 19-061-PH-S****Petitioner,****v.****SMITH'S PHARMACY #366****License No. PH01771,****Respondent.****STATEMENT TO THE RESPONDENT
NOTICE OF INTENDED ACTION
AND ACCUSATION
RIGHT TO HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

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III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

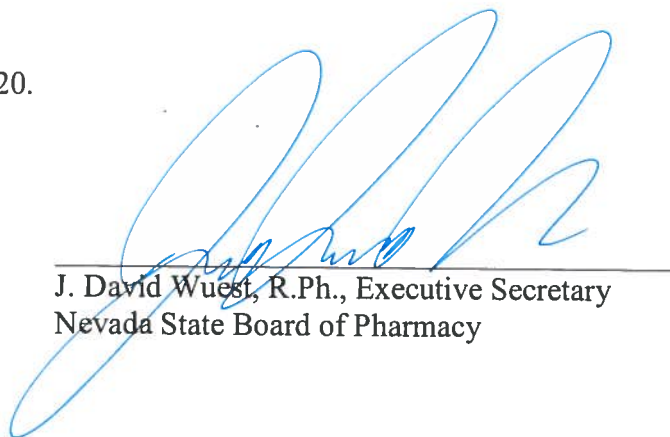
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Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of July, 2020.



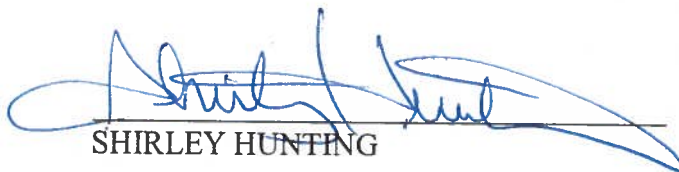
J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jerald Clyde, R.Ph.
2378 Goldfire Circle
Henderson, NV 89052

Smith's Pharmacy #366
55 South Valle Verde Drive
Henderson, NV 89012



SHIRLEY HUNTING

FILED

AUG 25 2020

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY****NEVADA STATE BOARD OF
PHARMACY,****PETITIONER,****v.****JERALD CLYDE, RPH
Certificate of Registration No. 10310, and****SMITH'S PHARMACY #366, License No.
PH01771,****RESPONDENTS.****CASE NO. 19-061-PH-S****ANSWER AND NOTICE OF DEFENSE**

Respondents above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, jointly declare:

1. That this objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against them, is hereby interposed on the following grounds: (State specific objections or insert "none").

None

2. That, in answer to the Notice of Intended Action and Accusations, Respondents jointly admit, deny and allege as follows:

Respondents are currently investigating these allegations. At this time, Respondents deny the allegations.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 25th day of August, 2020.

Roger N. Morris

TYPE OR PRINT NAME



AUTHORIZED REPRESENTATIVE FOR
SMITH'S PHARMACY #366 AND
JERALD CLYDE

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**JERALD CLYDE, RPH,
Certificate of Registration No. 10310, and**

**SMITH'S PHARMACY #366,
License No. PH01771,**

Respondents.

**CASE NOS. 19-061-RPH-S
19-061-PH-S**

STIPULATION AND ORDER

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), Respondent Jerald Clyde, R.Ph., Certificate of Registration No. 10310 (Clyde), and Respondent Smith's Pharmacy #366, License No. PH01771, by and through counsel, Nick Meza, Esq., **HEREBY**

STIPULATE AND AGREE THAT:

1. The Board has jurisdiction over Respondents and this matter.
2. On or about July 30, 2020, Board Staff properly served Respondents with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.
3. On or about August 25, 2020, Respondents jointly filed an Answer and Notice of Defense to the Accusation.
4. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.
5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to Respondents pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of Paragraphs 9, 10, 15 and 16 below, Respondents hereby freely and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondents do not admit to the allegations in the Accusation, but acknowledge that, if proven at a contested administrative hearing, Board staff prosecuting this case could establish a factual basis for the violations alleged therein, to wit, that:

A. Clyde violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when he verified the scanned data and final product on prescription no. 6027081 as accurate when it was not, which resulted in Smith's dispensing *Duloxetine* 60 mg. capsules rather than the *Dexilant* 60 mg. capsules as prescribed. Clyde is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

B. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Smith's Pharmacy #366 is responsible for any violations of law by Clyde pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Clyde stipulate to the following penalties. Respondent Jerald Clyde, R.Ph., Certificate of Registration No. 10310, shall:

A. Accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a registered pharmacist;

B. Pay a fine of One-Thousand Dollars (\$1,000.00) for the alleged violations; and

C. Pay One-Thousand Dollars (\$1,000.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

10. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Smith's Pharmacy #366 stipulate to the following penalties. Respondent Smith's Pharmacy #366, License No. PH01771, shall:

A. Pay a fine of One-Thousand Dollars (\$1,000.00) for the alleged violations;
and

B. Pay One-Thousand Dollars (\$1,000.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

11. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by that Respondent, the Board may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2020. Respondents and/or their authorized representative(s) will appear telephonically or via Zoom at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents are not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board it shall be a public record pursuant to NRS 622.330.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by cashier's check or certified check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order.

16. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and costs agreed to herein by cashier's check or certified check or money order made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondents, and each of them, agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents, and each of them, have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of October, 2020

Signed this ____ day of October, 2020

**JERALD CLYDE, RPH,
Certificate of Registration No. 10310**

Signed this ____ day of October, 2020

**BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy**

**SMITH'S PHARMACY #366,
License No. PH01771**

**APPROVED AS TO FORM AND
CONTENT this ____ day of October, 2020**

**Nick Meza
Counsel for Respondents**

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Jerald Clyde, R.Ph., Certificate of Registration No. 10310, and Respondent Smith's Pharmacy #366, License No. PH01771, in Case No. 19-061, and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ____ day of October, 2020.

Helen Park, President
Nevada State Board of Pharmacy

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JUL 24 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ABDEL M. KHALEK, MD,
Certificate of Registration Nos. CS19745 and
PD00722,

ROBERT CHANCELLOR, MD,
Certificate of Registration Nos. CS22616 and
PD27416, and

LINDSAY HOFFMAN, PA-C,
Certificate of Registration Nos. CS18262 and
PD00177,

Respondents.

Case Nos. 19-003-CS-A-S
19-003-CS-B-S
19-003-CS-C-S

NOTICE OF INTENDED ACTION
AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Abdel M. Khalek, MD (Khalek), held a controlled substance registration, Certificate of Registration No. CS19745, and dispensing practitioner registration, Certificate of Registration No. PD00722; Respondent Robert Chancellor, MD (Chancellor), held a controlled substance registration, Certificate of Registration No. CS22616, and dispensing practitioner registration, Certificate of Registration No. PD27416; and Lindsay Hoffman, PA-C (Hoffman), held a controlled substance registration, Certificate of Registration No. CS18262, and dispensing practitioner registration, Certificate of Registration No. PD00177, all issued by the Board.

FACTUAL ALLEGATIONS

2. Vinay Kumar Bararia, MD (Bararia) was not registered with the Board at the time of the events alleged herein.
3. Bararia voluntarily surrendered his license to practice medicine, License No. 11355, to the Nevada State Board of Medical Examiners (NSBME) on March 8, 2013, and was sentenced in federal court for distribution of controlled substances in September 2014.
4. Bararia has owned and operated Nevada Health Services, LLC aka Trimcare (Trimcare), located at 5375 South Fort Apache Road, Suites 102 and 103, in Las Vegas, since August 2018.
5. Khalek co-owned and/or was employed at Trimcare from October 2018 to April 2019.
6. Chancellor co-owned and/or was employed by Trimcare from November 2018 to the present.
7. Hoffman was employed by Trimcare from August 2018 to present.
8. Ageless Aesthetics (Ageless Aesthetics), an unnamed third party, is a medical spa that operates at 5375 South Fort Apache Road, Suite 101, Las Vegas, Nevada 89148, next door to Trimcare, for which Khalek was the medical director from approximately October 2018 to April 2019.
9. Investigators from the Board, the Nevada State Board of Medical Examiners (BME) and the Drug Enforcement Administration (DEA) conducted a joint investigation of Trimcare and found evidence of misconduct and violations involving the unlawful possession, administration, prescribing and dispensing of controlled substances and/or dangerous drugs.
10. Khalek, Chancellor and Hoffman permitted Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another

practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state.

11. Khalek unlawfully prescribed controlled substances and/or dangerous drugs, including, without limitation, Testosterone, Phentermine, Phendimetrazine, Topamax, Botox, and Juvederm, for at least two-hundred ninety-eight (298) patients with whom he did not have a bona fide therapeutic relationship from September 2018 to April 2019 by pre-signing prescriptions, providing his log-on information to e-scribing systems to Bararia, and/or failing to secure his secondary authenticator for e-scribing CII medications.

12. Chancellor unlawfully prescribed controlled substances and/or dangerous drugs, including, without limitation, Adderall, Phentermine, and Topamax, for at least ten (10) patients with whom he did not have a bona fide therapeutic relationship from November 2018 to present by pre-signing prescriptions, his log-on information to e-scribing systems to Bararia, and/or failing to secure his secondary authenticator for e-scribing CII medications.

13. Hoffman unlawfully prescribed controlled substances/dangerous drugs, including, but not limited to, Phentermine, and Topamax for at least two (2) patients with whom she did not have a bona fide therapeutic relationship in April 2019 by pre-signing prescriptions.

14. Khalek, Chancellor and Hoffman permitted access of their inventory of controlled substances and dangerous drugs to unlicensed employees of Trimcare and/or Ageless Aesthetics.

15. Khalek, Chancellor and Hoffman failed to issue a written prescription for each medication dispensed, failed to verify medications for accuracy prior to dispensing, failed to maintain complete, accurate and readily retrievable records of all controlled substances and dangerous drugs purchased and dispensed, failed to inventory controlled substances at least once every two (2) years, failed to properly store and maintain the inventory, failed to maintain the

security of the inventory from unauthorized access, and failed to segregate and/or dispose of adulterated and/or expired dangerous drugs.

16. Chancellor and Hoffman had possession of pre-drawn, unlabeled syringes containing an unidentified dangerous drug.

17. On or about July 7, 2020, Board staff served Bararia with an order pursuant to NRS 639.2895(1) to immediately cease and desist possessing, administering, prescribing and/or dispensing controlled substances and dangerous drugs for Nevada patients from Trimcare.

APPLICABLE LAW

18. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).

19. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.381(1).

20. It is unlawful for a practitioner to prescribe or dispense a controlled substance or dangerous drug except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS 454.215; NRS 454.301, NRS 639.100(1); NRS 639.23505; NAC 453.410; NAC 639.742; NAC 639.745.

21. It is unlawful for a person to purchase, possess, administer or furnish a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321 and/or NRS 454.356.

22. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(c), (d), (f), (h) and (i).

23. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.281(1); NRS 639.2813(1).

24. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(1)(a).

25. A dispensing practitioner must issue a written prescription for each medication dispensed, verify medications for accuracy prior to dispensing, maintain complete, accurate and readily retrievable records of all controlled substances and dangerous drugs purchased and dispensed, inventory controlled substances at least once every two (2) years, properly store and maintain the inventory, maintain the security of the inventory from unauthorized access, and segregate and/or dispose of adulterated and/or expired dangerous drugs. NRS 453.246; NRS 585.370; NRS 585.420; NRS 639.282; NAC 453.400; NAC 453.410; NAC 453.475; NAC 454.040; NAC 639.475; NAC 639.476; NAC 639.510; NAC 639.601; NAC 639.742, NAC 639.743; NAC 639.745; 21 U.S.C. § 842(a)(5); 21 CFR 1304.11; 21 CFR 1304.21.

26. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

27. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to

NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Dispensing a drug as a dispensing practitioner or prescribing a drug as a prescribing practitioner to a patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

30. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

31. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

32. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

FIRST CAUSE OF ACTION

Unprofessional Conduct – Party to a Fraudulent/Deceitful Practice/Transaction

33. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including pre-

signing prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

SECOND CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

34. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including pre-signing prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman performed their duties as the holders of controlled substance registrations and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

THIRD CAUSE OF ACTION

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

35. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the

practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including pre-signing prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman aided or abetted a person not licensed to practice pharmacy in the State of Nevada and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(j), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH CAUSE OF ACTION

Unprofessional Conduct – Prescribing/Dispensing Without Bona Fide Therapeutic Relationship

36. By unlawfully prescribing and dispensing controlled substances to patients with whom they did not have a bona fide therapeutic relationship, Khalek, Chancellor and Hoffman engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(n) and (o), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FIFTH CAUSE OF ACTION

Violations of Federal Controlled Substances Act

37. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including pre-signing prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and

Hoffman violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and 21 CFR §§ 1306.03–1306.05, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11).

SIXTH CAUSE OF ACTION

Violations of State Law for Unlicensed Practice

38. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including pre-signing prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of NRS 453.226, NRS 453.316, NRS 453.321(1)(a), NRS 453.331 (1)(c)(d)(f)&(i), NRS 453.381(1), NRS 453.401(l)(a), NRS 454.213, NRS 454.215, NRS 454.221, NRS 454.311, NRS 454.316, NRS 454.321, NRS 639.100(1), NRS 639.235, NRS 639.23505, NRS 639.281, NRS 639.2813 and NRS 639.310, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

SEVENTH CAUSE OF ACTION

Failure to Maintain Security of Controlled Substances or Dangerous Drugs

39. By failing to maintain proper locked security of their inventory of controlled substances and dangerous drugs and/or permitting unauthorized access to their inventory by Bararia and/or other unlicensed employees of Trimcare and/or Ageless Aesthetics, Khalek,

Chancellor and Hoffman violated NAC 453.400, NAC 453.410(1)(d), NAC 454.040, NAC 639.742(3)(c), NAC 639.742(3)(a)(b)(c)&(e), and NAC 639.745(1)(c), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

EIGHTH CAUSE OF ACTION

Failure to Maintain Records for Controlled Substances Dispensed

40. By failing to keep complete, accurate, and readily retrievable records of all controlled substances dispensed, including failing to issue a written prescription for each medication dispensed and failing to inform the patient that he or she may request a written prescription to have it filled at another location of their choice, Khalek, Chancellor, and Hoffman violated NRS 453.246, NAC 453.410(1)(a)(B) and (2), NAC 639.745(2) and (3)(b)(2), 21 U.S.C. § 842(a)(5), 21 CFR 1304.11 and 21 CFR § 1304.21, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11), (12) and (17).

NINTH CAUSE OF ACTION

Failure to Verify Dispensed Medications for Accuracy

41. By failing to verify medications for accuracy prior to dispensing, Khalek, Chancellor, and Hoffman violated NAC 639.743(2)(a) and (b), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

TENTH CAUSE OF ACTION

Failure to Inventory Controlled Substances Every Two Years

42. By failing to inventory controlled substances at least once every two (2) years, Khalek, Chancellor, and Hoffman violated NRS 453.246, NAC 453.475(1)(b), 21 U.S.C. § 842(a)(5), 21 CFR 1304.11 and 21 CFR § 1304.21 and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11), (12) and (17).

ELEVENTH CAUSE OF ACTION

Failure to Properly Segregate/Dispose Adulterated/Expired Drugs

43. By failing to properly segregate and/or dispose of adulterated and/or expired dangerous drugs for administration, Khalek, Chancellor, and Hoffman violated NRS 585.370(1), NRS 639.282(1)(d), NAC 639.050(2), NAC 639.473(1) and (3), NAC 639.510(3) and NAC 639.601(1), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

TWELFTH CAUSE OF ACTION

Failure to Properly Label Pre-Filled Syringes Against

44. By pre-filling syringes without proper labels and/or temperature control, Chancellor and Hoffman violated NRS 585.420, NRS 639.282 (1)(e), NAC 639.476 and NAC 639.510, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210 (12).

THIRTEENTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

45. By their actions as set forth herein, Khalek, Chancellor and Hoffman have committed acts that render their registrations to prescribe or otherwise dispense a controlled substance inconsistent with the public interest pursuant to NRS 453.231, and are subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

DATED this 24th day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-A-S

Petitioner,

v.

**ABDEL M. KHALEK, MD,
Certificate of Registration Nos. CS19745 and
PD00722,**

**STATEMENT TO
THE RESPONDENT
AND NOTICE OF HEARING**

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

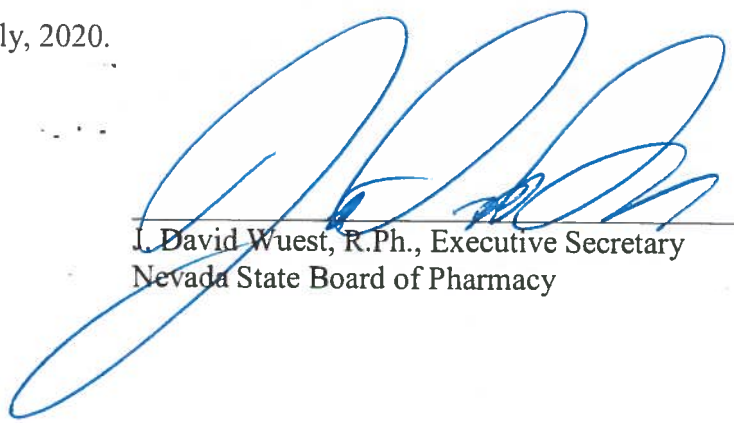
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

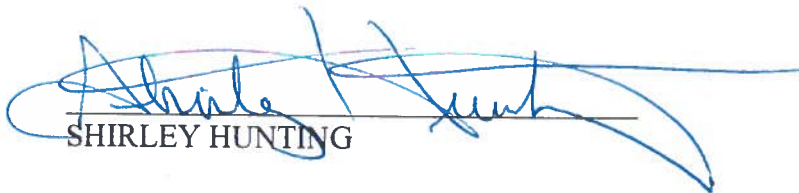
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Las Vegas, NV 89118

E. Brent Bryson, Esq.
7730 W. Sahara Ave., Ste. 109
Las Vegas, NV 89117




SHIRLEY HUNTING

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S.

Mail to the following:

Abdel M. Khalek, MD
8600 Starboard Avenue
Las Vegas, NV 89117


Shirley Hunting

FILED

AUG 23 2020

NEVADA STATE BOARD
OF PHARMACY

LEWIS BRISBOIS BISGAARD & SMITH LLP
JILL M. CHASE
Nevada Bar No. 5250
6385 S. Rainbow Boulevard, Suite 600
Las Vegas, Nevada 89118
Telephone: 702.893.3383
Facsimile: 702.893.3789
Email: Jill.Chase@lewisbrisbois.com
Attorney for Abdel M. Khalek, M.D.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF
PHARMACY,

CASE NO. 19-090-CS-S

ANSWER AND NOTICE OF DEFENSE

Petitioner,

vs.

ABDEL M. KHALEK, M.D.,
Certificate of Registration No. CS19745
and PD00722

Respondent.

ABDEL M. KHALEK, M.D., ("Dr. Khalek"), by and through his counsel, JILL M. CHASE, ESQ. of the law firm of LEWIS BRISBOIS BISGAARD & SMITH, LLP hereby submits his Answer and Notice of Defense.

JURISDICTION

1. Answering Paragraph 1, Respondent objects to this paragraph as it calls for a legal conclusion; notwithstanding, Respondent admits that he held a Board-issued controlled substance registration, Certificate of Registration No. CS19745 and PD00722.

FACTUAL ALLEGATIONS

2. Answering Paragraph 2, Respondent admits that Vinay Kumar Bararia, M.D. was not registered with the Board at the time of the alleged events herein.

3. Answering Paragraph 3, Respondent is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph III and therefore denies these allegations.

4. Answering Paragraph 4, Respondent is without sufficient knowledge,

1 information upon which to base a belief as to the truth or falsity of the allegations
2 contained in Paragraph 4 and therefore denies these allegations. .

3 5. Answering Paragraph 5, Respondent admits he was employed at Trimcare
4 from October 2018 to April 2019.

5 6. Answering Paragraph 6, Respondent is without sufficient knowledge,
6 information upon which to base a belief as to the truth or falsity of the allegations
7 contained in Paragraph 6 and therefore denies these allegations.

8 7. Answering Paragraph 7, Respondent is without sufficient knowledge,
9 information upon which to base a belief as to the truth or falsity of the allegations
10 contained in Paragraph 7 and therefore denies these allegations.

11 8. Answering Paragraph 8, Respondent denies that he was the medical
12 director of Ageless Aesthetics from October 2018 to April 2019.

13 9. Answering Paragraph 9, Respondent is without sufficient knowledge,
14 information upon which to base a belief as to the truth or falsity of the allegations
15 contained in Paragraph 9 and therefore denies these allegations.

16 10. Answering Paragraph 10, Respondent denies these allegations as to this
17 Respondent, but is without sufficient knowledge, information upon which to base a belief
18 as to the truth or falsity of the remaining allegations contained in Paragraph 10 and
19 therefore denies these allegations.

20 11. Answering Paragraph 11, Respondent denies these allegations.

21 12. Answering Paragraph 12, Respondent is without sufficient knowledge,
22 information upon which to base a belief as to the truth or falsity of the allegations
23 contained in Paragraph 12 and therefore denies these allegations.

24 13. Answering Paragraph 13, this allegation is not directed to this Respondent
25 is without sufficient knowledge, information upon which to base a belief as to the truth or
26 falsity of the allegations contained in Paragraph 13 and therefore denies these
27 allegations.

28 14. Answering Paragraph 14, Respondent denies these allegations as to this

1 Respondent, but is without sufficient knowledge, information upon which to base a belief
2 as to the truth or falsity of the remaining allegations contained in Paragraph 14 and
3 therefore denies these allegations.

4 15. Answering Paragraph 15, Respondent denies these allegations as to this
5 Respondent, but is without sufficient knowledge, information upon which to base a belief
6 as to the truth or falsity of the remaining allegations contained in Paragraph 15 and
7 therefore denies these allegations.

8 16. Answering Paragraph 16, Respondent is without sufficient knowledge,
9 information upon which to base a belief as to the truth or falsity of the allegations
10 contained in Paragraph 16 and therefore denies these allegations.

11 17. Answering Paragraph 17, Respondent is without sufficient knowledge,
12 information upon which to base a belief as to the truth or falsity of the allegations
13 contained in Paragraph 17 and therefore denies these allegations

14 APPLICABLE LAW

15 18. Answering Paragraph 18, Respondent objects to this paragraph as it calls
16 for a legal conclusion, for which no response is required.

17 19. Answering Paragraph 19, Respondent objects to this paragraph as it calls
18 for a legal conclusion, for which no response is required.

19 20. Answering Paragraph 20, Respondent objects to this paragraph as it calls
20 for a legal conclusion, for which no response is required.

21 21. Answering Paragraph 21, Respondent objects to this paragraph as it calls
22 for a legal conclusion, for which no response is required.

23 22. Answering Paragraph 22, Respondent objects to this paragraph as it calls
24 for a legal conclusion, for which no response is required.

25 23. Answering Paragraph 23, Respondent objects to this paragraph as it calls
26 for a legal conclusion, for which no response is required.

27 24. Answering Paragraph 24, Respondent objects to this paragraph as it calls
28 for a legal conclusion, for which no response is required.

26. Answering Paragraph 26, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

27. Answering Paragraph 27, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

28. Answering Paragraph 28, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

29. Answering Paragraph 29, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

30. Answering Paragraph 30, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

31. Answering Paragraph 31, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

32. Answering Paragraph 32, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

FIRST CAUSE OF ACTION

Unprofessional Conduct-Party to a Fraudulent/Deceitful Practice/Transaction

33. Answering Paragraph 33, Respondent denies that he permitted Bararia to perform any unlawful acts alleged in Paragraph 33, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 33 as to the remaining Respondents and therefore denies these allegations.

SECOND CAUSE OF ACTION

Unprofessional Conduct-Incompetent, Unskillful or Negligent Performance of Duties

34. Answering Paragraph 34, Respondent denies that he permitted Bararia to perform any unlawful acts alleged in Paragraph 34, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations

1 contained in Paragraph 34 as to the remaining Respondents and therefore denies these
2 allegations.

3 THIRD CAUSE OF ACTION

4 Unprofessional Conduct-Aiding and Abetting Unlicensed Practice

5 35. Answering Paragraph 35, Respondent denies that he permitted Bararia to
6 perform any unlawful acts alleged in Paragraph 35, but is without sufficient knowledge,
7 information upon which to base a belief as to the truth or falsity of the allegations
8 contained in Paragraph 35 as to the remaining Respondents and therefore denies these
9 allegations.

10 FOURTH CAUSE OF ACTION

11 Unprofessional Conduct-Prescribing/Dispensing Without Bona Fide Therapeutic 12 Relationship

13 36. Answering Paragraph 36, Respondent denies that he performed any
14 unlawful acts alleged in Paragraph 36, but is without sufficient knowledge, information
15 upon which to base a belief as to the truth or falsity of the allegations contained in
16 Paragraph 36 as to the remaining Respondents and therefore denies these allegations.

17 FIFTH CAUSE OF ACTION

18 Violations of Federal Controlled Substances Act

19 37. Answering Paragraph 37, Respondent denies that he permitted Bararia to
20 perform any unlawful acts alleged in Paragraph 37, but is without sufficient knowledge,
21 information upon which to base a belief as to the truth or falsity of the allegations
22 contained in Paragraph 37 as to the remaining Respondents and therefore denies these
23 allegations.

24 ///

25 ///

26 ///

27 ///

28 ///

SIXTH CAUSE OF ACTION

Violations of State Law for Unlicensed Practice

38. Answering Paragraph 38, Respondent denies that he permitted Bararia to perform any unlawful acts alleged in Paragraph 38, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 38 as to the remaining Respondents and therefore denies these allegations.

SEVENTH CAUSE OF ACTION

Failure to Maintain Security of Controlled Substances or Dangerous Drugs

39. Answering Paragraph 39, Respondent denies that he permitted Bararia and/or other unlicensed employees of Trimcare and/or Ageless Aesthetics to perform any unlawful acts alleged in Paragraph 39, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 39 as to the remaining Respondents and therefore denies these allegations.

EIGHTH CAUSE OF ACTION

Failure to Maintain Records for Controlled Substances Dispensed

40. Answering Paragraph 40, Respondent denies that he performed or committed any of the unlawful acts alleged in Paragraph 40, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 40 as to the remaining Respondents and therefore denies these allegations.

NINTH CAUSE OF ACTION

Failure to Verify Dispensed Medications for Accuracy

41. Answering Paragraph 41, Respondent denies that he performed any unlawful acts alleged in Paragraph 41, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 41 as to the remaining Respondents and therefore denies these allegations.

///

TENTH CAUSE OF ACTION

Failure to Inventory Controlled Substances Every Two Years

42. Answering Paragraph 42, Respondent denies that he performed any unlawful acts alleged in Paragraph 42, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 42 as to the remaining Respondents and therefore denies these allegations.

ELEVENTH CAUSE OF ACTION

Failure to Properly Segregate/Dispose Adulterated/Expired Drugs

43. Answering Paragraph 43, Respondent denies that he performed or committed any of the unlawful acts alleged in Paragraph 43, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 43 as to the remaining Respondents and therefore denies these allegations.

TWELFTH CAUSE OF ACTION

Failure to Properly Label Pre-Filled Syringes Against

44. Answering Paragraph 44, Respondent states that this allegation seeks information about other Respondents for which he is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 44 as to the remaining Respondents and therefore denies these allegations.

THIRTEENTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

45. Answering Paragraph 45, Respondent denies this paragraph as to himself, but is without sufficient knowledge, information upon which to base a belief as to the truth or falsity of the allegations contained in Paragraph 45 as to the remaining Respondents and therefore denies these allegations.

///

///

1 AFFIRMATIVE DEFENSES

2 FIRST AFFIRMATIVE DEFENSE

3 The Board's Complaint fails to state a claim on which relief may be granted.

4 SECOND AFFIRMATIVE DEFENSE

5 The Board's Complaint, and each cause of action therein, is barred by the doctrine
6 of laches, estoppel, and the doctrine of unclean hands.

7 THIRD AFFIRMATIVE DEFENSE

8 Respondent denies each and every allegation of the Board's Complaint not
9 specifically admitted or otherwise pled to herein.

10 WHEREFORE, Respondent prays for judgment as follows:

11 1. That all charges against him be dismissed;

12 2. For such other and further relief as may be deemed just and proper in these
13 premises.

14 DATED: August 28, 2020

Respectfully submitted,

15 Jill M. Chase
16 LEWIS BRISBOIS BISGAARD & SMITH LLP

17 /s/ Jill M. Chase

18 By: _____
19 Attorneys for Abdel Khalek, M.D.

5H

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-B-S

Petitioner,

v.

**ROBERT CHANCELLOR, MD,
Certificate of Registration Nos. CS22616 and
PD27416,**

**STATEMENT TO
THE RESPONDENT
AND NOTICE OF HEARING**

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

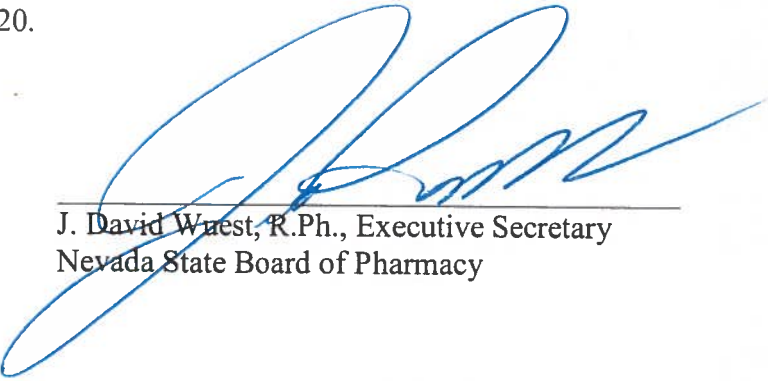
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

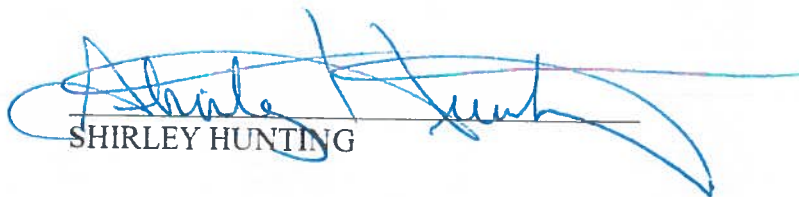
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E. Brent Bryson, Esq.
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Las Vegas, NV 89117


SHIRLEY HUNTING

FILED

AUG 17 2020

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

NEVADA STATE BOARD OF PHARMACY,)	Case No.: 19-003-CS-B-S
)	
Petitioner,)	
)	
vs.)	ANSWER AND NOTICE OF
)	DEFENSE
ROBERT CHANCELLOR, MD,)	
Certificate of Registration No. CS22616 and)	
PD27416,)	
)	
Respondent.)	
)	
)	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: None.

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

Respondent Denies the allegations contained in the Notice of Intended Action and Accusation, Case No. 19-003-CS-B-S.

I hereby, declare under penalty or perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

Date this 11th day of August, 2020.

Robert Chancellor MD
ROBERT CHANCELLOR, MD

51

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-C-S

Petitioner,

v.

**LINDSAY HOFFMAN, PA-C,
Certificate of Registration Nos. CS18262 and
PD00177,**

**STATEMENT TO
THE RESPONDENT
AND NOTICE OF HEARING**

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

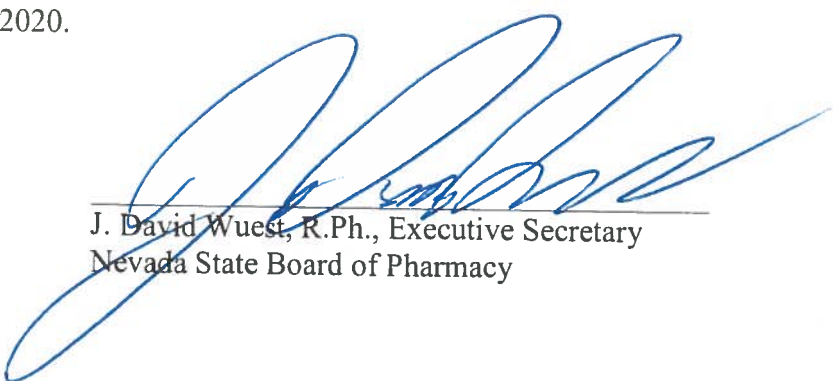
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

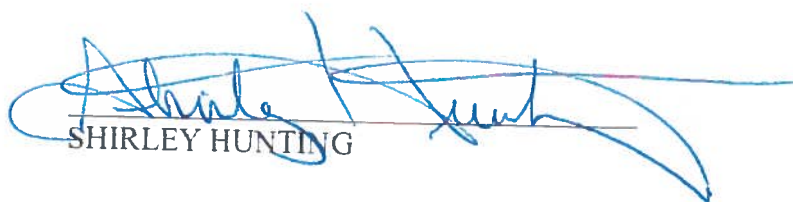
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Las Vegas, NV 89117


SHIRLEY HUNTING

AUG 17 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	Case No.: 19-003-CS-C-S
)	
Petitioner,)	
)	
vs.)	ANSWER AND NOTICE OF
)	DEFENSE
LINDSAY HOFFMAN, P-AC,)	
Certificate of Registration No. CS18262 and)	
PD00177,)	
)	
Respondent.)	
)	
)	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against her, is hereby interposed on the following grounds: None.

2. That, in answer to the Notice of Intended Action and Accusation, she admits, denies and alleges as follows:

Respondent Denies the allegations contained in the Notice of Intended Action and Accusation, Case No. 19-003-CS-C-S.

I hereby, declare under penalty or perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

Date this 11th day of August, 2020.



LINDSAY HOFFMAN, PA-C

5J

AUG 03 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

BERNARD KOFI ADDO-QUAYE, MD,
Certificate of Registration No. CS10103,MUKWEL AIYUK, APRN,
Certificate of Registration No. CS25545, andSOLOMON JOSHUA, APRN,
Certificate of Registration No. CS27011,

Respondents.

Case Nos. 19-242-CS-A-S

19-242-CS-B-S

19-242-CS-C-S

NOTICE OF INTENDED ACTION
AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Bernard Addo-Quaye, MD ("Addo-Quaye"), held a controlled substance registration, Certificate of Registration No. CS10103; Respondent Mukwel Aiyuk, APRN ("Aiyuk"), held a controlled substance registration, Certificate of Registration No. CS25545; and Solomon Joshua, APRN ("Joshua"), held a controlled substance registration, Certificate of Registration No. CS27011, all issued by the Board.

FACTUAL ALLEGATIONS

2. Victor R. Bruce, MD (“Bruce”) was not registered with the Board at the time of the events alleged herein.
3. On December 31, 2014, the Nevada State Board of Medical Examiners (“NSBME”) revoked Bruce’s license to practice medicine, as a result of a federal court criminal judgment entered against Bruce for distribution of a controlled substance.
4. Respondent Bernard Addo-Quaye, MD (“Addo-Quaye”) owns and operates Bernard Addo-Quaye, MD PC dba TruCare Medical Center (“TruCare”) from November 14, 2000 to present. TruCare is located at 2290 McDaniel Street, Suite 2A, North Las Vegas, Nevada.
5. Addo-Quaye was out of the country during certain relevant timeframes in 2018 and 2019.
6. Bruce received a reinstated license to practice medicine from the NSBME, with a restriction from prescribing controlled substances, in September 2018.
7. Addo-Quaye served as Bruce’s preceptor from September 2018 to approximately September 2019.
8. Bruce was employed by TruCare from September 2018 to present.
9. Aiyuk was an independent contractor and/or employed by TruCare during the relevant timeframes in question.
10. Joshua was an independent contractor and/or employed by TruCare during the relevant timeframes in question.
11. Investigators from the Board, the Nevada State Board of Medical Examiners (“NSBME”) conducted an investigation of TruCare and found evidence of misconduct and violations involving the unlawful possession, administration, and prescribing of controlled substances and/or dangerous drugs.

12. Addo-Quaye permitted Bruce, who was restricted from prescribing controlled substances, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe controlled substances and/or dangerous drugs under Addo-Quaye's name and credentials, and/or otherwise falsely represent himself as a practitioner entitled to write or e-scribe controlled substance prescriptions in this state.

13. Addo-Quaye unlawfully prescribed controlled substances and/or dangerous drugs, including, without limitation, Citalopram, Estradiol, Cyanocobalamin, Fluticasone Propionate, Androgel, Focalin, and Lisinopril, for at least four (4) patients with whom he did not have a bona fide therapeutic relationship from September 1, 2019 to September 20, 2019 by providing his blank prescription pads, providing his log-on information to e-scribing systems to Bruce, Aiyuk and/or Joshua and/or failing to secure his secondary authenticator for e-scribing controlled substance and dangerous medications.

14. Aiyuk unlawfully prescribed controlled substances/dangerous drugs under Addo-Quaye's name and credentials, including, but not limited to Norco, Valium, Flexeril, Morphine Sulfate ER, Percocet, Ambien, Hydromorphone, and Clonazepam, for at least three (3) patients from July 8, 2019 to July 10, 2019.

15. Joshua unlawfully prescribed controlled substances/dangerous drugs under Addo-Quaye's name and credentials, including, but not limited to Tramadol, Sumatriptan, Gabapentin, Clonazepam, Ambien, Methadone, Norco, and Narcan, for at least three (3) patients from October 30, 2018 to December 19, 2018.

16. On or about July 21, 2020, Board staff served Bruce with an order pursuant to NRS 639.2895(1) to immediately cease and desist possessing, administering, prescribing and/or dispensing controlled substances and/or dangerous drugs under another practitioner's credentials for Nevada patients from TruCare.

APPLICABLE LAW

17. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).
18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.381(1).
19. It is unlawful for a practitioner to prescribe a controlled substance or dangerous drug except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS 454.215; NRS 454.301, NRS 639.100(1); NRS 639.23505; NAC 453.410; NAC 639.742; NAC 639.745.
20. It is unlawful for a person to possess, administer or furnish a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321 and/or NRS 454.356.
21. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(c), (d), (f), (h) and (i).
22. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.281(1); NRS 639.2813(1).
23. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).
24. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

25. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

26. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

27. Prescribing a drug as a prescribing practitioner to a patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

29. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

30. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

FIRST CAUSE OF ACTION

Unprofessional Conduct – Party to a Fraudulent/Deceitful Practice/Transaction

31. By permitting Bruce, who had a restricted license excluding prescription of controlled substances, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye was a party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

SECOND CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

32. By permitting Bruce, who had a restricted license excluding controlled substance prescriptions, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient, and/or otherwise falsely represent himself as a practitioner entitled to write controlled substance prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged

in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

33. By permitting Aiyuk to treat patients and to utilize Addo-Quaye's name and credentials by providing log-on information to e-scribing systems, and/or failing to secure the secondary authenticator for e-scribing controlled substance medications, Addo-Quaye and Aiyuk performed their duties as holders of controlled substance registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

34. By permitting Joshua to treat patients, and to utilize Addo-Quaye's name and credentials by providing log-on information to e-scribing systems, and/or failing to secure the secondary authenticator for e-scribing controlled substance medications, Addo-Quaye and Joshua performed their duties as holders of controlled substance registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

THIRD CAUSE OF ACTION

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

35. By permitting Bruce, who had a restricted license excluding prescriptions of controlled substances, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient, and/or otherwise falsely represent himself as a practitioner entitled to write controlled substance prescriptions in this state, including providing blank prescription pads,

providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye aided or abetted a person not fully licensed to practice pharmacy in the State of Nevada and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH CAUSE OF ACTION

Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship

36. By unlawfully prescribing controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Addo-Quaye engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(n) and (o), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FIFTH CAUSE OF ACTION

Violations of Federal Controlled Substances Act

37. By permitting Bruce, who had a restricted license excluding controlled substance prescriptions, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure the secondary authenticator for e-scribing controlled substance medications, Addo-Quaye violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. §

842(a), 21 U.S.C. § 846 and 21 CFR §§ 1306.03–1306.05, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11).

SIXTH CAUSE OF ACTION
Violations of State Law for Unlicensed Practice

38. By permitting Bruce, who had a restricted license excluding controlled substance prescriptions, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write controlled substance prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of NRS 453.226, NRS 453.316, NRS 453.321(1)(a), NRS 453.331 (1)(c)(d)(f)&(i), NRS 453.381(1), NRS 453.401(1)(a), NRS 454.213, NRS 454.215, NRS 454.221, NRS 454.311, NRS 454.316, NRS 454.321, NRS 639.100(1), NRS 639.235, NRS 639.23505, NRS 639.281, NRS 639.2813 and NRS 639.310, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).


SEVENTH CAUSE OF ACTION
Commission of Acts that Render Registration Inconsistent with the Public Interest

39. By their actions as set forth herein, Addo-Quaye, Aiyuk, and Bruce have committed acts that render their registrations to prescribe controlled substances inconsistent with

the public interest pursuant to NRS 453.231, and are subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these Respondents.

DATED this 3rd day of August, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**BERNARD KOFI ADDO-QUAYE, MD,
Certificate of Registration No. CS10103,**

Respondent.

CASE NO. 19-242-CS-A-S

**STATEMENT TO THE RESPONDENT
AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

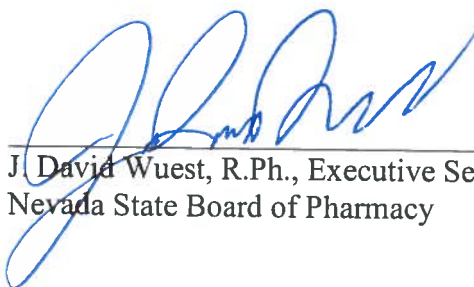
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of August, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S.

Mail to the following:

BERNARD KOFI ADDO-QUAYE, MD
2290 MCDANIEL ST #2A
N. LAS VEGAS, NV 89030

MUKWEL AIYUK, APRN
2021 S JONES BLVD
LAS VEGAS, NV 89146

MUKWEL AIYUK, APRN
304 S JONES BLVD
LAS VEGAS, NV 89107

SOLOMON JOSHUA, APRN
2290 MCDANIEL ST #2A
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SOLOMON JOSHUA, A.P.R.N.
3305 EAST ROME BLVD #2068
NORTH LAS VEGAS, NV 89086

JOHN A. HUNT, ESQ.
CLARK HILL PLC
3800 HOWARD HUGHES PARKWAY
LAS VEGAS, NV 89169



SHIRLEY HUNTING

FILED**AUG 24 2020****NEVADA STATE BOARD
OF PHARMACY**

260552836

1 John A. Hunt, Esq. (NSBN 1888)
 2 Bert Wuester Jr., Esq. (NSBN 5556)
 3 **CLARK HILL, PLLC**
 3800 Howard Hughes Pkwy, Suite 500
 4 Las Vegas, Nevada 89169
 ph. (702) 862-8300; fax (702) 862-8400
 5 email: jhunt@clarkhill.com
 email: bwuester@clarkhill.com
 6 Attorneys for Respondent, Bernard Kofi Addo-Quaye, MD

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

vs.

12 BERNARD KOFI ADDO-QUAYE, MD,
 13 Certificate of Registration No. CS10103,

14 MUKWEI, AIYUK, APRN,
 15 Certificate of Registration No. CS25545, and

16 SOLOMON JOSHUA, APRN,
 17 Certificate of Registration No, CS27011,

Respondents.

Case Nos. 19-242-CS-A-S
 19-242-CS-B-S
 19-242-CS-C-S

**ANSWER AND NOTICE OF
 DEFENSE OF RESPONDENT,
 BERNARD KOFI ADDO-QUAYE,
 MD**

19 Respondent, Bernard Kofi Addo-Quaye, MD ("Dr. Addo-Quaye"), by and through
 20 counsel, hereby submit his Answer and Notice of Defense ("Answer"), pursuant to NRS
 21 639.244¹, to the *Notice of Intended Action and Accusation* dated August 3, 2020 ("Accusation"),
 22

24 ¹ NRS 639.244 Notice of Defense: Form; effect of failure to file.

25 1. The form for the Notice of Defense must be prepared and furnished by the Board and permit the respondent, by
 26 completing and signing the notice, to:

(a) Object to the accusation as being incomplete and failing to set forth clearly the charges; and
 (b) Deny or admit, in part or in whole, the violations alleged.

27 2. The Notice of Defense must be signed by the respondent or his or her attorney under penalty of perjury. Failure
 28 to file a Notice of Defense constitutes a waiver of the respondent's right to a hearing, but the Board may grant a
 hearing.

1 with the Nevada State Board of Pharmacy (the "Board"), in the above-captioned action.

2
3 1. Pursuant to NRS 639.244(1)(a), Dr. Addo-Quaye objects to the Accusation as being
4 incomplete and failing to set forth clearly the charges against him.

5
6 2. Pursuant to NRS 639.244(1)(b), Dr. Addo-Quaye denies in whole the violations alleged
7 against him in the Accusation.
8

9
10 3. Pursuant to NRS 639.244(2), by filing this Answer, Dr. Addo-Quaye has not waived the
11 right to a hearing before the Board.
12

13
14 AFFIRMATIVE DEFENSES

15 1. The allegations contained in the Board's Accusation fail to state a cause of action upon
16 which relief can be granted.

17
18 2. The violations alleged against Respondent in the Board's Accusation are subject to a
19 demand/application pursuant to NRS 233B.121(2)(d) for a more definite and detailed statement.
20 By this defense, Dr. Addo-Quaye specifically provides that he does not waive the right to such a
21 demand/application even in light of this Answer.

22
23 3. Pursuant to NRS 622A.330, even though Dr. Addo-Quaye has provided this Answer, he
24 specifically reserves the right to request a copy of all documents and other evidence intended to
25 be presented by the Board at the hearing in support of its Accusation, as well as a list of proposed
26 witnesses it intends to call at the hearing.

1 4. The answering Respondent hereby incorporates by reference those affirmative defenses
 2 enumerated in Rule 8 of the Nevada Rules of Civil Procedure as if fully set forth herein. In the
 3 event further investigation or discovery reveals the applicability of such defenses, this answering
 4 Respondent reserves the right to seek leave of the Board or appropriate authority to amend this
 5 Answer to specifically assert the same. Such defenses are herein incorporated by reference for
 6 the specific purpose of not waiving the same.

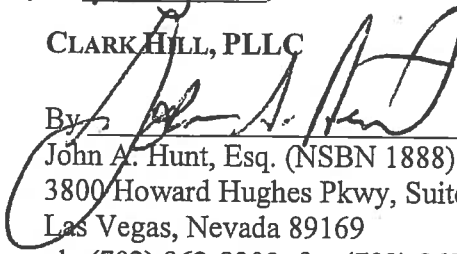
7
 8 5. It has been necessary for this answering Respondent to employ the services of an attorney
 9 to defend this action and a reasonable sum should be allowed as and for attorney's fees, together
 10 with the costs expended in this action.

11
 12 WHEREFORE, Dr. Addo-Quaye prays the Accusation be dismissed, no discipline issue,
 13 that the initiating party take nothing by way of its Accusation and go hence with its costs.

14 Pursuant to NRS 639.244(2), this Answer is hereby signed by the answering
 15 Respondent's attorney.

16
 17 Respectfully submitted this 18 day of Aug, 2020.

18 CLARK HILL, PLLC

19 By 
 20 John A. Hunt, Esq. (NSBN 1888)
 21 3800 Howard Hughes Pkwy, Suite 500
 22 Las Vegas, Nevada 89169
 23 ph. (702) 862-8300; fax (702) 862-8400
 24 email: jhunt@clarkhill.com
 25 Attorneys for Respondent,
 26 Bernard Kofi Addo-Quaye, MD
 27
 28

CERTIFICATE OF SERVICE

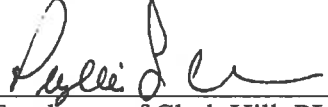
I HEREBY CERTIFY that on the 18th day of August, 2020, I caused the above and foregoing **ANSWER AND NOTICE OF DEFENSE OF RESPONDENT, BERNARD KOFI ADDO-QUAYE, MD** to be served by placing a true and correct copy of the same in the U.S. Mail, at Las Vegas, Nevada, first class postage fully prepaid and addressed to the following **AND** via email as follows:

Courtney K. Lee, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

email: c.lee@pharmacy.nv.gov

J. David Wuest, R. Ph.
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

email: dwuest@pharmacy.nv.gov

By 
An Employee of Clark Hill, PLLC

5K

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**MUKWEL AIYUK, APRN,
Certificate of Registration No. CS25545,**

Respondent.

CASE NO. 19-242-CS-B-S

**STATEMENT TO THE RESPONDENT
AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

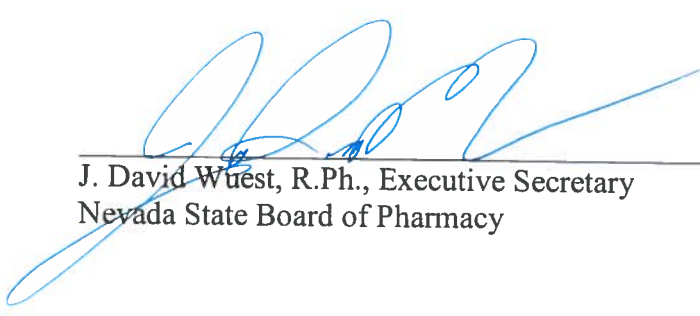
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of August, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

BERNARD KOFI ADDO-QUAYE, MD
2290 MCDANIEL ST #2A
N. LAS VEGAS, NV 89030

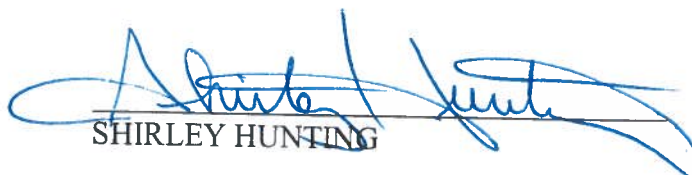
MUKWEL AIYUK, APRN
2021 S JONES BLVD
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MUKWEL AIYUK, APRN
304 S JONES BLVD
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SOLOMON JOSHUA, APRN
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SOLOMON JOSHUA, A.P.R.N.
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JOHN A. HUNT, ESQ.
CLARK HILL PLC
3800 HOWARD HUGHES PARKWAY
LAS VEGAS, NV 89169



SHIRLEY HUNTING

FILED

AUG 24 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-B-S

Petitioner,

v.

MUKWEL AIYUK, APRN,
Certificate of Registration No. CS25545,ANSWER AND NOTICE
OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

I did not prescribe any Substances/dangerous drugs using the name and Credentials of Bernard Addo-Quaye. As an advanced practice registered nurse (APRN) in the State of Nevada, holder of a DEA registration and authorized to prescribe medications/Controlled Substances in the State, I had no reason or incentive to use another person's name and Credentials to prescribe medications/Controlled Substances. I was never given and did not have possession of Bernard Addo-Quaye's blank prescription pads; I did not have his e-Scribing log-in information, and did not use the Computer Systems in Bernard Addo-Quaye's office, or any other Computer System, to e-Scribe medications/Substances.

2. That, in answer to the Notice of Intended Action and Accusation, he ~~admits~~, denies and alleges as follows:

I provided my Credentials (licenses, diplomas, registrations, et to this clinic prior to Commencing work there and assumed the their systems had been set up to ensure that my orders reflect the fact that they came from me.

I was never given and did not have possession of Bernard Addo-Quaye's blank prescription pads.

I did not use the Computer Systems in Bernard Addo-Quaye Office, or any other Computer System, to e-cribe medical or Controlled Substances.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 21st day of August, 2020.


MUKWEL AIYUK, APRN

FILED

SEP 22 2020

BEFORE THE NEVADA STATE BOARD OF PHARMACY NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO.	19-242-CS-A-S
)		19-242-CS-B-S
Petitioner,)		19-242-CS-C-S
)		
v.)		
)		
BERNARD KOFI ADDO-QUAYE, M.D.)		
Certificate of Registration No. CS10103,)		
)		
MUKWEL AIYUK, APRN,)		
Certificate of Registration No. CS25545, and)		
)		
SOLOMON JOSHUA, APRN,)		
Certificate of Registration No. CS27011)		
Respondent.)		
	/		

**ANSWER AND NOTICE OF DEFENSE
OF RESPONDENT MUKWEL AIYUK, APRN**

Respondent Mukwel Aiyuk, APRN hereby files with the Nevada State Board of Pharmacy ("Board"), his Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on August 3, 2020.

ANSWER TO ACCUSATION

1. Mr. Aiyuk hereby declares that he does not object to the Accusation as being incomplete or failing to state clearly the charges against him and acknowledges that the Board has jurisdiction in this matter as Mr. Aiyuk currently holds an active controlled substance registration with the Board.

2. Mr. Aiyuk answers the Factual Allegations contained in the Accusation as follows:

Paragraph 2: Mr. Aiyuk is without sufficient knowledge or information to address the accuracy of the assertions contained therein;

Paragraph 3: Mr. Aiyuk is without sufficient knowledge or information to address the accuracy of the assertions contained therein;

Paragraph 4: Mr. Aiyuk agrees with the assertions therein to the extent that to his knowledge and belief, Dr. Addo-Quaye is the owner of TruCare Medical Center (“TruCare”). He is without sufficient knowledge to address the accuracy of the other assertions set forth in Paragraph 4;

Paragraph 5: Mr. Aiyuk agrees with the assertions set forth therein to the extent that he was informed Dr. Addo-Quaye was traveling out of the country during the limit times he provided coverage at TruCare.

Paragraph 6: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the assertions set forth therein;

Paragraph 7: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the assertions set forth therein;

Paragraph 8: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the assertions set forth therein;

Paragraph 9: Mr. Aiyuk agrees with the assertions set forth therein to the extent that he was an independent contract with TruCare in order to provide limited coverage services for Dr. Addo-Quaye.

Paragraph 10: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the assertions set forth therein, however he asserts that he never met Mr. Joshua and to his knowledge Mr. Joshua did not provide services at TruCare as an APRN during September 2019 during the time Mr. Aiyuk was present at TruCare;

Paragraph 11: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the assertions set forth therein.

Paragraph 12: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the allegations set forth therein

Paragraph 13: Mr. Aiyuk denies the allegations contained therein to the extent that Dr. Addo-Quaye did not provide him with or provide access to blank prescription pads and asserts that he was never provided Dr. Addo-Quaye's login information for his e-prescribing system nor access to such a system. Mr. Aiyuk is without sufficient knowledge and information to address the other allegations contained therein.

Paragraph 14: Mr. Aiyuk denies that he unlawfully prescribed controlled substances and/or dangerous drugs under Dr. Addo-Quaye's name and credentials. Mr. Aiyuk admits that he saw established patients at TruCare for a few days in July and a few days in September 2019. Mr. Aiyuk noted prescription orders on medical charts he signed for patient he personally saw and provide the charts to staff to transmit to the appropriate pharmacies as further discussed below.

Paragraph 15: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the allegations set forth therein;

Paragraph 16: Mr. Aiyuk is without sufficient knowledge and information to address the accuracy of the assertions set forth therein;

3. As to the Second and Seventh Causes of Action which name Mr. Aiyuk, he hereby denies all allegations contained therein. No further Cause of Action set forth in the Accusation pertains to Mr. Aiyuk and therefore he submits no answer to those Causes of Action.

NOTICE OF DEFENSE

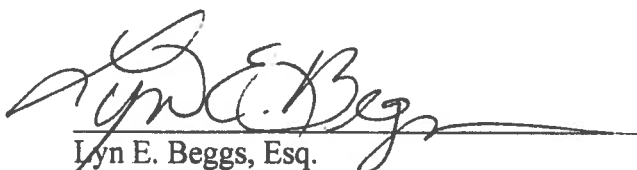
Mr. Aiyuk holds an Advanced Practice Registered Nurse license with the Nevada State Board of Nursing with prescribing privileges and a controlled substance registration with the Board. Mr. Aiyuk provided coverage for Dr. Addo-Quaye as an independent contractor at TruCare while Dr. Addo-Quaye was out of the country for very short durations of time. Mr. Aiyuk had no interactions with any other providers at TruCare during this time, including Dr. Bruce or Mr. Joshua.

During the limited time that Mr. Aiyuk provided coverage for Dr. Addo-Quaye, per practice protocols, he saw established patients of the practice and performed appropriate examinations prior to ordering primarily refills of medications for the patients he personally saw. Mr. Aiyuk signed all paper chart notes for patient encounters he performed as reflected in the records of TruCare. Upon completion of a patient encounter, Mr. Aiyuk, as directed by Dr. Addo-Quaye, provided the chart notes to TruCare medical assistants who carried out any orders and transmitted the prescriptions using the electronic prescription system of the practice. Mr. Aiyuk was unaware that staff was transmitting prescriptions under Dr. Addo-Quaye's name. Mr. Aiyuk would have no reason to believe prescriptions would not be transmitted under his credentials as he is legally authorized to prescribe dangerous drugs and controlled substances and the chart notes authorizing the prescriptions bear his signature.

NAC 639.7102(1)(b) authorizes a practitioner to delegate the task of transmitting a prescription to a pharmacy via a computer system authorized by the Board. To Mr. Aiyuk's knowledge, the e-prescribing system utilized by TruCare was approved by the Board and therefore he appropriately delegated the task of transmitting the prescriptions to staff who he was informed were authorized to do so by Dr. Addo-Quaye.

As indicated above, Mr. Aiyuk denies that he has committed any violation as set forth in the Second and Seventh Causes of Action set forth in the Accusation.

Respectfully submitted this 21st day of September, 2020.

A handwritten signature in black ink, appearing to read "Lyn E. Beggs", with a long horizontal flourish extending to the right.

Lyn E. Beggs, Esq.
Attorney for Respondent Mukwel Aiyuk, APRN

5L

FILED**MAY 26 2020****NEVADA STATE BOARD
OF PHARMACY****BEFORE THE NEVADA STATE BOARD OF PHARMACY****NEVADA STATE BOARD OF PHARMACY,****Case No. 20-001-CS-N****Petitioner,****v.****NOTICE OF INTENDED ACTION
AND ACCUSATION****JEFF CHEN, M.D.,
Certificate of Registration No. CS18013,****Respondent.**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION**I.**

The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Jeff Chen, M.D. (Chen), held a Nevada Controlled Substance Registration, Certificate No. CS18013, issued by the Board.

FACTUAL ALLEGATIONS**II.**

In December 2019, Chen was the medical director of Breathe Bar located on South Center Street in Reno, Nevada.

III.

Amy Burkett (Burkett) owned and operated Breathe Bar. Burkett is not a practitioner licensed by the Nevada State Board of Pharmacy, Nevada State Board of Medical Examiners, Nevada State Board of Osteopathic Medicine, or Nevada State Board of Nursing.

IV.

Breathe Bar employed registered nurses (“RNs”).

V.

Breathe Bar’s RN staff provided patient assessments using a proprietary Intravenous (IV)/Intramuscular (IM) Therapy Intake Form. An RN would then communicate his/her assessment of the patient to Chen by telephone or text, in response to which Chen would then approve the medication(s) by telephone or text.

VI.

Chen had no direct contact with, did not examine and did not establish a *bona fide* therapeutic relationship with the patients.

VII.

With Chen’s knowledge and authorization and at his direction, Breathe Bar’s RN staff provided on-site medical treatment to patients, including the administration of dangerous drugs through intravenous (“IV”) therapy and/or injections without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication.

VIII.

Chen directed Breathe Bar’s RN staff and Burkett to obtain, access, possess, and store dangerous drugs from Breathe Bar’s inventory, and administer dangerous drugs to patients when he was not on site.

IX.

Chen directed Breathe Bar’s RN staff to counsel patients regarding their medical treatment, including the administration of dangerous drugs.

X.

Chen permitted opened, undated multi-dose injectables to be used for treatment of Breathe Bar patients.

APPLICABLE LAW

XI.

No person may possess or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356.

XII.

A practitioner can give a registered nurse (RN) limited authority to possess and administer dangerous drugs without the practitioner on-site by way of NRS 454.213(1)(c), which states in relevant part:

a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, *or pursuant to a chart order, for administration to a patient at another location.*

NRS 454.213(1)(a) (*emphasis added*); see also NRS 639.100(1).

XIII.

Chart orders must be written (NRS 454.223) and are patient-specific and medication-specific.¹

XIV.

Multi-dose injectable vials must be dated at the time the seal of the multi-dose container is breached. The contents of the container may be used within 28 days after the breach of the seal occurred. Contents not used within the period set forth may not be used and must be destroyed. NAC 639.67057(2)

¹ See NRS 639.004 “Chart order” means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

XV.

NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.

1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

....

(g) Supplying or diverting drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles.

(h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.

(i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

(j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.

(k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.

....

(n) Dispensing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship.

....

XVI.

NRS 639.210 Grounds for suspension or revocation of certificate, license, registration or permit or denial of application. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant:

....

4. Is guilty of unprofessional conduct or conduct contrary to the public interest;

....

12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this

chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit;

....

XVII.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

XVIII.

FIRST CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs (Statutory Violations)

XIX.

By allowing Breathe Bar's RN staff to operate Breathe Bar and to obtain, access, possess administer and/or store dangerous drugs when he was not on site, before he examined the patient, before he wrote a patient-specific order and without his direct supervision, Chen violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213(1), NRS 454.316, NRS 454.221, NRS 454.321, NRS 454.356 and NRS 639.100(1), and is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs (Unprofessional Conduct)

XX.

By allowing Breathe Bar's RN staff to operate Breathe Bar and to obtain, access, possess administer and/or store dangerous drugs when he was not on site, before he examined the patient, before he wrote a patient-specific order and without his direct supervision, Chen performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or

negligent manner, was party to a fraudulent or deceitful practice or transaction, and engaged in, or aided and abetted Breathe Bar's staff to engage in, unprofessional conduct as defined in NAC 639.945(g), (h), (i), (j) and (k), and is subject to discipline pursuant to NRS 639.210(4).

THIRD CAUSE OF ACTION

Unlawful Administration of Dangerous Drugs – No Bona Fide Therapeutic Relationship and No Authority to Determine Medical Necessity

XXI.

By authorizing Breathe Bar's RN staff to act under his authority to operate BREATHE BAR, to administer dangerous drugs to patients who had not been examined by a practitioner, with whom Chen did not have a *bona fide* therapeutic relationship and for whom Chen had neither diagnosed or determined that a dangerous drug was medically necessary, Chen engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(o), and is subject to discipline pursuant to NRS 639.210(4).

FOURTH CAUSE OF ACTION

Failure to Follow Procedures Following Breach of the Seal of a Multi-Dose Injectable Container

XXII.

By failing to follow procedures to reflect expiration dates on opened multi-dose injectable vials, Chen violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.67057(2), and is subject to discipline pursuant to NRS 639.210(12).

FIFTH CAUSE OF ACTION

Controlled Substance Registration Inconsistent with the Public Interest

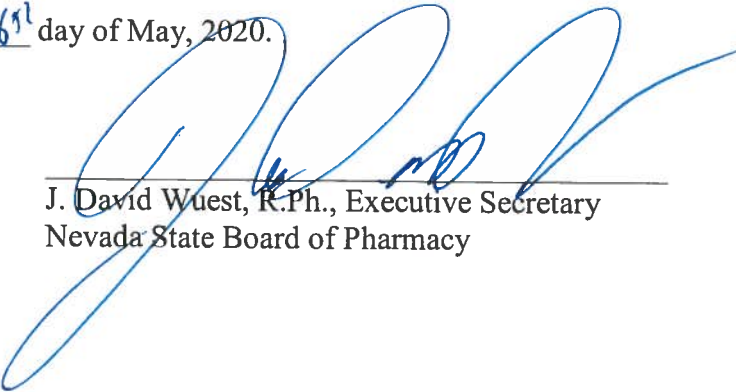
XXIII.

By his actions as set forth herein, Chen has committed acts that render his controlled substance registration inconsistent with the public interest pursuant to NRS 453.231, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

XXIV.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 26th day of May, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 20-001-CS-N

Petitioner,

v.

**JEFF CHEN, M.D.,
Certificate of Registration No. CS18013,**

**STATEMENT TO
THE RESPONDENT
AND NOTICE OF HEARING**

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, December 2, 2020, 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada.

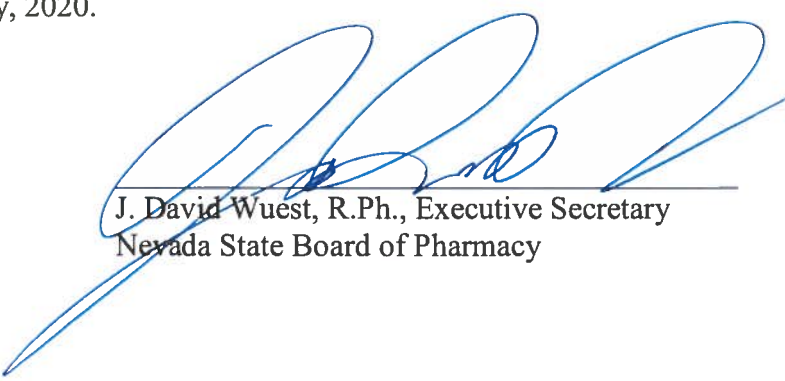
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of May, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of May, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jeff Chen, MD
847 Marsh Avenue
Reno, NV 89509



SHIRLEY HUNTING

FILED

JUL 13 2020

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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NEVADA STATE BOARD OF PHARMACY,

Petitioner

v.

**JEFF CHEN, M.D.,
Certificate of Registration No. CS18013**

Respondent

Case No.: 20-001-CS-N

**ANSWER AND NOTICE
OF DEFENSE**

COMES NOW, Respondent JEFF CHEN, M.D., by and through his counsel of record, EDWARD J. LEMONS, ESQ. and LEMONS, GRUNDY & EISENBERG, and in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

The findings alleged misrepresent the roles and actions of Dr. Chen while serving as Medical Director of Breathe Bar for intravenous fluid therapy. On December 19, 2019, Joseph Depczynski, investigator for the Nevada Board of Pharmacy, and Samuel McCord, director of nursing practice for the Nevada Board of Nursing, made an unannounced visit to Breathe Bar stating that there had been a complaint filed regarding questionable practices at the facility which is owned by Amy Burkett. Ms. Burkett is the owner and founder of Breathe Bar, and was present for the site visit. Dr. Chen was not present for the site visit. In

1 support of this objection, the statement of Ms. Burkett regarding her recollection
2 of the events that took place that day is attached as **Exhibit A**. It was relayed
3 to her that the complaint was not made by any patient or the result of any
4 patient harm, but likely a competing business in town, however, Mr. Depczynski
5 and Mr. McCord did not provide any further details regarding the identity of the
6 person who filed the complaint. Ms. Burkett provided information regarding
7 Breathe Bar practices with discussion of how they operated the medical
8 treatments at Breathe Bar. At the resolution of the meeting, apparently it was
9 deemed inappropriate that Ms. Burkett had keys to the treatment room and keys
10 to the lock securing the medications utilized for treatment of patients, and the
11 gentlemen confiscated the medications from the locked storage unit and left
12 with the medical inventory. Apparently, however, sometime later, the
13 gentlemen returned to the Breathe Bar and returned the medications stating
14 that they shouldn't have taken the inventory. On information and belief,
15 however, the keys to the storage lock and IV fluid bags were confiscated and
16 Ms. Burkett was instructed that Dr. Chen, as medical director and physician in
17 charge of the medications, would need to contact Mr. Depczynski to set up a
18 meeting where Dr. Chen could obtain the keys in person.

19 After several attempts, Dr. Chen set up a meeting between him, Mr.
20 David Wuest, the executive secretary of the BOP, Ms. Yen Long, the deputy
21 secretary of the BOP, and Ms. Burkett on January 3, 2020 to discuss their
22 concerns and repossess the keys to the medications. At that meeting, the
23 representatives for the Board of Pharmacy stated that their concern was related
24 to Ms. Burkett having access to the keys for the locked medications as she was
25 not medically trained or licensed. They also expressed concern regarding the
26 nursing staff having access to the medications, in particular, if Dr. Chen wasn't
27 present on site for the entire treatment period. Dr. Chen reassured Mr.
28 Depczynski and Mr. Wuest that they maintained high levels of security and

1 safety with regards to the medications, and if they felt this was not the case,
2 then they would make any recommended changes they suggested in order to
3 be in compliance. They also detailed to the Board representatives the typical
4 treatment course for patients at Breathe Bar.

5 Dr. Chen was asked by Amy Burkett to be medical director of Breathe Bar
6 to help assist in developing an intravenous fluid hydration and treatment
7 program for her business. She felt that he was an optimal candidate because of
8 his clinical background in anesthesiology. As a board certified clinician that has
9 treated over 20,000 patients with intravenous fluids for resuscitation of all
10 clinical situations in his 14-year career, and utilized many forms of medications
11 in those treatment protocols, it was felt that Dr. Chen could provide the proper
12 skill set and guidance for her to safely and properly start a program at her
13 health institution. Thus, in May of 2019, Dr. Chen accepted her offer and began
14 developing and establishing protocols to ensure that patients coming through
15 Breathe Bar for treatment would get the same level of care that they could come
16 to expect in a hospital or surgery center setting.

17 As the medical director, Dr. Chen developed all the necessary intake
18 forms, questionnaires, consent forms including HIPPA compliance, order forms,
19 progress notes, and informational packets for each patient, which were adapted
20 from hospital forms. He also established relationships with accredited
21 distributors of medical supplies and medications/IV fluids and opened an
22 account to procure all the necessary inventory. Dr. Chen established practice
23 protocols for sterility, safety, and compliance that fell in line with those one
24 would see at a hospital or surgery center. And for the first two months of trialing
25 the launch of services at Breathe Bar, Dr. Chen was the sole provider and
26 caretaker for all patients receiving treatment at the facility.

27 As patient demand grew, Ms. Burkett asked to expand services by
28 recruiting registered nurses to help with the intake and treatment portions of the

1 therapy. All nurses who were employed by Ms. Burkett had been nurses that
2 Dr. Chen directly worked with or were familiar with through his years as an
3 anesthesiologist in the community. They only hired highly competent nurses
4 who had excellent records of service and provided the highest quality care
5 throughout their careers. They were specifically mentored and proctored by Dr.
6 Chen to ensure that the quality measures in place were achieved for each and
7 every patient. Dr. Chen has provided a copy of the nursing guidelines and
8 operating procedures that each new hire was given for reference regarding the
9 expectations he had for them at Breathe Bar, attached hereto as **Exhibit B**.

10 Based on the guidelines, they maintained strict protocols for how patients
11 were evaluated and treated. In summary, all patients would be evaluated and
12 answer a questionnaire by Dr. Chen and/or a nurse. They would discuss
13 treatment options, benefits, and risks of each treatment option, provide informed
14 consent, and answer any questions from the patient. If nurses provided the
15 initial intake actions, Dr. Chen would go over the findings with each nurse and
16 come up with a treatment plan tailored to the individual needs of every patient.
17 An order form would be filled out and signed by Dr. Chen as the ordering
18 physician, and the nurse would carry out the order and monitor the patient
19 during the infusion treatment. Once the treatment was complete, a final
20 evaluation of the patient was done, and discharge home instructions were
21 provided on what to expect and issues to report. Once the patient was
22 discharged, they would follow-up with the patients the following day to ensure
23 there were no issues or complications.

24 Reviewing the allegations contained in the Board of Pharmacy's notice
25 letter, the "factual allegations" are objected to as being incomplete, erroneous
26 and the same are denied. The following is to provide further clarification and to
27 correct erroneous statements.

28 ///

1 The nurses and/or Dr. Chen provided patient assessments using the
2 designated intake form which provided a clinical history for each patient. The
3 nurses would communicate with Dr. Chen regarding the assessment for each
4 patient prior to any treatments, and once a clear and defined plan was created,
5 an order would be given on the order sheet which was signed by the physician
6 and carried out by the physician or nursing staff. The false, incomplete,
7 erroneous, and misleading statement is that these orders and communications
8 only occurred via telephone or text, and not in person. Text and telephone
9 messages were used to communicate that patients were ready for their
10 treatment and initial discussions were made via those methods if Dr. Chen was
11 not directly present at the time. Dr. Chen would always come to the facility to
12 sign off on the intake forms, discuss any needs regarding the patient, and sign
13 off on the orders for treatment. This can be verified in all the patient records and
14 charts. It is not unusual that discussions and treatment plans occur over
15 telephone or text messaging. For a physician taking call in the community,
16 there are countless occasions where a nurse will evaluate a patient, call the
17 physician to discuss any issues, and request orders which would be given via
18 telephone or text and signed at a later time. In these instances, physicians are
19 not present on site during these discussions nor when executing an order for
20 the nurse to complete.

21 Dr. Chen was the primary caregiver for patients when this program was
22 initiated, and thus assessed, examined, treated, and followed-up with every
23 single patient coming through Breathe Bar. When nurses were added to the
24 care team at Breathe Bar, they were expected to follow guidelines for treatment
25 consistent with their nursing requirements. They may have provided initial
26 assessments but contacted Dr. Chen for each patient to discuss and receive
27 orders, and Dr. Chen would be in person to sign orders and verify information
28 gathered by the nurses as evidenced in each patient's medical record. Each

1 patient was counseled by Dr. Chen or the nursing staff, and they knew that at
2 any time, he could be contacted and be present for any issues or questions that
3 arose. See **Exhibit B** for the applicable operating procedures.

4 Dr. Chen had knowledge and authorized the RNs at Breathe Bar to
5 provide care and treatments to the patients after a thorough evaluation,
6 discussion, and formulation of a safe and adequate plan. Orders were signed
7 and given to provide specific medications and treatments and are readily
8 available for review in the patient records. Of note, the Board of Nursing
9 conducted an investigation of the nurses at Breathe Bar which was initiated by
10 Samuel McCord. **Exhibit C** shows copies of letters which include the Board of
11 Nursing Notice of Investigation, the reply from the nursing staff, and the ultimate
12 decision for the Board of Nursing that they were not practicing independently
13 without supervision and were not practicing outside of their scope, and thus the
14 case was dismissed. Those conclusions support the denial of the allegations
15 and show that the care was provided in accord with state and national
16 standards.

17 Regarding allegations about the role of Ms. Burkett, she was never
18 directed to handle any of the medication inventory. Dr. Chen was in charge of
19 ordering, stocking, safeguarding, and prescribing the medications. Ms. Burkett
20 had a key to the medication/treatment room, and a key to the lock, but as owner
21 of the facility and as the employer, it was felt that this was appropriate. The
22 nurses had access to the medications to obtain them, but only after receiving an
23 order from the physician. And Dr. Chen kept inventory of all the medications to
24 account for all usage on a weekly basis to ensure there was no issues with
25 expiration or theft. Also, of note, the "dangerous drugs" referenced above
26 specifically dealt with Lactated Ringer's IV solution, ondansetron, ketorolac,
27 Vitamin B, and Vitamin C. From the standpoint of community health concern, it
28 was ensured that they utilized drugs that are commonly used with a high safety

1 profile and there was absolutely no utilization of any Schedule 2 medications.
2 Hydration fluid, anti-nausea medications, non-steroidal anti-inflammatory drugs,
3 and vitamins are widely accepted as being safe, have minimal risks, and
4 patients were screened for risk factors before any treatment. As stated earlier,
5 Dr. Chen has practiced for 14 years and conducted over 20,000 intravenous
6 fluid and medication treatments to patients, and with those particular fluids and
7 medications, has never encountered any issue of fluid overload, QT
8 prolongation (ondansetron), renal failure resulting from afferent vasoconstriction
9 (ketorolac), gastritis (ketorolac), or any other potential side effects from these
10 medications and vitamins. Dr. Chen allowed nurses to perform their duties
11 within their scope of practice, which includes assessing patients, treating
12 patients under physician orders, and administering medications to patients to
13 execute orders provided to them. Please refer to **Exhibit C** for the investigation
14 by the Board of Nursing which found that the nurses acted within their scope of
15 practice while working at Breathe Bar.

16 The multi-dose medication referenced in the Notice of Intended Action
17 was lidocaine 1% which was used as an anesthetic prior to placement of an
18 intravenous catheter. There were two vials that were uncapped and had not
19 been adequately dated and initialed by the practitioner as is expected for multi-
20 dose vials. This is not a practice that Dr. Chen permitted; however, it was an
21 error that once made aware, was addressed, and taken care of. Dr. Chen
22 reminded both nursing staff and himself of the importance to date and initial
23 when a multi-dose vial is opened, and to discard within 28 days of opening. This
24 was not permitted, and the lidocaine 1% is the only multi-dose medication used
25 at Breathe Bar.

26 Dr. Chen offers the above explanation and attached documents to correct
27 the misinformation and the vague, incomplete, erroneous, and unclear
28 allegations made against Dr. Chen. Allegations that he engaged in actions

1 constituting "unprofessional conduct or conduct contrary to the public interest"
2 and that he "violated, attempted to violate, assisted or abetted in the violation of
3 or conspired to violate NRS statutes" are made against him without reasonable
4 basis and in contradiction of the true facts. Those true facts were not verified
5 before these allegations were made against Dr. Chen. At no point during the
6 investigation did anyone from the Board of Pharmacy ask to see how a typical
7 interaction and care for a patient would take place, nor did they witness any
8 normal operating procedures at Breathe Bar. Secondly, there was no
9 attempt or discussion of any opportunity for improvement or reconciliation of
10 issues that were found. Dr. Chen serves on multiple peer review boards and
11 serves as the chair for that committee at Saint Mary's Regional Medical Center,
12 and knows that it has always been customary for any allegations to be verified
13 either by direct witness or obtaining first-hand testimony of the actions in
14 question. Once this was achieved, it was also customary to specifically speak to
15 person in question directly to get their point of view, and if findings were
16 accurate regarding deficits in the actions, there would be an opportunity for the
17 practitioner to make corrective actions without punitive consequences. Only
18 after repeated episodes would a peer review committee escalate the issue to a
19 level of potential reprimand and punishment. This practice is also consistent
20 with national accrediting bodies like the Joint Commission (JCAHO) and
21 Accreditation Association for Ambulatory Health Care (AAAHC) which oversee
22 operations and compliance of hospitals and surgery centers, respectively.
23 During these direct observation surveys, if deficits are found, the hospitals or
24 surgery centers are given the opportunity to address and rectify any
25 circumstances they deem substandard and would not be punitive without giving
26 an opportunity for correction. Unfortunately, it does not feel that Dr. Chen has
27 been given the same opportunity to correct any perceived deficits to the
28 satisfaction of the Board of Pharmacy. Instead, he is being asked to defend

1 himself to the Board for these "factual allegations" which suggest that he has
2 been derelict of his duty as a medical professional and threaten his standing
3 with the Board.

4 In closing, Dr. Chen is a native Nevadan and born and raised in Reno.
5 He understandably takes great pride in the city he grew up in and sees his
6 service in the medical community as an opportunity to give back to a community
7 that has given him so much. In his 15-year medical career, he has had a
8 spotless professional record, with no claims against him, being in good standing
9 at all affiliated hospitals and surgery centers, and no issues with any of the
10 Boards for which he serves as a member. He has served in many leadership
11 roles in the community from Medical Director of Surgical Services and member
12 of the Medical Executive Committee at Northern Nevada Medical Center to
13 serving as Medical Director of Surgical Services, Chair of the Professional Peer
14 Review Committee, Chair of Pharmacy and Therapeutics Committee, Vice
15 Chief of Staff, and currently Chief of Staff and Governing Board Member at
16 Saint Mary's Regional Medical Center, and during these times, he has taken
17 pride in serving those positions with integrity, honesty, and responsibility. He
18 currently serves as clinical faculty at the University of Nevada School of
19 Medicine and at Oregon Health and Sciences University in Portland, Oregon in
20 the department of Surgery and Anesthesia, and he always emphasizes to future
21 physicians the importance of doing each patient right and doing no harm,
22 leading by example, and always putting humanity and humility first. He would
23 like the Board to know that he takes his roles and responsibilities as a medical
24 professional seriously and treats every patient as he would a family member.
25 He expects excellence of himself and of his care for each person he
26 encounters. To have these erroneous accusations presented against him is
27 objectionable as stated herein. He will present this case in person to the Board
28 on December 2nd, 2020.

1 **2. That, in answer to the Notice of Intended Action and**
 2 **Accusation, he admits, denies and alleges as follows:**

3 **JURISDICTION**

4 **I.**

5 Respondent admits the allegations contained in paragraph I of the Notice
 6 of Intended Action and Accusation.

7 **FACTUAL ALLEGATIONS**

8 **II.**

9 Respondent admits the allegations contained in paragraph II of the Notice
 10 of Intended Action and Accusation.

11 **III.**

12 Respondent admits the allegations contained in paragraph III of the
 13 Notice of Intended Action and Accusation.

14 **IV.**

15 Respondent admits the allegations contained in paragraph IV of the
 16 Notice of Intended Action and Accusation.

17 **V.**

18 Respondent denies each and every allegation contained in paragraph V
 19 of the Notice of Intended Action and Accusation.

20 **VI.**

21 Respondent denies each and every allegation contained in paragraph VI
 22 of the Notice of Intended Action and Accusation.

23 **VII.**

24 Respondent denies each and every allegation contained in paragraph VII
 25 of the Notice of Intended Action and Accusation.

26 **VIII.**

27 Respondent denies each and every allegation contained in paragraph VIII
 28 of the Notice of Intended Action and Accusation.

IX.

Respondent denies each and every allegation contained in paragraph IX of the Notice of Intended Action and Accusation.

X.

Respondent denies each and every allegation contained in paragraph X of the Notice of Intended Action and Accusation.

APPLICABLE LAW**XI.**

Respondent denies that the statutes contained in paragraph XI of the Notice of Intended Action and Accusation were violated.

XII.

Respondent denies that the statutes contained in paragraph XII of the Notice of Intended Action and Accusation were violated.

XIII.

Respondent denies that the statute contained in paragraph XIII of the Notice of Intended Action and Accusation was violated.

XIV.

Respondent denies that the statute contained in paragraph XIV of the Notice of Intended Action and Accusation was violated.

XV.

Respondent denies that the statute contained in paragraph XV of the Notice of Intended Action and Accusation was violated.

XVI.

Respondent denies that the statute contained in paragraph XVI of the Notice of Intended Action and Accusation was violated.

XVII.

Respondent denies that the statutes contained in paragraph XVII of the Notice of Intended Action and Accusation were violated.

XVIII. (sic)

FIRST CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs (Statutory Violations)

XIX.

Respondent denies each and every allegation contained in paragraph XIX of the Notice of Intended Action and Accusation.

SECOND CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs (Unprofessional Conduct)

XX.

Respondent denies each and every allegation contained in paragraph XX of the Notice of Intended Action and Accusation.

THIRD CAUSE OF ACTION

Unlawful Administration of Dangerous Drugs – No Bona Fide Therapeutic Relationship and No Authority to Determine Medical Necessity

XXI.

Respondent denies each and every allegation contained in paragraph XXI of the Notice of Intended Action and Accusation.

FOURTH CAUSE OF ACTION

Failure to Follow Procedures Following Breach of the Seal of a Multi-Dose Injectable Container

XXII.

Respondent denies each and every allegation contained in paragraph XXII of the Notice of Intended Action and Accusation.

FIFTH CAUSE OF ACTION

Controlled Substance Registration Inconsistent with the Public Interest

XXIII.

Respondent denies each and every allegation contained in paragraph XXIII of the Notice of Intended Action and Accusation.

AFFIRMATIVE DEFENSES

Respondent states his Affirmative Defenses as follows:

First Affirmative Defense

Petitioner has failed to state a claim upon which any professional discipline or sanction can be based.

Second Affirmative Defense

The incidents alleged in the Notice of Intended Action and Accusation, and the resulting damage, if any, which this Respondent denies, was caused by the acts of third persons other than Respondent and who are not agents, servants or employees of this Respondent.

Third Affirmative Defense

Respondent did not violate any of the statutes contained in Petitioner's Notice of Intended Action and Accusation.

Fourth Affirmative Defense

Petitioner has failed to provide any information or evidence to prove by a preponderance of the evidence that Respondent violated any of the statutes contained in Petitioner's Notice of Intended Action and Accusation.

Fifth Affirmative Defense

Petitioner has failed to establish via expert affidavit or declaration that Respondent committed malpractice in any manner or violated any additional statutes under NRS 6309 *et al.*.

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1 WHEREFORE, Respondent prays that the Nevada State Board of
2 Pharmacy determines that Respondent met all applicable standards of care and
3 followed all applicable statutes and did not violate the same.

4 DATED this 8th day of July, 2020.

5 LEMONS, GRUNDY & EISENBERG
6 Attorneys for Respondent
7 Jeff Chen, M.D.

8 BY: 

9 EDWARD J. LEMONS, ESQ.
10 Nevada Bar No. 699
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CERTIFICATE OF SERVICE

I declare that I am an employee of LEMONS, GRUNDY & EISENBERG, and that I am over the age of 18 and not a party to the within action. My business address is 6005 Plumas Street, Third Floor, Reno, NV 89519.

On this date I served a true and correct copy of the ***Answer and Notice of Defense*** by mailing via U.S. Mail to the following:

J. David Wuest, R.Ph, *Executive Secretary*
NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Dated: July 8, 2020

A. Sellman

INDEX OF EXHIBITS

No.	Description	No. Pages
A.	Statement of Amy Burkett	1
B.	Breathe Bar Nursing Guidelines and Operating Procedures	5
C.	Board of Nursing investigation letters to nurses Natisha Zevnick and Natalie Fuller at Breathe Bar; reply letters from Nurse Zevnick and Nurse Fuller; Board of Nursing decision letters to nurses Zevnick and Fuller	8



777 S. Center Street Suite 201 Reno, NV 89501 775.232.0449 info@renobreathebar.com

To whom it may concern:

In regards to the visit on January 19th by The Nursing Board and Pharmacy Board this is my recount of what happened.

3 Individuals walked into Breathe Bar around 10:30am unannounced. They told me they were doing a courtesy check because of a complaint. Mr. Sam McCord from the Nursing Board handed me a Nursing magazine and told me that in order to be compliant, we had to have a Doctor or Nurse practitioner on site for IVs to be administered. As Dr. Chen and I were told he could be off site but in constant contact with the nurse performing the IV through TigerText a HIPPA certified medical texting app, Facetime or on the phone. I asked both Mr. McCord and Mr. Joe Depczynski which was the exact statute and they were not sure which was lawful or unlawful. They proceeded to tell me what I am doing is unlawful as stated in the article written by Mr McCord. They told me I needed to cease and desist my business immediately. They then asked me to show them the IV treatment room and inspected it thoroughly. When Mr. Depczynski asked me for the key to the refrigerator that held the vitamins, Zofran and Ketorolac I got them from our locked cabinet and let him inspect the meds. After looking at the meds he told me he would need to confiscate said meds and all LR bags I had in the room too. He loaded everything up into a box and took it out of Breathe Bar at approximately noon. He then came back to Breathe Bar around 1:30 with the box of meds and replaced them into the refrigerator and kept the LR and also took the refrigerator key when he left the second time. As my business is still on cease and desist, 4 of the nurses received subpoenas for records for the time they were working with Breathe Bar. After 4 months of waiting, they received full release of all charges by the Board of Nursing. I was forced to remove IV Hydration from Breathe Bar because of this proven "grey area" that is not yet in a NRS for our area.

Dr. Chen did the majority of IVs at Breathe Bar, always with the utmost professionalism. His kind and caring bedside manner always made our customers feel safe and taken care of. His charts were impeccable and thorough. It is disheartening that so many "grey areas" prevented my business from continuing to provide IV Hydration. The one service Dr. Chen and I hoped to provide for our community.

With Regards,

Amy Burkett
Owner, Breathe Bar

Welcome to the Breathe Bar Hydration and Wellness Team!

Greetings, I just wanted to introduce myself and explain the goals of our team here at Breathe Bar. Amy Burkett, the owner, has established an amazing establishment for rest, relaxation, rejuvenation, and health at Breathe Bar. She has asked me to serve as Medical Director to help develop and oversee IV hydration therapy and wellness. My background is that I am an anesthesiologist who has worked in town for 10 years, however, like Amy, I am a native and a local. When Amy asked if I would be interested in joining the team, I thought it would be a great opportunity to work with some different people than what I normally deal with, and hopefully it would allow me to see a different way to help people in the community.

My mission statement for our Breathe Bar Hydration and Wellness Team is as follows:

To provide a consistent, exceptional experience that strengthens trust and confidence with our patients, their families, and the community.

I want to make sure every patient experience is of the highest quality and safety, and I am grateful that you have joined the team to help achieve this goal. Even though we are a business in Midtown, I do have some expectations similar to those that we see in the medical arena. My core principles are listed below:

- **Integrity:** We will strive to provide the best and most honest care to each patient. We will practice in a manner which we would expect for each of our own family members. If we have that mindset, we will always provide first class care for all in the community.
- **Professionalism:** We will maintain proper codes of conduct and dress at all times as we are representatives of the medical community as a whole. We also represent Breathe Bar and have a duty to be the best possible stewards for the business and community.
- **Responsibility:** We will practice in a manner that is always above board and work towards achieving a highly reliable medical practice. We will abide by all safety guidelines published by respected medical organizations like the World Health Organization (WHO) and others. We will hold each other accountable to always choose the right.
- **Confidentiality:** We will always respect each individual's privacy and protect their information as we would any patient we care for in the community.
- **Joy:** I want every team member to be happy and enjoy what they are doing. We chose to accept this role because I believe we all wanted to help people, but in a different way than what we are accustomed to. I want this to be a pleasant experience, as our happiness and enthusiasm is palpable and transferable to those that we help!



Patient Intake Forms

- Each patient will receive a patient intake form which will include a demographics and patient history forms, informed consent, HIPAA statement, patient informational sheet, physician order sheet, and progress notes for the procedures.
- For the demographics sheet, important to just ensure that the patient has their name and contact information (i.e. phone number), as we will follow-up with the patients the following day to see how their treatment went.
- For the history intake form, please review all pertinent history, medications, and allergies with the patient. For vital signs, please either document it on the sheet, or else keep a copy so that I can fill in the vitals on my assessment.
- For the informed consent, ensure that each line is initialed and that the patient signs the final sheet. You will also sign the final sheet as well, and I will cosign as well.
- For the HIPAA sheet, inform the patient that we will keep their records private, and they have access to them at any time. Have them sign this sheet as well.
- For the patient orders sheet, we will review the patient history and medical conditions and what the patient requests for treatment. After discussion, I will provide you with an order that you will fulfill for that particular patient. Remember, what the patient requests vs. what we decide and agree upon for treatment may be different. Our order sheet will reflect what we actually decide is best for the patient during their care. I will sign the order sheets and either you or me will fill out the "reviewed by" portion depending on who takes out the medications.
- For the Progress Note, I made sheets that are standardized. Please complete the forms as thoroughly as possible. Please ensure that you sign and date and time the progress notes as these are part of the patient's treatment course and documentation is reflective of what actually happens with the patients.
- For the patient informational sheets, please remove from packet and give to each patient to take home. Notify each patient that we plan on reaching out to them at some point after the treatment to ensure that their care was up their expectations.

IV placement and infusions/IM injections

- Once the intake forms are received and we have reviewed the patient's medical history and developed a treatment plan, I will give orders for what each patient will need. At that point, we begin the treatment phase.
- We shall treat every patient as if we were taking care of them in the hospital, surgery center, or outpatient setting, meaning that we will ensure the same sterility, and precautions as we would in a medical setting.
- Hand washing: either wash your hands with soap and water per WHO recommendations or use the sterilizing hand gel *prior to* and *after* each interaction with a patient. After washing your hands, gloves are provided and I request that you use them for each patient during their care.

- Please prep each patient at minimum with alcohol preps before placing an intravenous catheter, or intramuscular injection. Chloroprep sticks will be provided in the IV start kits, and this is superior to the alcohol wipes, so please utilize this as a first option for the IV placement. If multiple attempts are required for a catheter placement, alcohol preps may be used.
- Once an IV is established, ensure that all sharps are placed in the sharps container, and all blood stained items are disposed of in the red hazard bags. Regular trash can be placed in the trash canister.
- Secure IVs as you are comfortable with, but ensure there is adequate fluid flow. Once you start an IV infusion, start with a free flow and monitor for 3-5 minutes to ensure that patient does not have a reaction to the fluids or having difficulty with their IV. Once they have shown the ability to tolerate, you can infuse quicker with the pressure bag if the patient wants a quicker treatment.
- If you have difficulty with IV placement, and it requires more than two attempts, I request that you notify me and I prefer to place the IV at that point in time. Please note that you will still get credit for taking care of the patient and be reimbursed for your care, but I just want to ensure that the patient has a positive experience.
- If medications are ordered and to be injected, please draw up each drug sterily (prep the vial with alcohol before drawing up with a new sterile filter needle and syringe) and deliver it in the selected port slowly (over 15 seconds) once it has been scrubbed with an alcohol prep. Please monitor closely over the next 15 minutes to ensure there is no adverse reactions or symptoms reported by the patient.
- If there is an allergic reaction to any medication, please notify me immediately, I will evaluate. If needed, we have epinephrine in the medication refrigerator.
- IM medications should be drawn up sterily and delivered sterily similar to the procedures noted above. Again, please use the filter needle for the glass vials.
- Once the treatment is complete, remove the IV and place all blood stained items in the red hazard bags, and the rest of the trash in the regular trash bin as noted above. Ensure that there is adequate hemostasis and provide bandages or compression bandages as needed.
- Please discuss what to expect with regards to potential side effects such as bruising and/or swelling, bleeding, etc.
- At the end of each of your shift, please check the equipment stock and fill up as needed. If you need something that we are out of, please let me know, and I will order them. Also, if there are items that makes your life easier, let me know as well and I will see if I can get them.

Medications

- For the medications, we will NOT be utilizing any Scheduled drugs (i.e. opioids). From the injectable medications standpoint we will only utilize Zofran (a nausea medication) and Toradol (an anti-inflammatory medication). We may consider adding an antacid medication (Ranitidine) ranitidine in the future. These are given via IV at the dose that I prescribe to you. The major medication for which I may make an adjustment is Toradol based on the patient's age and comorbidities. At our proctoring sessions, I will go over each drug with you, their side effects to look for, and when we would consider not giving the medication.
- For vitamins, we have Vitamin B12, Bcomplex, and C currently, but will see if we want to add any other supplements and vitamins at a later time. These are okay to inject both IM or IV, though we prefer the IM route because it remains in the system a little longer. Again, we will review the risks and benefits of these vitamins at our proctoring session and go over what to expect.
- All medications and vitamins need to be locked up in the refrigerator, and the key will be kept in a safe place with Amy and I have a spare key as well. Please take note of expiration dates for ALL medications before you deliver them.
- I expect everyone to practice the READ mnemonic when administering medications:
 - o R- Review every administered drug to make sure it is correct
 - o E- Expiration date, ensure it is valid
 - o A- Administer according to the route prescribed
 - o D- Dosing, ensure that you have the correct amount
- If medications are running low, please notify me directly, I will need to order from our distributor which takes about 3 days.
- IV bags will be brought in weekly and kept in the IV room, I will bring in the amount that is scheduled for the week. Extras will be stored in my office at work, so let me know if extra is needed and I will bring it in but we have a good estimate based on Vagaro scheduling for the week.

Scheduling/Communications

- All scheduling will take place on Vagaro which Amy will set up for you once you are onboarded. Remember, you will not be able to put on the schedule until we complete the two proctored patients so that I can evaluate and provide feedback.
- All schedules will open up for filling once I have determined my availability for the week and I try to do this 2 weeks in advance. It will be a first come first serve basis. We will mostly have weekend slots available for work as I still have clinical duties during the week several weeks throughout the year.
- All communications not patient related can go through normal text, my number is . All communications regarding PATIENT CARE must go through TigerText, which is our HIPAA compliant app.

- I find that the best flow is to text me when the patient is completing the intake form as I am usually 5 minutes away from Breathe Bar. I will head up, evaluate the patient with you, sign the orders, and you can complete the tasks necessary.
- Once completed, notify the front desk of what procedures you complete for the day and you will receive credit. Amy handles all payroll and payment aspects, so direct any questions regarding that stuff to her.

Essentially, these are the basics to get started. Again, welcome to the Breathe Bar team! If you have any questions, please don't hesitate to ask during our proctoring sessions, or text/call me anytime. I am available to help you out and hopefully you have fun doing something a little different than the typical patient care.

Nevada State Board of Nursing

January 27, 2020

NOTICE OF COMPLAINT/ INVESTIGATION

Natisha Zevnick
9350 Double R Blvd. 3018
Reno, NV 89521

Re: Complaint submitted by Board staff

Dear Ms. Zevnick:

On December 19, 2019, the Nevada State Board of Nursing Board staff conducted a site survey at Reno Breathe Bar and the findings revealed the following:

On or about October 15, 2019, through December 15, 2019, while working as a Registered Nurse at Reno Breathe Bar, you allegedly accessed and possessed IV fluids without authorization. You also practiced beyond scope by administering IV fluids to patients who had not been seen and examined by a licensed practitioner.

Should these allegations be substantiated, you may have violated the following statutes and/or regulations of the Nevada Nurse Practice Act including but not limited to, NRS 632.347 (1)(g) unprofessional conduct, and/or NAC 632.89 (2) practice beyond scope, (21) obtain, possess, furnish prescription drugs without authorization, and/or (27) customary standards of practice.

Pursuant to NRS 233B.127(3) this letter is to notify you of the allegations and offer you the opportunity to respond if you so choose. The Board will conduct an independent investigation to determine if there has been a violation of the Nurse Practice Act.

Due to the potential for possible action against your license/certificate in Nevada, you need to be aware of the following. You have the right to consult with an attorney before you make any response to the allegations, or at any time during the course of an investigation however, it is not mandatory that you have an attorney represent you in any matters before the Board. Disciplinary action against you may affect a license/certificate issued by the Nevada State Board of Nursing

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6576 (phone) 775-687-7700 (fax)
4220 S. Maryland Pkwy., Suite 300, Las Vegas, NV 89119-7524 (phone) 702-488-5800 (fax)
www.nevadanursingboard.org • 888-590-6726 • nursingboard@nsbn.state

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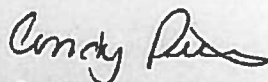
or any other state. In the event that there is formal disciplinary action taken by the Board, you may be charged for all financial costs related to investigation, settlement, and/or formal hearing of the complaint pursuant to NRS 622.400.

If you are a nursing assistant and the complaint is related to abuse, neglect, or misappropriation, the Board will investigate the alleged misconduct on behalf of the Bureau of Health Care Quality and Compliance. The Bureau may place a federal finding on your certificate in addition to any disciplinary action that may be taken by the Board.

Please return your response to the allegation(s) within (2) two weeks of receipt of this letter (as identified by the date upon which you sign the return receipt). Upon completion of the investigation, all information on file regarding the allegations will be reviewed to determine if further steps are appropriate. You will be contacted with the outcome of the investigation.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77727.

Sincerely,
NEVADA STATE BOARD OF NURSING



Cindy Peterson, RN
Investigator

Enclosure: Nursing Fact Sheet

To the Nevada State Board of Nursing:

This letter is in response to the letter dated January 24, 2020 addressing the allegation brought against me.

There is an allegation that between the dates of October 15, 2019 and December 15, 2019 I "accessed and possessed IV fluids without authorization and practiced beyond my scope by administering IV fluids to patients who had not been seen and examined by a licensed practitioner".

To address the above allegation, I can acknowledge that I was briefly employed by Reno Breathe Bar for the purpose of completing research for a project assigned in a course in my RN to BSN program. My experience at Reno Breathe Bar, though minimal, provided me with insight surrounding available resources in this community that promote overall health and wellness from a holistic and integrative approach compared to those that focus primarily on the prevention and management of disease. Throughout the time frame stated above, I was only present at Reno Breathe Bar on two dates: October 22, 2019 and November 15, 2019. I participated in the care of a total of two patients, only one of which received IV fluids. I was under the direct proctoring supervision of the staff physician, and then, Medical Director, Dr. Jeff Chen during the entirety of each of these patient interactions. At no point in time did I access, possess, nor administer medications and/or IV fluids without the staff physician being physically present, without having received his direct orders after his examination of each patient, nor without acting in accordance with the policies and procedures established by the medical director. All documentation of care supports this.

I am willing and able to answer any further questions and address any other concerns that the Board of Nursing may have, but please understand that I know my scope of practice as a Registered Nurse and that I hold my licensure in the highest regards. I am proud to serve this community as a nurse, and I would not act nor have I acted in a way that compromises my ability to do so and jeopardizes my standing with the Nevada State Board of Nursing. I made a career change to become an RN, and my experience in serving patients in both the Trauma Intensive Care Unit and the Operating Room at Renown has not only reinforced every decision and sacrifice that I made in order to facilitate that change; it has also sparked a desire to continue my education and to grow in this profession. With that being said, please consider that my participation at Reno Breathe Bar was proctored and supervised by the medical director/staff physician, and in no way did I practice outside of my scope of practice as a Registered Nurse.

Sincerely,

Natisha Zevnick, RN 90706

Nevada State Board of
NURSING

April 17, 2020

Natisha Zevnick
Double R Blvd.
Reno, NV 89521

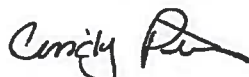
Re: Complaint submitted by Board staff

Dear Ms.Zevnick:

This letter is to inform you of the disposition of the Nevada State Board of Nursing regarding the complaint filed against you. After a thorough investigation and review of the evidence, the complaint has been closed. Once an investigation is closed, the contents of the investigation remain confidential. However, if new evidence is discovered, the matter may at any time be opened again and investigated further if circumstances so warrant.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact this office in writing, or by telephone at 888-590-6726 ext. 77727.

Sincerely,
NEVADA STATE BOARD OF NURSING



Cindy Peterson, RN
Investigator

Nevada State Board of NURSING

January 27, 2020

NOTICE OF COMPLAINT/ INVESTIGATION

Natalie Fuller
Watt St.
Reno, NV 89509

Re: Complaint submitted by Board staff

Dear Ms. Fuller:

On December 19, 2019, the Nevada State Board of Nursing Board staff conducted a site survey at Reno Breathe Bar and the findings revealed the following:

On or about October 15, 2019 through December 15, 2019, while working as a Registered Nurse at Reno Breathe Bar, you allegedly accessed and possessed IV fluids without authorization. You also practiced beyond scope by administering IV fluids to patients who had not been seen and examined by a licensed practitioner.

Should these allegations be substantiated, you may have violated the following statutes and/or regulations of the Nevada Nurse Practice Act including but not limited to, NRS 632.347 (1)(g) unprofessional conduct, and/or NAC 632.89 (2) practice beyond scope, (21) obtain, possess, furnish prescription drugs without authorization, and/or (27) customary standards of practice.

Pursuant to NRS 233B.127(3) this letter is to notify you of the allegations and offer you the opportunity to respond if you so choose. The Board will conduct an independent investigation to determine if there has been a violation of the Nurse Practice Act.

Due to the potential for possible action against your license/certificate in Nevada, you need to be aware of the following. You have the right to consult with an attorney before you make any response to the allegations, or at any time during the course of an investigation however, it is not mandatory that you have an attorney represent you in any matters before the Board. Disciplinary action against you may affect a license/certificate issued by the Nevada State Board of Nursing

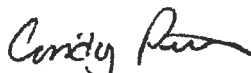
or any other state. In the event that there is formal disciplinary action taken by the Board, you may be charged for all financial costs related to investigation, settlement, and/or formal hearing of the complaint pursuant to NRS 622.400.

If you are a nursing assistant and the complaint is related to abuse, neglect, or misappropriation, the Board will investigate the alleged misconduct on behalf of the Bureau of Health Care Quality and Compliance. The Bureau may place a federal finding on your certificate in addition to any disciplinary action that may be taken by the Board.

Please return your response to the allegation(s) within (2) two weeks of receipt of this letter (as identified by the date upon which you sign the return receipt). Upon completion of the investigation, all information on file regarding the allegations will be reviewed to determine if further steps are appropriate. You will be contacted with the outcome of the investigation.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77727.

Sincerely,
NEVADA STATE BOARD OF NURSING



Cindy Peterson, RN
Investigator

Enclosure: Nursing Fact Sheet



Natalie Fuller <eagernat@gmail.com>

Response to complaint/allegations by NV State Nursing Board

Natalie Fuller gmail.com>
 To: info@renobreathebar.com <info@renobreathebar.com>

Tue, Feb 4, 8:17 PM

February 4, 2020

Re: Complaint filed by Board Staff

To the NV State Nursing Board:

This letter is in response to the letter dated January 27th, 2020, and received by me on February 4th, 2020.

The allegations stated that between the dates of October 15, 2019 through December 15, 2019, while working as an RN at Reno Breathe Bar, that I accessed and administered IV fluids without prior authorization by a licensed practitioner. It states that I practiced beyond my scope.

In response to these allegations, I confirm that I was an employee of Reno Breathe Bar. Per the protocol issued by the Medical Director of Breathe Bar, and reviewed before start of employment, I discussed and reviewed each case with the staff physician. This was done either in person, via the phone, or via HIPPA compliant software Tiger Text. I worked directly under the physician's orders to administer IV fluids and medications. Under no circumstances did I provide care without the prior authorization of the staff physician, and all documentation of patient care reflects this. Neither was I ever in possession of IV fluids without the authorization of the staff physician. After reviewing and discussing each patient case, history, and assessment with the physician, orders were then received and completed.

I can attest that my file as a Registered Nurse is completely clean. I have been a nurse in this state for nearly 38 years, and have never received a complaint from the Board of Nursing. I hold my profession with very high regard, and would not do anything to jeopardize my license or standing with the Board. I have served this community since 1982, from the tiniest of patients in the NICU and Peds ICU, to my present full-time job in Outpatient Radiology.

I am available if there are any more questions, but I assure you that I did not possess IV fluids without authorization, nor did I practice independently while performing my duties at the Breathe Bar.

Should any of this practice be found concerning, I can honestly say that it was completely unintentional. As my first complaint, I sincerely hope that you take into consideration my nursing history and clean record. I am willing to make any necessary changes deemed necessary to stay in compliance with the Board.

Sincerely,

Natalie Jo Fuller
 RN License 12814

Nevada State Board of
NURSING

April 17, 2020

Natalie Fuller
Watt St.
Reno, NV 89509

Re: Complaint submitted by Board staff

Dear Ms. Fuller:

This letter is to inform you of the disposition of the Nevada State Board of Nursing regarding the complaint filed against you. After a thorough investigation and review of the evidence, the complaint has been closed. Once an investigation is closed, the contents of the investigation remain confidential. However, if new evidence is discovered, the matter may at any time be opened again and investigated further if circumstances so warrant.

Board staff would issue this statement of caution to you. You must ensure in the future that you practice within your scope as a Registered Nurse in regards to administering IV hydration at remote locations. Board staff recommends you review the article titled "IV Hydration Scope of Practice: What Registered Nurses Need to Know" in the September 2019 issue of the Nevada State Board of Nursing Nursing News. Archived issues of the publication can be obtained on the Board's website: www.nevadanursingboard.org.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact this office in writing, or by telephone at 888-590-6726.

Sincerely,
NEVADA STATE BOARD OF NURSING



Cindy Peterson, RN
Investigator

5M

FILED

JUN 13 2019

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 19-090-CS-S
)	
Petitioner,)	NOTICE OF INTENDED ACTION
v.)	AND ACCUSATION
)	
KIARASH L. MIRKIA, M.D.,)	
Certificate of Registration No. CS15197,)	
)	
Respondent.	/	

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Kiarash L. Mirkia, M.D., Certificate of Registration No. CS15197 ("Dr. Mirkia") held a Board-issued controlled substance registration.

FACTUAL ALLEGATIONS

II.

In April 2018, Dr. Mirkia owned and was the Medical Director of Mirkia IV, PLLC ("Mirkia IV").

III.

Mirkia IV provided intravenous rehydration treatments to patients in the Las Vegas area using registered nurses who work for the company either directly or on a contract basis.

IV.

Dr. Mirkia allowed Mirkia IV's office staff, including office manager Alex Zukovski ("Zukovski"), who is not a practitioner or registered nurse, to possess the information and keys necessary to access Mirkia IV's inventory of dangerous drugs.

V.

Under Dr. Mirkia's direction, Zukovski or other Mirkia IV office staff accessed and possessed Mirkia IV's inventory of dangerous drugs and provided supplies of dangerous drugs to registered nurses without a practitioner on site, without a practitioner's direct supervision, before Dr. Mirkia or any other practitioner examined the patient, and before there was a patient-specific and medication-specific written order for the patient and/or the medication.

VI.

Dr. Mirkia directed the registered nurses who were employed by or contracted with Mirkia IV to possess and control dangerous drugs from Mirkia IV's inventory, including storing them at their homes, without a practitioner on site, without direct practitioner supervision, without a patient-specific and medication-specific written order for the patient and/or medication. Dr. Mirkia allowed those nurses to possess and store dangerous drugs from Mirkia IV's inventory for up to three days at a time in anticipation that Dr. Mirkia might examine a patient and issue an order for administration.

VII.

Dr. Mirkia allowed registered nurses to transport the dangerous drugs he put into their possession and control without a patient-specific and medication-specific order.

VIII.

Dr. Mirkia generally had no contact—did not examine and did not establish a bona fide therapeutic relationship with the patient—until after one of Mirkia IV's registered nurses transported the dangerous drugs in his/her possession to the patient's location.

IX.

After completing an “examination” of the patient by telephone, Dr. Mirkia would approve, deny or modify a pre-determined order authorizing the patient to receive treatment using an electronic medical record (“EMR”) system.

X.

After Dr. Mirkia issued an order to administer medication to the patient, the registered nurse purportedly performed his/her own assessment.

XI.

Mirkia IV’s nurses were directed to upsell, and often upsold, additional medications to the patient beyond what Dr. Mirkia initially ordered.

XII.

When an RN was successful in upselling additional dangerous drugs to a patient, an “on call” practitioner purportedly was available to amend the patient’s order prior to administration.

XIII.

Dr. Mirkia purchased sterile compounded dangerous drugs from Fusion IV Pharmaceuticals, Inc., *dba* Axia Pharmaceuticals (“Fusion”), in Los Angeles, California.

XIV.

Fusion sold compounded sterile products to practitioners in Nevada, including Dr. Mirkia and/or Mirkia IV.

XV.

Fusion is not licensed in Nevada.

APPLICABLE LAW

XVI.

No person may possess a dangerous drug in Nevada without specific statutory authority to do so. *See* NRS 454.213, NRS 454.316, NRS 454.321.

XVII.

A practitioner can give a registered nurse limited authority to possess and administer dangerous drugs without the practitioner onsite by way of NRS 454.213(1)(c), which says in relevant part:

a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, *or pursuant to a chart order, for administration to a patient at another location.*

NRS 454.213(1)(a)(*emphasis added*); see also NRS 639.100.

XVIII.

Chart orders must be written (NRS 454.223) and are patient-specific and medication-specific.¹

XIX.

“Except as otherwise specifically provided, every person who violates any provision of NRS 454.181 to 454.371, inclusive, is guilty of a misdemeanor.” NRS 454.356.

XX.

A practitioner must first establish a *bona fide therapeutic relationship* with a patient by examination before he or she can determine that a medication is medically necessary and direct and/or authorize a RN to possess and administer a dangerous drug on-site or issue a chart order for off-site administration of a dangerous drug to treat the patient’s medical condition. See NAC 639.945(1)(o) and NRS 454.213(1)(a).

¹ See NRS 639.004 “Chart order” means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

XXI.

[A] bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics . . . by the practitioner within the 6 months immediately preceding the date the practitioner . . . prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed.

NRS 639.945(3).

XXII.

An outsourcing facility that is engaged in the compounding of sterile drugs in this State [Nevada] or for shipment into this State shall:

1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;
2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and
3. Comply with all the requirements of 21 U.S.C. § 353b.

NAC 639.6915

XXIII.

“Supplying . . . medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles” constitutes “unprofessional conduct and conduct contrary to the public interest.”

NAC 639.945(1)(g).

XXIV.

A licensee “[p]erforming any of his or her duties as the holder of a license, certificate or registration issued by the Board . . . in an incompetent, unskillful or negligent manner” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(i).

XXV.

“Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(k).

XXVI.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

XXVII.

Engaging in conduct that constitutes unprofessional conduct or that is contrary to the public interest is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

XXVIII.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs - Statutory Violations

XXIX.

By allowing Mirkia IV's staff, including its office manager and its registered nurses, none of whom were practitioners and none of whom were licensed to possess or prescribe dangerous drugs, to operate Mirkia IV and/or to obtain, access, possess and store dangerous drugs when he was not on site, before he examined the patient and before he wrote a patient-specific order, Dr. Mirkia violated, or assisted and abetted his staff in violating, NRS 454.213(1), NRS 454.316 and/or NRS 454.356. Because of that conduct, which violates Nevada law and is

inconsistent with the public interest, Dr. Mirkia's controlled substance registration, Certificate of Registration No. CS15197, is subject to discipline pursuant NRS 639.210(12), NRS 453.236(1)(d) and NRS 453.241(1).

SECOND CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs – Unprofessional Conduct

XXX.

By allowing Mirkia IV's staff, including its office manager and its registered nurses, none of whom were practitioners and none of whom were licensed to possess or prescribe dangerous drugs, to operate Mirkia IV and/or to obtain, access, possess and store dangerous drugs when he was not on site, before he examined the patient and before he wrote a patient-specific order, Dr. Mirkia engaged, or assisted and abetted his staff to engage, in unprofessional conduct as defined in NAC 639.945(1)(g), (i), and (k). For that conduct, Dr. Mirkia's controlled substance registration, Certificate of Registration No. CS15197, is subject to discipline pursuant to NRS 639.210(4), NRS 453.236(1)(d) and/or NRS 639.255.

THIRD CAUSE OF ACTION

Purchasing Sterile Compounded Drugs from an Unlicensed Pharmacy

XXXI.

By purchasing sterile compounded dangerous drugs from a pharmacy not licensed with the Board, Dr. Mirkia violated, or assisted and abetted that pharmacy in violating, NRS 639.233, NRS 639.285 and/or NAC 639.6915. Because of that conduct, Dr. Mirkia's controlled substance registration, Certificate of Registration No. CS15197 is subject to discipline pursuant to NRS 639.210(4) and (12), NRS 453.236(1)(d); NRS 453.241(1) and/or NRS 639.255.

[THIS SPACE INTENTIONALLY LEFT BLANK]

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 17th day of June 2019.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 19-090-CS-S
)	
Petitioner,)	
v.)	
)	STATEMENT TO THE
KIARASH L. MIRKIA, M.D.,)	RESPONDENT
Certificate of Registration No. CS15197,)	NOTICE OF INTENDED ACTION
)	AND ACCUSATION
Respondent.	/	RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 17, 2019, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

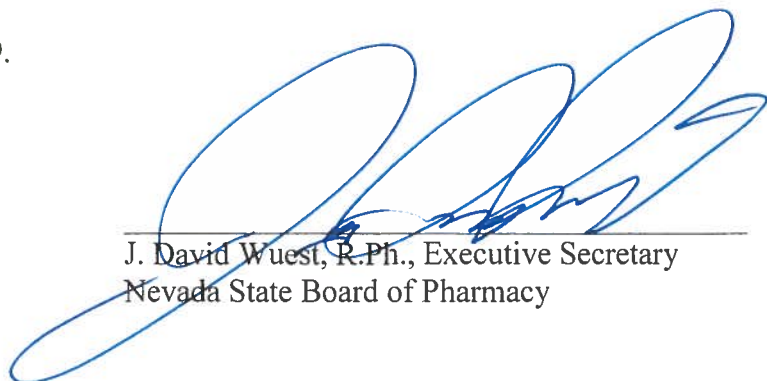
IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 13th day of June, 2019.

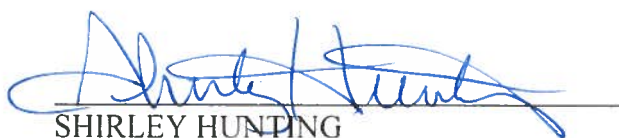


J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of June, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

**Kiarash L. Mirkia, MD
1878 Morro Vista Drive
Las Vegas, NV 89135**



SHIRLEY HUNTING

FILED

MAR 20 2020

NEVADA STATE BOARD
OF PHARMACY

1 LEWIS BRISBOIS BISGAARD & SMITH LLP
 2 KEITH A. WEAVER
 3 Nevada Bar No. 10271
 4 MELANIE L. THOMAS
 5 Nevada Bar No. 12576
 6385 S. Rainbow Boulevard, Suite 600
 7 Las Vegas, Nevada 89118
 8 Telephone: 702.893.3383
 9 Facsimile: 702.893.3789

10 Attorneys for Kiarash L. Mirkia, M.D.

11

12 BEFORE THE NEVADA STATE BOARD OF PHARMACY

13 NEVADA STATE BOARD OF	CASE NO. 19-090-CS-S
14 PHARMACY,	ANSWER AND NOTICE OF DEFENSE
15 Petitioner,	
16 vs.	
17 KIARASH L. MIRKIA, M.D.,	
18 Certificate of Registration No. CS15197,	
19 Respondent.	

20

21 KIARASH L. MIRKIA, M.D. ("Dr. Mirkia"), by and through his counsel LEWIS
 22 BRISBOIS BISGAARD & SMITH, LLP hereby submits his Answer and Notice of Defense.

23 JURISDICTION

24 I. Answering Paragraph I, Respondent objects to this paragraph as it calls for
 25 a legal conclusion; notwithstanding, Respondent admits that he held a Board-issued
 26 controlled substance registration, Certificate of Registration No. CS15197.

27 FACTUAL ALLEGATIONS

28 II. Answering Paragraph II, Respondent admits that he was the owner of
 Mirkia IV, PLLC, but denies the remainder of the allegations.

III. Answering Paragraph III, Respondent admits that Mirkia IV provided
 intravenous rehydration treatments to patients in the Las Vegas area using registered
 nurses who are independent contractors paid by 1099s, and denies that the registered
 nurses were directly employed.

1 IV. Answering Paragraph IV, Respondent admits that Alex Zukovski was the
2 office manager of Mirkia IV, and had information and keys necessary to access Mirkia
3 IV's inventory, and denies the remainder of the allegations as to any other office staff.

4 V. Answering Paragraph V, Respondent admits that Zukovski accessed and
5 provided supplies to registered nurses after notifying Respondent, who was at times
6 supervising remotely through the use of onsite cameras and a logbook, before
7 Respondent or any other practitioner examined the patient and before there was a
8 patient-specific and medication-specific written order for the patient and/or medication.
9 Respondent denies the remainder of the allegations, including those related to other
10 office staff.

11 VI. Answering Paragraph VI, Respondent denies these allegations.

12 VII. Answering Paragraph VII, Respondent admits that registered nurses were
13 permitted to possess and transport inventory up to the end of their shift when they were
14 required to return it to Mirkia IV.

15 VIII. Answering Paragraph VIII, Respondent admits that he would be on
16 videoconference with the patient and nurse listening, would obtain past medical history,
17 current medications, allergies and symptoms, would approve certain supplements. The
18 nurse would provide the vital signs and run down on the patient. The application
19 WhatsApp was utilized to perform these functions because it is encrypted.

20 IX. Answering Paragraph IX, Respondent denies that he examined the
21 patients by telephone, but admits performing exams on video-conference with the patient
22 and nurse present, and afterwards would approve, deny or modify the regimen the patient
23 selected when requesting the IV services.¹ Respondent admits that patients would select
24 packages for a desired regimen, but there would not be an order given until Respondent
25 approved of the desired regimen.

26

27

¹ The regimens were set forth on the

28

1 X. Answering Paragraph X, Respondent denies these allegations, as the
2 registered nurse performed their assessment of the patient, including obtaining vital
3 signs, prior to calling Respondent to examine the patient and obtain orders.

4 XI. Answering Paragraph XI, Respondent denies nurses were directed to
5 upsell, and often upsold, additional medications to the patient beyond what Respondent
6 ordered. If a registered nurse believed that additional treatment was needed, they would
7 contact Respondent for additional orders or receive direction to call emergency services.

8 XII. Answering Paragraph XII, Respondent denies these allegations.

9 XIII. Answering Paragraph XIII, Respondent admits to purchasing from Fusion IV
10 Pharmaceuticals on behalf of Mirkia IV, PLLC for a period of time before learning from the
11 Board of Pharmacy that they were not licensed in Nevada, at which time Respondent
12 discontinued the relationship.

13 XIV. Answering Paragraph XIV, Respondent admits that Fusion sold products to
14 Mirkia IV, but denies that products were sold to Dr. Mirkia individually. Respondent is
15 without sufficient knowledge or information to form a belief as to the truth or falsity of the
16 allegations contained therein as it relates to other "practitioners in Nevada," and on that
17 basis denies those allegations.

18 XV. Answering Paragraph XV, Respondent admits that he became aware
19 through the Board of Pharmacy that Fusion is not licensed in Nevada.

20 APPLICABLE LAW

21 XVI. Answering Paragraph XVI, Respondent objects to this paragraph as it calls
22 for a legal conclusion, for which no response is required.

23 XVII. Answering Paragraph XVII, Respondent objects to this paragraph as it calls
24 for a legal conclusion, for which no response is required.

25 XVIII. Answering Paragraph XVIII, Respondent objects to this paragraph as it calls
26 for a legal conclusion, for which no response is required.

27 XIX. Answering Paragraph XIX, Respondent objects to this paragraph as it calls
28 for a legal conclusion, for which no response is required.

1 XX. Answering Paragraph XX, Respondent objects to this paragraph as it calls
2 for a legal conclusion, for which no response is required.

3 XXI. Answering Paragraph XXI, Respondent objects to this paragraph as it calls
4 for a legal conclusion, for which no response is required.

5 XXII. Answering Paragraph XXII, Respondent objects to this paragraph as it calls
6 for a legal conclusion, for which no response is required.

7 XXIII. Answering Paragraph XXIII, Respondent objects to this paragraph as it calls
8 for a legal conclusion, for which no response is required.

9 XXIV. Answering Paragraph XXIV, Respondent objects to this paragraph as it
10 calls for a legal conclusion, for which no response is required.

11 XXV. Answering Paragraph XXV, Respondent objects to this paragraph as it calls
12 for a legal conclusion, for which no response is required.

13 XXVI. Answering Paragraph XXVI, Respondent objects to this paragraph as it
14 calls for a legal conclusion, for which no response is required.

15 XXVII. Answering Paragraph XXVII, Respondent objects to this paragraph as it
16 calls for a legal conclusion, for which no response is required.

17 XXVIII. Answering Paragraph XXVIII, Respondent objects to this paragraph
18 as it calls for a legal conclusion, for which no response is required.

19 FIRST CAUSE OF ACTION

20 **Unlawful Access and Possession of Dangerous Drugs—Statutory Violations**

21 XXIX. Answering Paragraph XXIX, Respondent objects to the extent that this
22 paragraphs calls for a legal conclusion, and denies the remainder of the allegations
23 generally and specifically.

24 SECOND CAUSE OF ACTION

25 **Unlawful Access and Possession of Dangerous Drugs—Unprofessional Conduct**

26 XXX. Answering Paragraph XXX, Respondent objects to the extent that this
27 paragraphs calls for a legal conclusion, and denies the remainder of the allegations
28 generally and specifically.

THIRD CAUSE OF ACTION

Purchasing Sterile Compounded Drugs from an Unlicensed Pharmacy

XXXI. Answering Paragraph XXXI, Respondent objects to the extent that this paragraphs calls for a legal conclusion, and denies the remainder of the allegations generally and specifically.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Board's Complaint fails to state a claim on which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

The Board's Complaint, and each cause of action therein, is barred by the doctrine of laches, estoppel, and the doctrine of unclean hands.

THIRD AFFIRMATIVE DEFENSE

Respondent denies each and every allegation of the Board's Complaint not specifically admitted or otherwise pled to herein.

WHEREFORE, Respondent prays for judgment as follows:

1. That all charges against him be dismissed;
2. For such other and further relief as may be deemed just and proper in these premises.

DATED: March 20, 2020

Respectfully submitted,

KEITH A. WEAVER
MELANIE L. THOMAS
LEWIS BRISBOIS BISGAARD & SMITH LLP

/s/ Melanie L. Thomas

By: _____
Attorneys for Kiarash L. Mirkia, M.D.

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FILED

AUG 03 2020

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

VINAY KUMAR BARARIA, MD,

Respondent.

Case Nos. 19-003-S

STATEMENT TO THE
RESPONDENT AND
NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.2895 and NRS 233B.121-.126, *inclusive*, an order to cease and desist, citation and fine was served upon Respondent Vinay Kumar Bararia, MD (Bararia) alleging violations of Nevada law as set forth herein.

2. On or about July 17, 2020, Bararia appealed the citation and fine and requested a hearing pursuant to NRS 639.2895(2).

FACTUAL ALLEGATIONS

3. Bararia was not registered with the Board to prescribe or dispense controlled substances or dangerous drugs for Nevada patients at the time of the events alleged herein.

4. Bararia voluntarily surrendered his license to practice medicine, License No. 11355, to the Nevada State Board of Medical Examiners (NSBME) on March 8, 2013, and was sentenced in federal court for distribution of controlled substances in September 2014.

5. Bararia has owned and operated Nevada Health Services, LLC aka Trimcare (Trimcare), located at 5375 South Fort Apache Road, Suites 102 and 103, in Las Vegas, since August 2018.

6. Abdel M. Khalek, MD (Khalek), co-owned and/or was employed at Trimcare from at least October 2018 to April 2019. Khalek held a controlled substance registration,

Certificate of Registration No. CS19745, and dispensing practitioner registration, Certificate of Registration No. PD00722.

3. Robert Chancellor, MD (Chancellor), co-owned and/or was employed by Trimcare from at least November 2018 to the present. Chancellor held a controlled substance registration, Certificate of Registration No. CS22616, and dispensing practitioner registration, Certificate of Registration No. PD27416

4. Lindsay Hoffman, PA-C (Hoffman), was employed by Trimcare from at least August 2018 to present. Hoffman held a controlled substance registration, Certificate of Registration No. CS 18262, and dispensing practitioner registration, Certificate of Registration No. PD

5. Bararia colluded with Khalek, Chancellor and Hoffman in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without the prescribing practitioner having a bona fide therapeutic relationship with patients, without the practitioner being present at the time prescriptions were dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state.

APPLICABLE LAW

6. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).

7. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.381(1).

8. It is unlawful for a practitioner to prescribe or dispense a controlled substance or dangerous drug except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS

454.215; NRS 454.301, NRS 639.100(1); NRS 639.23505; NAC 453.410; NAC 639.742; NAC 639.745.

9. It is unlawful for a person to purchase, possess, administer or furnish a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321 and/or NRS 454.356.

10. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(c), (d), (f), (h) and (i).

11. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.281(1); NRS 639.2813(1).

12. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

VIOLATIONS OF LAW ALLEGED

13. Bararia has purchased, accessed, stored, possessed, administered, furnished, prescribed and/or dispensed controlled substances and dangerous drugs and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state. This constitutes a violation of Nevada law, including NRS 453.226, NRS 453.316, NRS 453.321(1)(a), NRS 453.331 (1)(c)(d)(f)&(i), NRS 453.381(1), NRS 453.401(l)(a), NRS 454.213, NRS 454.215, NRS 454.221, NRS 454.311, NRS 454.316, NRS 454.321, NRS 639.100(1), NRS 639.235, NRS 639.23505, NRS 639.281, NRS 639.2813, and NRS 639.310. This also constitutes a violation of 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and 21 CFR §§ 1306.03–1306.05.

14. Khalek, Chancellor and Hoffman have been charged in a corresponding administrative action, Case Nos. 19-003-A-S, 19-003-B-S, and 19-003-C-S.

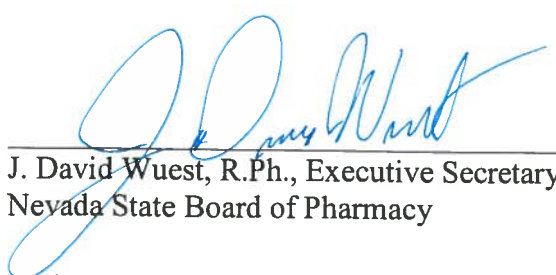
NOTICE OF HEARING

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn located at 7830 South Las Vegas Blvd., Las Vegas, Nevada.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

DATED this 3rd day of August, 2020.



J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Vinay Kumar Bararia, MD
5375 S. Ft. Apache Rd., Ste. 103
Las Vegas, NV 89148

Vinay Kumar Bararia, MD
6850 N DURANGO DR #205
Las Vegas, NV 89149

E. Brent Bryson, Esq.
7730 W. Sahara Avenue – Suite 109
Las Vegas, NV 89117


SHIRLEY HUNTING

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway – Suite 206 • Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

September 10, 2020

VIA CERTIFIED U.S. MAIL AND EMAIL

Daniel Niel
Las Vegas Boulevard South
Las Vegas, NV 89158

Re: Notice of Immediate Suspension of Pharmacist License No. 19767

Dear Mr. Niel:

The Nevada State Board of Pharmacy ("Board") has been informed that you have been hospitalized for mental illness.

The hospitalization for mental illness operates as an immediate suspension of your Pharmacist License No. 19767 with the Board pursuant to NRS 639.211. YOU SHOULD CEASE AND DESIST PRACTICING AS A PHARMACIST.

You may petition the Board and submit proof of mental competency for reinstatement of your license. See NRS 639.212. Please forward such petition to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, NV 89521.

Please be aware that the foregoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440, 702-486-6420 ext. 151, or c.lee@pharmacy.nv.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Courtney K. Lee".

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

Y

APPLICATION BY EXAMINATION AS A PHARMACIST

If you are requesting examination eligibility for initial licensure and/or you don't meet the requirements for reciprocity.

Total Fee: \$250.00 (non-refundable check or credit card)

Made payable to: Nevada State Board of Pharmacy

Complete Name (no abbreviations):

First: MICHAEL Middle: MANABU Last: SHIMOIDE

Mailing Address: E CLARKSON AVE

City: KINGSBURG State: CA Zip Code: 93631

Telephone: _____ E-mail Address: hotmail.com

Date of Birth: _____ Place of Birth: FRESNO, CALIFORNIA

Social Security Number: _____ Sex: ☒ M or ☐ F
(Full Number Required)

College of Pharmacy Information

Graduation Date: 05/13/99
(mm/dd/yy)

Degree Received: ☒ PharmD ☐ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: UNIVERSITY OF SOUTHERN CALIFORNIA

Location of School: LOS ANGELES, CALIFORNIA

If you are a **foreign graduate** you must attach a copy of your FPGE certificate to THIS APPLICATION. You also need to complete the college of pharmacy information

Board Use Only

Processed: _____ Amount: 250.00 Entity #: _____
Email: _____ NAPLEX: _____ MPJE: _____

Other states where you are (or were) licensed as a pharmacist or print "none"

State	Lic#	Is the license Active?	State	Lic #	Is the License Active?
CA	50927	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>

**Attach separate sheet if needed

Have you ever served in the military, either active, reserve or retired?

Yes ☒ No ☐

Branch: ARMY

Military Occupation/Specialty: 91Q

Dates of Service: 11/1990 - 6/2002

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

						Yes	No																																
1. Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?						<input type="checkbox"/>	<input checked="" type="checkbox"/>																																
2. Been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?						<input type="checkbox"/>	<input checked="" type="checkbox"/>																																
3. Been the subject of a board citation or an administrative action or board citation whether completed or pending in <u>any</u> state						<input checked="" type="checkbox"/>	<input type="checkbox"/>																																
4. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?						<input type="checkbox"/>	<input checked="" type="checkbox"/>																																
<p>If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation and/or documentation:</p> <table border="1"> <tr> <td>Board Administrative Action:</td> <td>State</td> <td>Date:</td> <td colspan="5">Case #:</td> </tr> <tr> <td>CITATION</td> <td>CA</td> <td>12/21/2015</td> <td colspan="5">CI 2015 68401</td> </tr> <tr> <td>Criminal Action:</td> <td>State</td> <td>Date:</td> <td>Case #:</td> <td>County</td> <td colspan="3">Court</td> </tr> <tr> <td></td> <td></td> <td>/ /</td> <td></td> <td></td> <td colspan="3"></td> </tr> </table>								Board Administrative Action:	State	Date:	Case #:					CITATION	CA	12/21/2015	CI 2015 68401					Criminal Action:	State	Date:	Case #:	County	Court					/ /					
Board Administrative Action:	State	Date:	Case #:																																				
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Criminal Action:	State	Date:	Case #:	County	Court																																		
		/ /																																					

FEDERALLY MANDATED REQUIREMENTS

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications.

4. Are you the subject of a court order for the support of a child?.....Yes ☐ No ☒
4a. If you marked Yes, to the question 4, are you in compliance with the court order?.....Yes ☐ No ☐

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

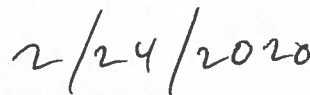
No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, its members, servants or employees because or by reason of the use of the authorization.

I attest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices.

I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.



Original Signature, no copies or stamps accepted



Date

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

CITATION AND FINE

Citation Number Name, License No
CI 2015 68401 MICHAEL MANABU SHIMOIDE , RPH 50927

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4113 subd. (c)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Title 21 CFR § 1305.12 subd. (d)/Title 21 CFR § 1305.05 subd. (a)	Procedure for executing DEA Forms 222/Orders for schedule I and II controlled substance - Power of Attorney	\$1,000.00
CCR Title 22 § 70263 subd.(c)(f)(3)(g)	Supplies of drugs for use in medical emergencies only shall be immediately available at each nursing unit or service area as required; the supply shall be inspected by a pharmacist at periodic intervals specified in written policies; such inspections shall occur no less frequently than every 30 days; records of such inspections shall be kept for at least three years; a pharmacy and therapeutics committee shall be established	\$2,000.00
Bus. & Prof. Code § 4059.5 subd. (a)	Dangerous drugs and devices may only be ordered by... and shall be delivered to licensed premises and signed for and received by a pharmacist...	\$1,000.00
Bus. & Prof. Code § 4115 subd. (a)(b)(c)	A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist	\$1,000.00

CONDUCT:

Code of Federal Regulations section 1305.12 (d) and 1305.05 (a) states in pertinent part each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under 1305.05. The name of the purchaser, if different from the individual signed the DEA Form 222, must also be inserted in the signature space. A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records. Michael Shimoide was not compliant. Michael Shimoide (RPH 50927) while working at Plumas District Hospital Pharmacy, located at 1065 Bucks Lake

9

9A

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521
PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION

Registration Fee: \$40.00 - (non-refundable money order only, no cash)

Complete Name (no abbreviations):

First: Aina Middle: Marie Last: Chiofolo
 Home Address: W. Mesquite Blvd Apt#: _____
 City: Mesquite State: NV Zip Code: 89027
 Telephone: _____ Social Security Number: _____
 Date of Birth: _____ Place of Birth: Cleveland, Ohio Sex: ☐ M or ☒ F
 E-mail Address: _____

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: _____

I am requesting registration at the following pharmacy:

Pharmacy: Walgreens Store #: 12446
 Address: 329 N. Birdhill Blvd.
 City: Mesquite State: NV Zip Code: 89027
 Signature of Managing Pharmacist: Kara Lockins Lic #: 13716 Date: 12-1-19

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☒ No ☐
 2. Are you a high school graduate or the equivalent? Yes ☒ No ☐
 (IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions (3-5) above, include the following information & provide an explanation & documentation:

Board Administrative Action:	State	Date:	Case #:	County	Court
Criminal Action:	NV	6/28/2017	17CR00339	Clark	Mesquite Municipal
	NV	2/11/2019	19CR00085	Clark	Mesquite Municipal

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

Are you the subject of a court order for the support of a child?..... Yes ☐ No ☒
 IF you marked YES to the question, above are you in compliance with the court order?..... Yes ☐ No ☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Original Signature, no copies or stamps accepted

Date

Board Use Only Date Processed:

Amount: 40.00

Maera L. Wallace

From: Gina Chiofolo <[REDACTED]>
Sent: Tuesday, December 24, 2019 1:28 PM
To: Maera L. Wallace
Subject: Re: Pharmaceutical Technician in Training Application

Hi Maera The 1st charge is 2017 is for petty larceny. I didn't take anything and didn't even know about it until we left the store, but because it was my car and I was driving I was charged for it also. The 2nd charge in 2019 was for a DWI. I got it on my 40th birthday and I have not had a single drink since. Feel free to contact me if you need more information.

Happy Holidays!
 Gina Chiofolo

On Mon, Dec 23, 2019 at 10:49 AM Maera L. Wallace <mwallace@pharmacy.nv.gov> wrote:

Hello Gina,

We are in receipt of your application for a pharmacy technician in training license. The application does not include the answers for the questions required by NRS639.129. I've attached a copy of your application so that you may review the questions.

We can't process the application without the answers so please provide them by email or by placing a phone call to (775) 850-1440.

Thank you,

Maera Wallace

Administrative Assistant

Nevada State Board of
 Pharmacy

775-850-1440



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure

**Mesquite Police Department**

Officer Report for Incident 170627-15

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6179 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Nature: DUI
Location: A

Address: 1120 W Pioneer Blvd; Walmart
Mesquite NV 89027

Received By: A Parnall How Received: T Agency: MES
Responding Officers: J Perry, J Smith, T Fails, M Magadan
Responsible Officer: J Perry Disposition: E 06/27/17
When Reported: 14:23:20 06/27/17 Occurred Between: 14:23:20 06/27/17 and 14:23:20 06/27/17

Assigned To:
Status:

Detail:
Status Date: **/**/**

Date Assigned: **/**/**
Due Date: **/**/**

Complainant: 35570

Last: Walmart

DOB: **/**/**

Race:

Sex:

First:

Dr Lic:

Phone:

Mid:

Address: 1120 W Pioneer Blvd

City: Mesquite, NV 89027

Offense Codes

Reported: Intoxicated Person

Additional Offense: DUI Driving Under the Influence

Additional Offense: TPSH Theft/Property/Shoplifting

Observed: Driving Under the Influence

Driving Under the
InfluenceTheft/Property/Shoplift
ing**Circumstances**

Highway/Road/Alley

Responding Officers:

J Perry

J Smith

T Fails

M Magadan

Unit :

A1

R1

S1

A2

Responsible Officer: J Perry

Received By: A Parnall

How Received: T Telephone

When Reported: 14:23:20 06/27/17

Judicial Status: MSD

Misc Entry:

Agency: MES

Last Radio Log: **/**/**

Clearance: CRO Cleared, Responding Officer

Disposition: E Date: 06/27/17

Occurred between: 14:23:20 06/27/17

and: 14:23:20 06/27/17

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6179 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 170627-15**Modus Operandi:****Description :****Method :****Involvements**

Date	Type	Description	Relationship
-------------	-------------	--------------------	---------------------

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 81799 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 170627-15

Synopsis

Officers were dispatched to a business reference a theft. An adult male was arrested for DUI and the female was cited for Petit Larceny.

Responsible LEO:

Approved by:

Date

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6179 Date: 01/16/2020
Page 4 of 6
MESQUITE POLICE DEPARTMENT

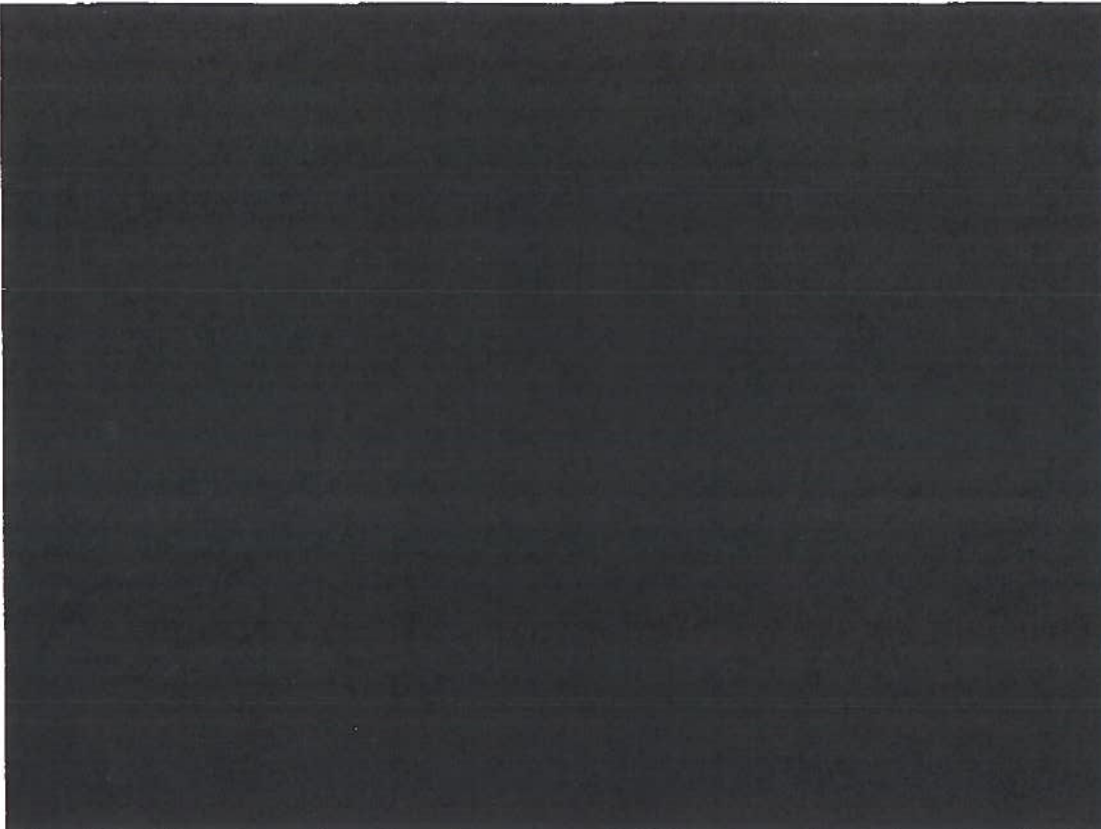
Officer Report for Incident 170627-15**Reports****Officers Report**

On Tuesday, 6/27/17, at approximately 1423 hours I, Officer J. Perry, responded to Walmart, located at 1120 West Pioneer Boulevard, reference a theft. While en route dispatched informed a female left the store with items that were not paid for. The female was seen getting into the passenger seat of a silver Toyota 4 runner Bearing Nevada license plate 351A14. The vehicle was seen crossing Pioneer Boulevard parking next to the Robertos Taco Shop. Sergeant Fails and Officer Smith responded to assist.

Upon arrival to the area I observed a silver Toyota 4 Runner Bearing Nevada License plate 351A14 traveling South on Pioneer Boulevard. I activated my lights and sirens and conducted a traffic stop on Pioneer Boulevard and Falcon Ridge Parkway.

As I approached the vehicle I made contact with an adult male driver, identified as David Calabrese, and adult female passenger Gina Chiofalo. As I spoke with the two individuals I could smell a strong odor of alcoholic based beverage coming from the vehicle. I asked David if he had been drinking and he stated he had a couple drinks earlier in the day.

I asked David to exit the vehicle so I could administer the Standardized Field Sobriety Tests (SFST) to determine if he was impaired. David agreed to take the tests.



UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6178 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 170627-15

[REDACTED]

David gave consent for officers to search the vehicle, and stated he had been drinking beers and the wine bottles were Gina's. While searching the vehicle I observed two open bottles of wine, and an open 24 ounce can of Bud Ice on the floor board of the back seat. Also in the back seat was a box of Oak Leaf Chardonnay. Gina stated the Chardonnay was what she purchased at Walmart.

I placed David in handcuffs and in custody for DUI-Alcohol (1st Offense). I placed David in Officer Smith's patrol vehicle and David was transported to the Mesquite Detention Center.

I spoke with Gina regarding the theft at Walmart. Gina stated she was attempting to return an item and purchase a box of wine. Gina stated she put the box of wine in her purse and left the store. Gina stated she thought she paid for the wine.

I placed Gina in the back of my patrol vehicle and relocated to Walmart. I spoke with Lost prevention employee Shandee Gurule. Shandee stated she observed a female individual conceal a box of wine in her purse and go directly to customer service. Shandee stated the female was intoxicated and stumbling while she walked. Shandee stated the female leaves customer service and exits the store without paying for the box of wine.

The box of wine had a value of \$11.86. I issued Gina citation MPD002752 for Petit Larceny and Shandee signed as the complainant.

I also issued Gina citation MPD002753 for Open Container in her vehicle. Gina was released from the Walmart.

Shandee provided surveillance photos and footage of the theft. Shandee also completed a voluntary statement. All will be attached to this report.

Anytime towing responded and took possession of the vehicle. An impound report sheet was completed and will be attached to this incident.

Officer Smith transported David to the Mesquite Detention Center. Officer Smith read the implied consent form, and David gave consent to take a breath test.

[REDACTED]

I completed a DP-45 form, and David was served an Order of Revocation which will be attached to this report. Officer Smith completed the Declaration of Breath Test Operator and the Intoxilyzer 8000 checklist and they will be attached to this report.

[REDACTED]

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.

Released To: Gina Chiofalo
By: M. Brey 6178 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 170627-15

Nothing further.

Tue Jun 27 17:08:36 PDT 2017

J. Perry 6171

**Mesquite Police Department**

Officer Report for Incident 190211-02

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6179 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Nature: DUI
Location: A

Address: 191 E Pioneer Blvd
Mesquite NV 89027

Received By: K Rowley How Received: 9 Agency: MES
Responding Officers: J Stout, C Empey, Z Wood
Responsible Officer: Z Wood Disposition: E 02/11/19
When Reported: 01:34:27 02/11/19 Occurred Between: 01:24:24 02/11/19 and 01:34:27 02/11/19

Assigned To: Detail: Date Assigned: **/**/**
Status: Status Date: **/**/** Due Date: **/**/**

Complainant: 9933

Last: McDonalds

First:

Mid:

DOB: **/**/**

Dr Lic:

Address: 190 E Pioneer Blvd

Race:

Sex:

Phone:

City: Mesquite, NV 89027

Offense Codes

Reported: Threatening

Observed: Driving Under the Influence

Additional Offense: DUI Driving Under the Influence

Driving Under the
Influence**Circumstances**

Parking Lot/Garage

Parking Lot/Garage

Responding Officers:

Unit :

J Stout

6168

C Empey

B2

Z Wood

R2

Responsible Officer: Z Wood

Agency: MES

Received By: K Rowley

Last Radio Log: **:**:** **/**/**

How Received: 9 911 Line

Clearance: CRO Cleared, Responding Officer

When Reported: 01:34:27 02/11/19

Disposition: E Date: 02/11/19

Judicial Status: MSD

Occurred between: 01:24:24 02/11/19

Misc Entry:

and: 01:34:27 02/11/19

Modus Operandi:

Description :

Method :

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6179 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 190211-02

Involvements

Date	Type	Description	Relationship
-------------	-------------	--------------------	---------------------

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Bray 6179 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 190211-02

Synopsis

Officers responded to a business on a report of threatening. There were no actual threats made and one female adult was arrested for DUI.

Responsible LEO:

Approved by:

Date

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofolo
By: M. Brey 6178 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 190211-02

Reports

Incident Report:

On Monday, February 11, 2019 at approximately 0124 hours I responded to McDonalds drive through located at 190 E Pioneer Blvd, on a report of threats.

I contacted the McDonalds employees who stated the passengers of a beige Ford Fusion sedan in the drive through began threatening them. The passenger was stating he was going to come and "pop" them all if they didn't get their order right. The McDonalds employees stated the passenger was acting as though he was on drugs.

Officer J. Stout and I contacted the driver and passenger of the vehicle. Officer Stout asked the passenger John Mcneal, to step out of the car while I spoke with the driver Gina Chiofolo. The vehicle was running and Gina told me she was driving because John was too intoxicated. While talking with the Gina I observed a strong odor of an alcoholic beverage coming from the vehicle. I asked Gina if she had been drinking. Gina stated she had three shots at noon on February 10, 2019. Gina's speech was slow and slurred. Gina's eyes were watery and bloodshot.

I asked Gina to exit the vehicle and she was very slow to respond. Gina struggled to exit the vehicle, grabbing the car for support. Gina stumbled as she walked to the back of the car. I again asked when she last drank, she replied it was her 40th birthday and she had her last drinks at midnight. Gina was swaying back and forth and was unable to stand still for short periods of time without taking steps to regain balance.

I advised Gina I was going to be conducting the standardized field sobriety tests(SFST's). I asked Gina the standard medical questions, and she answered no to all of the questions.

Prior to beginning the test I explained and demonstrated each test to Gina. I began the SFST's by having Gina stand in a well lit area of the McDonald's parking lot, where the ground was even, and there were parking stall lines to reference. The results of the test were as follows:

HORIZONTAL GAZE NYSTAGMUS

During the instruction phase of this test, Gina continued to sway side to side. Gina did not follow instructions and had to be told to keep her head still several times. During this test I observed a lack of smooth pursuit in both eyes. I observed a distinct and sustained nystagmus at maximum deviation, and nystagmus prior to forty five degrees in both eyes. The indications of this test led me to believe Gina was impaired.

WALK AND TURN

Gina attempted to get into the starting position and could not keep her balance, she had to take a step to the side to keep from falling. Gina was unable to move her right foot in line with her left foot without stumbling and stepping off the line. Gina continued to try and do this a few more times before giving up. Gina said that she was unable to do this test.

ONE LEG STAND

UNLAWFUL DISSEMINATION OF THIS
Restricted Information is PROHIBITED.
Violation will subject the offender to
Criminal and Civil Liability.
Released To: Gina Chiofalo
By: M. Brey 6179 Date: 01/16/2020
MESQUITE POLICE DEPARTMENT

Officer Report for Incident 190211-02

I began to explain the test to Gina to which she cut me off, and said she would not be able to do this test. Gina was informed that it would be to her benefit to attempt the test to which she refused.

I explained the portable breath test to Gina and informed her she needed to blow a constant flow of air until I told her to stop. Gina began by giving me a small breath, when told to blow harder she was able to give me a constant flow of air but the machine only registered a partial. The results of the portable breath test were .250 BrAC. Based on the totality of the circumstances and Gina's performance on the standardized field sobriety test, I arrested her for driving under the influence of alcohol.

Officer C. Empey transported Gina to the Mesquite Detention Center. At 0210 hours I read Gina the Nevada Implied Consent Warning and she agreed to provide a blood sample. Phlebotomist Verna Carnesecca arrived and collected two vials of blood at 0310 hours, which I took custody of and placed into a refrigerated evidence vault at the Mesquite Detention Center to be sent off for testing.

While at the detention center, I checked Gina's criminal history and learned she had been convicted of a prior DUI arrest on 08/14/2014 in Colorado. I issued Gina Citation # MPD043027 for DUI second offense. I completed the state DP-45 Form and explained it to Gina and gave her a copy. I completed the Field sobriety checklist, declaration for the withdrawal of whole blood sample and the Henderson Lab Request forms. All forms will be attached to this case file.

No Further.

Z. Wood 6188

Mon Feb 11 04:06:05 PST 2019

**MESQUITE MUNICIPAL COURT
FULL CASE HISTORY**

Defendant: CHIOFOLO, GINA MARIE

Case #: 17 CR 00339 8Q

File Date: 06/28/2017

Tkt/Cit #: MPD002752

Language Spoken: unknown

Status: **CLOSED**

Prosecuting Attorney: **MESQUITE CITY ATTORNEY**

Defense Attorney: **PRO PER**

CHARGE AND SENTENCE INFORMATION

1	PETIT LARCENY		MISDEMEANOR	Offense Date: 06/27/2017
	Plea:	No Plea	Jail:	
	Disposition:	08/10/2017 NO CONTEST		Accident:

FINANCIAL SUMMARY

	Original Amt	Amt Paid	Amt Dismissed	Amt Due
AA FEE	\$120.00	\$0.00	\$120.00	\$0.00
FINE	\$750.00	\$0.00	\$750.00	\$0.00
GENETIC MARKER ANALYSIS FEE	\$3.00	\$0.00	\$3.00	\$0.00
SPECIALTY COURT FEE	\$7.00	\$0.00	\$7.00	\$0.00
	<u>\$880.00</u>	<u>\$0.00</u>	<u>\$880.00</u>	<u>\$0.00</u>

CONDITIONS

Ordered Dt:
Next Proof Dt:
Balance:
Completed Dt:

I HEREBY CERTIFY that this is
a full, true and correct copy of the
original on file with the Mesquite
Municipal Court.

Maria A. Haslam
COURT CLERK

MESQUITE MUNICIPAL COURT FULL CASE HISTORY

Defendant: CHIOFOLO, GINA MARIE

Case # 17 TR 00550 8Q

File Date: 06/04/2017

Tkt/Cit #: MPD016869

Language Spoken: unknown

Status: CLOSED

Prosecuting Attorney: MESQUITE CITY ATTORNEY

Defense Attorney: PRO PER

CHARGE AND SENTENCE INFORMATION

I DUTY UPON DAMAGING UNATTENDED VEHICLE OR OTHER MISDEMEANOR Offense Date: 06/02/2017
PROPERTY
Plea: No Plea Jail:
Disposition: 07/11/2017 GUILTY Accident:

FINANCIAL SUMMARY

	Original Amt	Amt Paid	Amt Dismissed	Amt Due
AA FEE	\$105.00	\$0.00	\$105.00	\$0.00
FINE	\$385.00	\$0.00	\$385.00	\$0.00
GENETIC MARKER ANALYSIS FEE	\$3.00	\$0.00	\$3.00	\$0.00
SPECIALTY COURT FEE	\$7.00	\$0.00	\$7.00	\$0.00
	<u>\$500.00</u>	<u>\$0.00</u>	<u>\$500.00</u>	<u>\$0.00</u>

CONDITIONS

Ordered Dt:
Next Proof Dt:
Balance:
Completed Dt:

I HEREBY CERTIFY that this is
a full, true and correct copy of the
original on file with the Mesquite
Municipal Court.

Maricela Haslam
COURT CLERK

MESQUITE MUNICIPAL COURT FULL CASE HISTORY

Defendant: CHIOFOLO, GINA MARIE

Case #: 17 TR 00708 8Q

File Date: 06/28/2017

Tkt/Cit #: MPD002753

Language Spoken: unknown

Status: **CLOSED**

Prosecuting Attorney: **MESQUITE CITY ATTORNEY**

Defense Attorney: **PRO PER**

CHARGE AND SENTENCE INFORMATION

1	OPEN ALCOHOL CONTAINER IN VEHICLE	MISDEMEANOR	Offense Date: 06/27/2017
Plea:	No Plea	Jail:	
Disposition:	08/10/2017 DISMISSED BEFORE TRIAL	Accident:	

FINANCIAL SUMMARY

NO FINES OR FEES ARE DUE ON THIS CASE.

CONDITIONS

Ordered Dt:	Am	Units
Next Proof Dt:		
Balance:		
Completed Dt:		

I HEREBY CERTIFY that this is
a full, true and correct copy of the
original on file with the Mesquite
Municipal Court.

Maricela Haslam
COURT CLERK

Kristopher Mangosing

From: Yen Long
Sent: Tuesday, August 18, 2020 9:13 AM
To: Kristopher Mangosing; Shannon Reichman
Subject: FW: Mesquite Court Records - Gina Chiofolo
Attachments: Mesquite Court Records - Gina Chiofolo.pdf

Kris and Shannon,

The attachment is regarding Gina Chiofolo's PTT application. Please place her on the October agenda for an appearance.

Thank you,
Yen

From: Mary Hanlon <reception@premieradoption.org>
Sent: Thursday, August 13, 2020 2:11 PM
To: Yen Long <ylong@pharmacy.nv.gov>
Cc: 'Gina Chiofolo' <gchiofolo@gmail.com>
Subject: Mesquite Court Records - Gina Chiofolo

Attached are the records I obtained from the court that you requested. You can contact Lindy Hulet at Mesquite Municipal Cour (702-346-5291) with any questions.

Thank you,

Gina Chiofolo

Ms. Yeah Long,

I met with the Mesquite Municipal Court clerks this afternoon. They informed me that I was in fact charged and convicted of petty larceny back in 2017.

In 2015 I went into an inpatient 7 month treatment program in Cleveland, Ohio. I did not have a drink for two years. I thought I would be ok to have casual drinks after that long of sobriety. Unfortunately I learned the hard way that I would never be able to drink like "normal" people again.

I learned a lot from my relapse. Mainly that I need to always be on top of this disease and that it needs a lifelong commitment to the rooms of A.A. and a lifelong commitment to sobriety.

Even though it took two horrible mistakes it fully opened my eyes to the severity of alcoholism and I take my sobriety very seriously. Without my relapse I would of never fully understood the importance and the benefits of an ongoing, lifelong attendance of A.A.

I would love to have the opportunity to meet with the Board again. I have been interested in becoming a pharmacy technician for quite a few years and feel like I would are a great member to any pharmacy team.

From: Gina Chiofolo

Subject: Make a copy and send this please

Date: Aug 30, 2020 at 11:20:28 PM

To: jkmcneal@gmail.com

Members of the Nevada Board of Pharmacy:
Hopefully this will be in more of an order.

I have my Petty Larceny charge from 2017. It was a horribly blurry moment and I had no intentions of not paying. I had the merchandise on the counter. I should of read my receipt better to make sure that my wine came out of the return that I was making. A horrible mistake on my part and I have been completely embarrassed my it ever since. That is not the kind of person I am.

On my 40th birthday I got my 2nd DUI. The Judge thought that I would be a good candidate for the Mesquite Breaking the Cycle program. By time I entered in to the program on July 13th my 1st DUI had passed the 7 year mark and it was no longer on my record, but since I was pulled over in February it was within the 7 years.

Judge Toone ordered me to a 3 month in-patient rehab at Crossroads in Las Vegas. Two weeks into my stay I fell on a water bottle and broke my hip and fractured my femur. I wasn't allowed to go back to rehab in my condition so I returned home after recovering from surgery with the understanding I had to stay sober. I knew I wanted to be sober and promised I would. I was asked to only take my pain medications if my pain was extreme. I was never into drugs of any form so I was just fine with only taking Ibuprofen.

From July of 2019-present I have urine tests randomly every week. I was ordered to do 7 A.A. meetings every week for the first 3 months and every 3 months after that he cuts 2 down. I have always gone to way more meetings than required. I am not required to go to any now and I average 4 a week. I hand in my signed papers when I go to court so I attached my current sheet. I have always had court twice a month. As of August I only will be going once a month. I also have substance abuse counseling once a week and that continues until I graduate in December.

I have thrived in this program. I have learned and taught a lot in the 14 months I have been there. My peers and the staff think highly of the serious attitude I have about the program and my sobriety. Enclosed are letters from Judge Toone and. My counselor Glen Horlacher. I know it is a lot of alcohol in my past and most people say "I'll never drink again" but for me it's not just the not drinking part it's also the amazing life that A.A. offers you.

I hope this has helped put things in order and I didn't get off topic or confusing. I am an honest and open book and will answer any questions you might have for

me

Thanks for your time. I look forward to seeing you in October.

**Mesquite Municipal Court
Clark County, Nevada****COMMITMENT ORDER****City of Mesquite,****PLAINTIFF,****vs.****GINA MARIE CHIOFOLO****DEFENDANT.****CASE NO: 17 CR 00339 30****DR #: 170627-15****DATE OF BIRTH:****SEX: Female RACE: WHITE****TO THE CHIEF OF POLICE, MESQUITE POLICE DEPT., MESQUITE, NEVADA:****WHEREAS the above-named defendant was duly adjudged to be guilty of****1. B06008MOONV8Q
PETIT LARCENY****on the 10 August 2017, and was thereupon
City Jail.****ADMINISTRATIVE FEE****You are hereby ordered to pay
placing him/her in the Mesquite City Jail
issued or fine is paid.****DONE AND ORDERED**

**Mesquite Municipal Court
Clark County, Nevada****COMMITMENT ORDER****City of Mesquite,****PLAINTIFF,****CASE NO: 17 CR 0033730****vs.****DR #: 170627-15****GINA MARIE CHIOFOLO****DEFENDANT.****DATE OF BIRTH: 02/11/1979****SEX: Female RACE: WHITE****TO THE CHIEF OF POLICE, MESQUITE POLICE DEPT., MESQUITE, NEVADA:****WHEREAS the above-named defendant was duly adjudged to be guilty of****1. B06008MO0NV3Q
PETIT LARCENY****on the 10 August 2017, and was thereupon committed to
City Jail.****ADMINISTRATIVE FEE****You are hereby ordered to pay the administrative fee of \$150.00
placing him/her in the Mesquite City Jail until the fee is paid or
issued or fine is paid.****DONE AND ORDERED**

Defendant: CHIOFOLO, GINA MARIE

Case #: 17 TR 00708 8Q

File Date: 06/28/2017

Tkt/Cit #: MPD002753

Language Spoken: unknown

Status: CLOSED

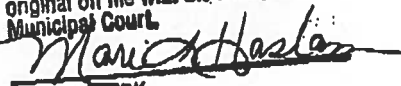
Prosecuting Attorney: MESQUITE CITY ATTORNEY

Defense Attorney: PRO PER

1	OPEN ALCOHOL CONTAINER IN VEHICLE	MISDEMEANOR	Offense Date: 06/27/2017
Plea:	No Plea	Jail:	
Disposition:	08/10/2017 DISMISSED BEFORE TRIAL	Accident:	

NO FINES OR FEES ARE DUE ON THIS CASE.

Ordered Dt:
Next Proof Dt:
Balance:
Completed Dt:

I HEREBY CERTIFY that this is
a full, true and correct copy of the
original on file with the Mesquite
Municipal Court.

COURT CLERK

**MESQUITE MUNICIPAL COURT**

August 5, 2020

Re: Gina Chiofolo – Participation in Mesquite Breaking the Cycle Program**To Whom It May Concern:**

Please allow this correspondence to provide you with information about Gina Chiofolo's participation in the Mesquite Breaking the Cycle specialty court program.

Gina entered this program on July 9, 2019 due to challenges related to alcohol. She is now in the final phase of the 5 phase program. She has attended weekly substance abuse counseling sessions, regularly attended support group meetings, maintained daily contact with our drug court coordinator, and participated in random drug and alcohol testing.

Gina has been a positive influence on others working to improve their lives in the program. She has performed many hours of volunteer service in the community this year, even though she was not required by the court to do so. Additionally, Gina has maintained employment at a local business.

Gina is working toward graduation from our program at the end of the year. It is anticipated that the matter bringing her into the program will be dismissed upon her successful completion of the program. As a specialty court team, we are fully supportive of Gina's efforts to achieve her education and career goals.

If you need any additional information please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to be "RT", written over a horizontal line.

Judge Ryan Toone
Mesquite Municipal Court

cc: Mesquite City Attorney's Office
Mesquite Breaking the Cycle Public Defender

Glen Horlacher MS, MFT**450 Hillside Dr. Building A****Mesquite, NV 89027****Tel (702) 346-1944 Fax (702) 345-4119****8-11-2020****Re: Gina Chiofolo, DOB: :****To: Whom it may concern,**

This letter is being written with permission of Ms. Chiofolo regarding her substance abuse treatment through Breaking the Cycle Drug Court in Mesquite, NV.

From the beginning of her programing, over 13 months ago, Ms. Chiofolo has been an outstanding participant. She is sober and understands recovery. She never fails to contribute insightful observations about her own experience in recovery. Furthermore she gives valuable feedback to others in the program who have less time in their sobriety.

She has attended group counseling on a weekly basis for over 13 months and her program still has several months to go, as we are very thorough in this stage of participants' recovery.

She has a bright, magnetic disposition, obvious intellect, a desire to demonstrate her efforts in earning her way in life, and a willingness to help others along the way.

As the clinical coordinator for Breaking the Cycle program, I have overseen every participant in the last 5 years. None have stood out more than Ms. Chiofolo. She is looking for a career and she has spoken longingly many times about getting into a pharmacy position.

It is *not* this clinician's opinion that Ms. Chiofolo is in need of any further counseling beyond her current program and in the months that follow she will continue to develop an after-care program for relapse prevention. She currently attends group counseling weekly, participates in AA sessions multiple times a week, holds down a full-time job, is drug tested on a reliable, variable schedule, is involved in a long-term romantic relationship, and is a great friend to people from all walks of life.

Please consider Ms. Chiofolo in highest regard for her pending career.

Respectfully,
Glen Horlacher, MFT

Addiction Recovery Group Meeting Attendance Log

This is to introduce: John C who is a participant of the Mesquite Municipal Court programs.
Please verify full meeting attendance at approved Addiction Recovery Group, A.A. or N.A. Thank you.

[illegible]

**MESQUITE MUNICIPAL COURT**

August 5, 2020

Re: Gina Chiofolo -- Participation in Mesquite Breaking the Cycle Program

To Whom It May Concern:

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Gina is working toward graduation from our program at the end of the year. It is anticipated that the matter bringing her into the program will be dismissed upon her successful completion of the program. As a specialty court team, we are fully supportive of Gina's efforts to achieve her education and career goals.

If you need any additional information please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "RT", is written over a horizontal line.

Judge Ryan Toone
Mesquite Municipal Court

cc: Mesquite City Attorney's Office
Mesquite Breaking the Cycle Public Defender

9B

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521
PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION

Registration Fee: \$40.00 - (non-refundable money order only, no cash)

Complete Name (no abbreviations):

First: Jasmine Middle: Ashley Last: McLaurie

Home Address: Gilded Flicker St. Apt#: _____

City: N. Las Vegas State: NV Zip Code: 89084

Telephone: _____ Social Security Num: _____

Date of Birth: _____ Place of Birth: Alexandria, LA Sex: ☐ M or ☒ F

E-mail Address: @gmail.com

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: _____

I am requesting registration at the following pharmacy:

Pharmacy: Pima Medical Institute Store #: N/A

Address: 3333 E Flamingo Rd

City: Las Vegas State: NV Zip Code: 89121

Signature of Managing Pharmacist: Lorinda Trinidad-Lohner Lic #: PT 10792 Date: 10/22/19

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☒ No ☐
 2. Are you a high school graduate or the equivalent? Yes ☒ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

- | | Yes | No |
|---|-------------------------------------|-------------------------------------|
| Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?..... | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 3. Been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4. Been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5. Had your license subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

If you marked YES to any of the numbered questions (3-5) above, include the following information & provide an explanation & documentation:

Board Administrative Action:	State	Date:	Case #:

Criminal Action:	State	Date:	Case #	County	Court
	VA	9/18/2014		Richmond City	Richmond City Circuit

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

- | | Yes | No |
|---|--------------------------|-------------------------------------|
| Are you the subject of a court order for the support of a child?..... | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| IF you marked YES to the question, above are you in compliance with the court order?..... | <input type="checkbox"/> | <input type="checkbox"/> |

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Original Signature, no copies or stamps accepted: [Signature] Date: 10/17/2019

Board Use Only Date Processed: _____ Amount: 40.00

Jasmine McLaurie

Gilded Flicker St.
North Las Vegas, NV 89084
Phone
E-Mail: j com

April 24, 2020

Dear Nevada Board of Pharmacy:

My name is Jasmine McLaurie and I am currently enrolled in the pharmacy technician program at PIMA Medical Institute in Las Vegas. I am at the last stretch of my courses and will be ready for externship by the summer pending me obtaining my license.

When filling out my application I answered "yes" to question 3, and I am writing to give a brief explanation, and have also attached documentation to verify that these matters have been resolved. My arrest record from Virginia stems from a toxic relationship that went on longer than it should have, thus leading me to the irrational and emotional decisions that cost me more than it was worth. I have matured immensely since this situation and have learned better ways to communicate and when to walk away from situations that are not productive. In addition to Virginia, I have attached documentation pertaining to a wrongful arrest, which was ultimately dismissed from court.

Although I cannot go back and change time, I have been doing a great job of staying focused and leading a positive life. I have fallen in love with pharmacy, and I have worked tediously to maintain a 3.4 GPA. I am looking forward to graduating this winter so that I can start my career as a pharmacy technician.

Thank you,

Jasmine McLaurie

Richmond-Marsh Criminal/Traffic General District Court at Manchester

Traffic/Criminal Case Details

Richmond-Marsh Crimi

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Case/Defendant Information

Case Number : GC12004217-00	Filed Date : 06/07/2012	Locality : COMMONWEALTH OF VA
Name : MCLAURIE, JASMINE ASHLEY	Status : Bail	Defense Attorney : FORD
Address : RICHMOND, VA 23222	AKA1 :	AKA2 :
Gender : Female	Race : Black	DO

Charge Information

Charge : THREATEN OVER PHONE		
Code Section : 18.2-427	Case Type : Misdemeanor	Class : 1
Offense Date : 11/09/2011	Arrest Date : 06/07/2012	Complainant : SPRATLEY, YOSHIKO
Amended Charge :	Amended Code :	Amended Case Type :

Hearing Information

Date	Time	Result	Hearing Type	Courtroom	Plea	Continuance Code
06/07/2012	09:01 AM	Continued	Arraignment			
07/26/2012	01:31 PM	Finalized	Adjudicatory			Trial

Service/Process

Disposition Information

Final Guilty Disposition :		
Sentence Time : 12Months 000Days 00Hours	Sentence Suspended Time : 12Months 000Days 00Hours	
Probation Type : Unsupervised Probation	Probation Time : 03Years 00Months 000Days	Probation Starts :
Operator License Suspension Time : 00Years 00Months 000Days	Restriction Effective Date :	
Operator License Restriction Codes :		
Fine :	Costs : \$197.00	Fine/ Costs Due :
Fine/ Costs Paid Paid :	Fine/ Costs Paid Date : 10/09/2012	VASAP :

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Richmond-Marsh Criminal/Traffic General District Court at Manchester

Traffic/Criminal Case Details

Richmond-Marsh Crimi

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Case/Defendant Information

Case Number : GC12004218-00	Filed Date : 06/07/2012	Locality : COMMONWEALTH OF VA
Name : MCLAURIE, JASMINE ASHLEY	Status : Bail	Defense Attorney : FORD
Address : RICHMOND, VA 23219	AKA1 :	AKA2 :
Gender : Female	Race : Black	Di :

Charge Information

Charge : STALKING: FEAR OF DEATH/ASSLT		
Code Section : 18.2-60.3	Case Type : Misdemeanor	Class : 1
Offense Date : 11/09/2011	Arrest Date : 06/07/2012	Complainant : SPRATLEY, YOSHIKO
Amended Charge :	Amended Code :	Amended Case Type :

Hearing Information

Date	Time	Result	Hearing Type	Courtroom	Plea	Continuance Code
06/07/2012	09:01 AM	Continued	Arraignment			
07/26/2012	01:31 PM	Finalized	Adjudicatory			Trial

Service/Process

Disposition Information

Final Disposition : Nolle Prosequi		
Sentence Time : 00Months 00Days 00Hours	Sentence Suspended Time : 00Months 00Days 00Hours	
Probation Type :	Probation Time : 00Years 00Months 00Days	Probation Starts :
Operator License Suspension Time : 00Years 00Months 00Days	Restriction Effective Date :	
Operator License Restriction Codes :		
Fine :	Costs :	Fine/ Costs Due :
Fine/ Costs Paid :	Fine/ Costs Paid Date :	VASAP :

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Richmond-Marsh Criminal/Traffic General District Court at Manchester

Traffic/Criminal Case Details

Richmond-Marsh Criminal

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Hearing Date Search

Service/Process Search

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Case/Defendant Information

Case Number : GC12004060-00	Filed Date : 06/01/2012	Locality : COMMONWEALTH OF VA
Name : MCLAURIE, JASMINE A	Status : Released On Recognizance	Defense Attorney : BRINSON
Address : RICHMOND, VA	AKA1 :	AKA2 :
Gender : Female	Race : Black	DOB :

Charge Information

Charge : THREATEN OVER THE PHONE		
Code Section : 18.2-427	Case Type : Misdemeanor	Class : 1
Offense Date : 05/19/2012	Arrest Date : 05/31/2012	Complainant : WOMACK, DAVID
Amended Charge :	Amended Code :	Amended Case Type :

Hearing Information

Date	Time	Result	Hearing Type	Courtroom	Plea	Continuance Code
06/01/2012	09:00 AM	Continued	Arraignment			
08/02/2012	10:00 AM	Finalized	Adjudicatory			Trial

Service/Process

Disposition Information

Final Disposition : Dismissed		
Sentence Time : 00Months 00Days 00Hours	Sentence Suspended Time : 00Months 00Days 00Hours	
Probation Type :	Probation Time : 00Years 00Months 00Days	Probation Starts :
Operator License Suspension Time : 00Years 00Months 00Days	Restriction Effective Date :	
Operator License Restriction Codes :		
Fine :	Costs :	Fine/ Costs Due :
Fine/ Costs Paid :	Fine/ Costs Paid Date :	VASAP :

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Richmond-Marsh Criminal/Traffic General District Court at Manchester

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Service/Process Search

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Case/Defendant Information

Case Number : GC14003395-00	Filed Date : 05/16/2014	Locality : COMMONWEALTH OF VA
Name : MCLAURIE, JASMINE A.	Status : Released On Summons	Defense Attorney : GERAGHTY, BRIDGET
Address : RICHMOND, VA 23222	AKA1 :	AKA2 :
Gender : Female	Race : Black	DOB :

Charge Information

Charge : ASSAULT & BATTERY		
Code Section : 18.2-57	Case Type : Misdemeanor	Class : 1
Offense Date : 05/08/2014	Arrest Date :	Complainant : BLACKWELL, P.R. (VCUPD)
Amended Charge :	Amended Code :	Amended Case Type :

Hearing Information

Date	Time	Result	Hearing Type	Courtroom	Plea	Continuance Code
06/18/2014	09:30 AM	Continued	Arraignment			
07/24/2014	09:30 AM	Continued	Adjudicatory			Trial
09/18/2014	10:30 AM	Finalized	Adjudicatory			Trial

Service/Process

Disposition Information

Final Disposition : Guilty		
Sentence Time : 12Months 000Days 00Hours	Sentence Suspended Time : 11Months 025Days 00Hours	
Probation Type :	Probation Time : 00Years 00Months 000Days	Probation Starts :
Operator License Suspension Time : 00Years 00Months 000Days	Restriction Effective Date :	
Operator License Restriction Codes :		
Fine :	Costs : \$197.00	Fine/Costs Due :
Fine/Costs Paid Paid :	Fine/Costs Paid Date : 02/10/2015	VASAP :

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Richmond-Marsh Criminal/Traffic General District Court at Manchester

Traffic/Criminal Case Details

Richmond-Marsh Crimi

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Case/Defendant Information

Case Number : GC14006077-00	Filed Date : 08/18/2014	Locality : COMMONWEALTH OF VA
Name : MCLAURIE, JASMINE A.	Status : Released On Recognizance	Defense Attorney : GERAGHTY
Address : RICHMOND, VA	AKA1 :	AKA2 :
Gender : Female	Race : Black	DOB :

Charge Information

Charge : ASSAULT AND BATTER		
Code Section : 18.2-57	Case Type : Misdemeanor	Class :
Offense Date : 05/09/2014	Arrest Date : 08/16/2014	Complainant : NGIN, PHIRUNNA
Amended Charge :	Amended Code :	Amended Case Type :

Hearing Information

Date	Time	Result	Hearing Type	Courtroom	Plea	Continuance Code
08/21/2014	09:00 AM	Continued	Arraignment			
09/18/2014	10:30 AM	Finalized	Adjudicatory			Trial

Service/Process

Disposition Information

Final Guilty Disposition :		
Sentence Time : 12Months 000Days 00Hours	Sentence Suspended Time : 12Months 000Days 00Hours	
Probation Type : Unsupervised Probation	Probation Time : 03Years 00Months 000Days	Probation Starts :
Operator License Suspension Time : 00Years 00Months 000Days	Restriction Effective Date :	
Operator License Restriction Codes :		
Fine :	Costs : \$172.00	Fine/Costs Due :
Fine/Costs Paid Paid :	Fine/Costs Paid Date : 02/10/2015	VASAP :

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Richmond-Marsh Criminal/Traffic General District Court at Manchester

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Richmond-Marsh Crimi

Name Search

Case Number Search

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Service/Process Search

Name Search

Case Number Search

Hearing Date Search

Service/Process Search

Case/Defendant Information

Case Number : GC12004217-01	Filed Date : 07/24/2014	Locality : COMMONWEALTH OF VA
Name : MCLAURIE, JASMINE ASHLEY	Status : Released On Summons	Defense Attorney : GERAGHTY
Address : RICHMOND, VA 23219	AKA1 :	AKA2 :
Gender : Female	Race : Black	DC :

Charge Information

Charge : S/FTC W/SUSP SENTENCE		
Code Section : 19.2-306	Case Type : Show Cause	Class : U
Offense Date : 07/12/2014	Arrest Date :	Complainant : COMM OF VA
Amended Charge :	Amended Code :	Amended Case Type :

Hearing Information

Date	Time	Result	Hearing Type	Courtroom	Plea	Continuance Code
07/24/2014	09:01 AM	Continued	Arraignment	2		
09/18/2014	10:30 AM	Finalized	Adjudicatory			Trial

Service/Process

Disposition Information

Final Disposition : Nolle Prosequi		
Sentence Time : 00Months 000Days 00Hours	Sentence Suspended Time :	
Probation Type :	Probation Time : 00Years 00Months 000Days	Probation Starts :
Operator License Suspension Time : 00Years 00Months 000Days	Restriction Effective Date :	
Operator License Restriction Codes :		
Fine :	Costs :	Fine/Costs Due :
Fine/Costs Paid :	Fine/Costs Paid Date :	VASAP :

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10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

Y

What types of drugs will you be dispensing?		
<input type="checkbox"/> Controlled Substances	<input type="checkbox"/> Dangerous Drugs	<input checked="" type="checkbox"/> Both
Do you, as a dispensing practitioner or in conjunction with other practitioners, wholly own your practice? Yes <input type="checkbox"/> No <input type="checkbox"/>		
If no, please complete the Application for Non-Practitioner Dispensing Site Owners as required by NAC 639.742 (2).		

Personal Information			
First: <u>Carrie</u>	Middle: <u>Lee</u>	Last: <u>Lambert</u>	
Date of Birth: <u> </u>	SSN: <u> </u>	Sex: <input type="checkbox"/> M or <input checked="" type="checkbox"/> F	
Email Address: <u> </u>	Degree: <u>DVM</u>	Practitioner License #: <u>1162</u>	
(You MUST be licensed with your respective BOARD before we will process this application)			

Practice Information (Submit addresses for all other dispensing sites on a separate sheet.)		
Practice Name (if any): <u>North Hills Veterinary Clinic</u>		
Practice Address: <u>1440 North Hills Blvd</u>	State: <u>NV</u>	Zip: <u>89506</u>
(This must be a Nevada practice address. A license will not be issued to a home or a PO Box address.)		
Work Telephone: <u>(775) 972-5566</u>	Work Fax: <u> </u>	

Personal and Professional History		Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Have you been the subject of an administrative action whether completed or pending in any state?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If you marked YES to any of the number questions (2-4) above, include the following information and provide documentation:			
Board Administrative Action:	State:	Date:	Case #:
<u>abeyance of license</u>	<u>Nevada</u>	<u>6-13-16</u>	<u>06-2016DVM-21</u>
Criminal Action:	State:	Date:	Case #:
<u>DC11-5B277</u>	<u>NV</u>	<u>12-31-17</u>	<u>CR18-1053</u>
		County:	Court:
		<u>Washoe</u>	<u>District</u>

Payment: Submit with this application a fee of \$150 by providing your credit or debit card information below or by submitting a check for \$150 made payable to Nevada State Board of Pharmacy			
Credit Type: <input checked="" type="checkbox"/> Visa <input type="checkbox"/> Mastercard <input type="checkbox"/> Discover <input type="checkbox"/> American Express	Exp Date: <u> </u> MM/YY	Amount Charge: \$150	
Credit Card # <u> </u>	CVV (3 digits on back of card): <u> </u>	Billing Zip: <u> </u>	

I hereby certify that the answers given in this application are true and correct to the best of my knowledge. I understand that the approval of this application provides me alone with the authority to dispense controlled substance or dangerous drugs or both to my own patients at the address stated on the application. I further understand that I may not delegate this authority to any other person. I further agree to abide by all statutes, rules or regulations governing practitioner dispensing and understand that a violation of any such statute, rules or regulations may be grounds for suspension or revocation of this permit of authorization.

Original Signature, no copies or stamps accepted.

Date

10/28/19

Board Use Only	Received: <u> </u>	Amount: <u> </u>
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10/28/2019

Nevada State Board of Pharmacy,

Enclosed are copies of all the information that was requested on the application for veterinarian authority to dispense drugs. I have been in recovery since becoming sober on 12/31/2017. Currently I am enrolled in the Nevada SB 277 diversion program and am in compliance with all the requirements. Please contact Heather Brown with Washoe County at if you have any questions about the SB 277 program or my progress.

I did a 90 day inpatient treatment for alcoholism with Step 2 here in Reno and completed that in April of 2018. Since then I have been seeing Carol Schaye RN, LDAC for counselling. Ms. Schaye can be reached at (). Part of my program requirements includes random drug and alcohol testing 5 times a month at Sober 24. I have never had a testing problem since starting this program over a year ago and will continue with that frequency of testing for the better part of the next 2 years. Alcoholics Anonymous is a large part of my life now.

Currently I am practicing at North Hills Veterinary Clinic and they are aware of my history and situation and I have been completely transparent with the Nevada State Veterinary Board as well. Please let me know if you have any questions or need any other information from me. Thank you for your time.

Sincerely,



Carrie Lambert, DVM
(775) 420-7886
dogscatstravel@gmail.com

BEFORE THE NEVADA STATE BOARD OF
VETERINARY MEDICAL EXAMINERS

NEVADA STATE BOARD OF
VETERINARY MEDICAL EXAMINERS,
v.
CARRIE LAMBERT, D.V.M.
License #1162.

Case No. 06-2016DVM-21

ORDER ALLOWNG REINSTATEMENT
OF RIGHT TO PRACTICE

On July 23, 2015, the Board ordered effective an Agreement and Order of Probation involving Dr. Lambert. The Agreement and Order of Probation contained numerous terms and conditions intended to address Dr. Lambert's alcohol addiction.

On June 13, 2016, Dr. William Taylor, then Investigating Board Member on Dr. Lambert's matter, sent Dr. Lambert a letter informing her that he was invoking the remedial paragraph of the Agreement and Order of Probation and was suspending her license effective June 13, 2016.

On June 23, 2016, the Board's staff filed an Accusation in this matter, alleging a single cause of action based upon Dr. Lambert's alleged violating of the terms of an Agreement and Order of Probation. The hearing on the Accusation was scheduled for the Board's regular meeting on July 28, 2016.

On July 8, 2016, Dr. Lambert wrote a letter to the Board informing the Board that she would be entering an in-patient rehabilitation program commencing July 11, 2016 and that, thus, she would be unable to attend the Board's meeting on July 28, 2016. Included with the letter was a document dated July 5, 2016 by which Dr. Lambert provided a detailed recovery plan. In subsequent conversations with Board staff, Dr. Lambert indicated that she hoped the Board would consider lifting the suspension of her license and allow her to place her license in abeyance subject to conditions deemed appropriate by the Board.

On July 28, 2016, the Board considered a presentation made by Board staff and Dr. Lambert's friend, Mr. Henry Wacker, who appeared at the Board's meeting at Dr. Lambert's request and on her behalf. The Board's staff and Mr. Wacker both supported the notion of lifting Dr. Lambert's suspension and allowing her to place her license into abeyance subject to conditions. As a result of the presentation made to the Board, the Board determined to lift the suspension of Dr. Lambert's license and allowed her

1 to place the license in abeyance subject to certain terms and conditions.

2 On July 28, 2016, the Board issued its Order Continuing Hearing and Granting Abeyance. By
3 this Order, the Board continued the scheduled hearing of the matter, lifted the suspension of Dr.
4 Lambert's license, and allowed Dr. Lambert to place her license into abeyance subject to several terms
5 and conditions: (1) Dr. Lambert would continue with and successfully complete the in-patient
6 rehabilitation that she entered on July 11, 2016; (2) Dr. Lambert would engage in such aftercare and
7 treatment as she deemed needed to assure her sobriety and continued mental and physical health; (3) Dr.
8 Lambert would continue to abide with all the terms and conditions of the Agreement and Order of
9 Probation ordered July 23, 2016, including but not limited to compliance with her substance abuse
10 treatment agreement with PRN; and (4) Dr. Lambert would not practice veterinary medicine unless and
11 until she appeared before the Board with a treatment provider and if the Board was satisfied based upon
12 Dr. Lambert's presentation that the health, safety, and welfare of the patients, clients, and public would
13 be served by her return to the practice of veterinary medicine, the Board could allow Dr. Lambert's
14 license to no longer be in abeyance and to allow her to return to the practice of veterinary medicine
15 subject to such additional terms and conditions as the Board then deemed necessary.

16 On January 24, 2019, the Board considered a presentation made by Dr. Lambert by which Dr.
17 Lambert sought to end the abeyance of her license and to allow her to practice veterinary medicine. Dr.
18 Lambert presented her testimony and the testimonies of Carol Schaye, RN, LADC, Dr. Lambert's
19 substance abuse treatment provider, and Susanne Byrne, RN, MSN, LADC, Dr. Lambert's AA sponsor.
20 Dr. Lambert also supported her request with numerous documents that were reviewed by the Board. The
21 presentation showed that after the July 28, 2016 Order, Dr. Lambert relapsed in November 2016, and
22 thereafter entered a 30-day in-patient treatment program in March 2017. In the Fall of 2017, Dr.
23 Lambert ceased complying with her substance abuse treatment contract with PRN, and she was
24 suspended on December 11, 2017. On December 20, 2017, Dr. Lambert was arrested for DUI in
25 Sparks, and since it was her third such arrest, it was a felony. Dr. Lambert's present sobriety started
26 shortly after her arrest when she began again her treatment contract with PRN and entered a 90-day in-
27 patient treatment program. Dr. Lambert was allowed by the Second Judicial District Court (Case No.
28

1 CR18-1053) to participate in Felony DUI Court, and on September 18, 2018, Dr. Lambert was sentenced
 2 for her DUI. She was ordered to complete three years of strict probation – including continued
 3 treatment and meeting, the constant wearing of a SCRAM anklet, and the installation of an interlock
 4 device on her car – and if she successfully completed the probation, she would not be convicted of a
 5 felony DUI and would, instead, be convicted of a second misdemeanor DUI. Ms. Schaye was Dr.
 6 Lambert's treatment provider who provides monthly reports to the Court. Dr. Lambert, Ms. Schaye, and
 7 Ms. Byrne all confirmed that Dr. Lambert has been continuously free of alcohol and other prohibited
 8 substances for over one year. Ms. Schaye stated that Dr. Lambert's reinstatement to the practice of
 9 veterinary medicine would further Dr. Lambert's recovery. Based upon Dr. Lambert's presentation, the
 10 Board determined to allow Dr. Lambert to take her license off abeyance and to lift any pending
 11 suspension to allow Dr. Lambert to again practice veterinary medicine.
 12

13 NOW THEREFORE, it is hereby ordered as follows:

14 1. Dr. Lambert's license shall no longer be in abeyance and is no longer suspended. Dr. Lambert
 15 may resume the practice of veterinary medicine subject to the following terms and conditions:

16 (a) Dr. Lambert shall comply with the terms and conditions in Agreement and Order of
 17 Probation entered July 23, 2015 as if all of the terms therein were set out herein;

18 (b) Dr. Lambert may not work as a veterinarian more than 30 hours in any one week, and any
 19 practice that employs Dr. Lambert shall not allow her work with animals without another veterinarian
 20 being present on the premises at all times that Dr. Lambert is working with animals;

21 (c) Dr. Lambert shall continue to comply with her substance abuse treatment agreement with
 22 PRN and shall continue to treat with Ms. Schaye and Ms. Byrne and shall comply with all terms and
 23 conditions imposed by the Second Judicial District Court, and Dr. Lambert, PRN, Ms. Schaye, and Ms.
 24 Byrne shall immediately report to the Board's office any relapses or any violations of any of the
 25 agreements or orders to which she is a party. Ms. Schaye shall provide quarterly reports to the Board's
 26 office related to Dr. Lambert's treatment. Any violations of this paragraph shall be deemed a violation of
 27 this Order and the preceding Agreement and Order of Probation;

28 (d) Dr. Lambert may petition to modify any of the terms of this Order or of the Agreement and

1 Order of Probation, and any such request for modification will require an appearance before the Board,
 2 at which appearance the Board may ask questions and seek information as it deems needed and may
 3 deny, grant, or grant with conditions any such petition based upon the Board's discretion and consistent
 4 with the protection of the health, safety, and welfare of Dr. Lambert and the clients and patients with
 5 whom she might interact;

6 (e) Dr. Lambert shall not be required to pay a fine or the Board's fees and costs.

7 (f) Dr. Lambert will complete a reinstatement application and proof of 20 hours of continuing
 8 education hours approved by the Board in the year immediately preceding the filing of the reinstatement
 9 application.

10 3. Should Dr. Lambert fail to comply with any of the terms and conditions set out above, her
 11 license will be immediately suspended pursuant to the terms of the Agreement and Order of Probation
 12 and the Board's staff and the Board will take such additional action as it deems necessary under the
 13 circumstances then occurring.

14 ORDERED AND EFFECTIVE this ____ day of February, 2019.

15
 16
 17 _____
 18 STEPHEN DAMONTE, D.V.M., President
 19
 20
 21
 22
 23
 24
 25
 26
 27
 28

1 **CODE 1391**
2
3
4

5 **IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA**
6 **IN AND FOR THE COUNTY OF WASHOE**
7

8 **STATE OF NEVADA,**

9 **Plaintiff,**

10 **vs.**

Case No. CR18-1053

11 **CARRIE LEE LAMBERT,**

Dept. No. 9

12 **Defendant.**
13 _____/

14 **ORDER PURSUANT TO NRS 484C.340**

15 1. The Defendant, Carrie Lee Lambert, having entered a plea of guilty to a
16 third DUI offense, and the Court having personally reviewed the prior convictions, made a
17 finding that the Defendant has suffered two (2) or more constitutionally valid prior DUI-
18 type convictions within the last seven (7) years, and the Defendant having elected to
19 enter the Diversion Program pursuant to NRS 484C.340, et seq., and the Defendant,
20 having been certified as required by statute, and after a hearing on the matter, is found to
21 be eligible for the program.

22 2. The Court does hereby suspend all further proceedings against the
23 Defendant in this matter and places the Defendant on probation for a minimum period of
24 three (3) years but not to exceed five (5) years upon the condition that he be accepted for
25 treatment by a treatment facility, that she complete the treatment program satisfactorily,
26 and that she comply with all conditions of probation.

27 3. The Defendant is advised that if she is accepted for treatment by such a
28 facility, she may be placed under the supervision of the facility for not more than five (5)

1 years and during treatment she may be confined in an institution or, at the discretion of
2 the treatment facility, released for treatment or supervised aftercare in the community.

3 4. The Defendant is advised that if she is not accepted for treatment by such
4 treatment facility, or if she fails to complete the treatment satisfactorily, the Court will
5 enter a judgment of conviction on the third DUI felony and the Defendant will be sent to
6 prison. Appropriate credit for time served for will be calculated at that time.

7 5. The Defendant is advised that if she satisfactorily completes the treatment,
8 this Court will enter a judgment of conviction for a violation of paragraph (b) of subsection
9 1 of NRS 484C.400(1)(b).

10 6. The following special conditions are imposed:

- 11 a. Defendant shall be monitored by the Department of Pre-
12 Trial Services and abide by their rules and regulations;
- 13 b. Defendant shall submit to residential confinement, at her
14 own expense, for a period of time not less than 6 months;
- 15 c. Defendant shall install, at her own expense, an alcohol
16 breath testing device for 36 months and that she not drive
17 any vehicle unless it is equipped with a device as described
18 in NRS 484C.450;
- 19 d. Defendant shall enter and successfully complete the
20 Specialty Court's DUI Diversion Court Program; she shall
21 immediately report to the Second Judicial District Specialty
22 Court, Room 126, for orientation;
- 23 e. Defendant shall submit her person, vehicle, residence and
24 property to search and seizure, without a warrant, to
25 determine the presence of alcohol and/or controlled
26 substances;
- 27 f. Defendant shall abstain from the use, possession and
28 control of any alcoholic beverages or controlled substances
during her participation in the program;
- g. Defendant shall submit to random urinalysis or other testing
to determine the presence of alcohol or controlled
substances, at her own expense, as deemed necessary by
the Court or the Department of Pre-Trial Services;

- 1 h. Defendant shall submit to a substance abuse intake
2 evaluation, at her own expense, and if necessary
3 participate in a counseling program as approved by Pre-
4 Trial Services until discharged by agreement of both
5 counselor and supervising officer during the term of
6 probation.
- 7 i. Defendant shall agree to all conditions as the Court deems
8 necessary;
- 9 j. Defendant shall pay the sum of \$500.00 as attorney's fees
10 for legal representation during the term of the Defendant's
11 participation in the DUI Diversion Court Program, payable
12 through the Washoe County Division of Collections; and
13 that she shall pay a \$25.00 administrative assessment fee,
14 a \$60.00 chemical analysis fee, \$3.00 as an administrative
15 assessment for obtaining a biological specimen and
16 conducting a genetic marker analysis, and \$50.00 per
17 month Department of Pre-Trial Services supervision fee to
18 the Clerk of the Second Judicial District Court.

19 7. Carrie Lee Lambert is hereby advised that:

20 **Any fine, fee or administrative assessment imposed today**
21 **(as reflected in this judgment of conviction) constitutes a**
22 **lien, as defined in Nevada Revised Statutes 176.275.**
23 **Should you not pay these fines, fees, or assessments,**
24 **collection efforts may be undertaken against you.**

25 8. It is further ordered that the Defendant's case is assigned to the Second
26 Judicial District – Specialty Court, which will exercise jurisdiction over this matter while
27 the Defendant is in Specialty Court. Should the Defendant be removed from the
28 Specialty Court Program, the Defendant shall be returned heretofore for all further
matters.

9. It is further ordered as of today's date, the Defendant has 6 days credit for
time served.

Dated this 13 day of September, 2018.


DISTRICT JUDGE

FILED
Electronically
CR18-1053
2018-09-18 04:44:21 PM
Jacqueline Bryant
Clerk of the Court
Transaction # 6886317 : cvera

1 **CODE 1080**
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4
5

6 **IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA**
7 **IN AND FOR THE COUNTY OF WASHOE**
8

9 **STATE OF NEVADA,**

10 **Plaintiff,**

11 **vs.**

Case No. CR18-1053

12 **CARRIE LAMBERT**

Dept. No. SCD

13 **Defendant.**
14

15 **AGREEMENT AND RULES FOR PARTICIPATION IN FELONY DUI COURT**
16

- 17 1. **Reporting:** You must report as ordered by your Specialty Court. Any re-arrests will
18 be viewed as grounds for removal from the Felony DUI Court. You are required to
19 appear for all court appearances drug and alcohol free or be subject to arrest for
20 contempt of Court.
21 2. **Residence:** Report any changes in residence, phone number, or contact
22 information immediately. Your living environment must be totally drug and alcohol
23 free.
24 3. **Employment:** You shall seek and maintain employment during your participation in
25 this program. Employment in or around an environment where alcohol is served
26 must be reviewed for approval. Report any changes in employment immediately.
27 4. **Alcohol/Controlled Substances:** You shall not consume any alcohol. You shall
28 not use, purchase or possess any alcohol, illegal drugs, synthetic drugs or any
prescription drugs, not approved by Specialty Courts. You shall immediately notify
Specialty Courts of any prescription received. Narcotics, opiate based, or synthetic
medications will not be allowed. You shall submit to alcohol and drug testing as
required by Specialty Courts or its agent (s) or any Peace Officer upon request.
5. **Gambling:** You shall not enter a gaming establishment or any business where
gaming is the main source of revenue other than for established, pre-approved
employment reasons. Participation in gambling or partaking in an event where
gaming is conducted shall not be allowed.

6. **Electronic Monitoring/Residential Confinement:** You shall be required to serve a minimum of (6) months of residential confinement and will be placed on electronic monitoring during this time.
7. **Driving:** You shall not drive at any time while your license is revoked or suspended. It is your responsibility to meet with the Department of Motor Vehicles regarding your license and the re-instatement of your driving privileges. You must also have interlock installed on all vehicles that you will be driving.
8. **Breath Ignition Interlock Device:** In order to have driving privileges, you must install, at your own expense, an approved breath ignition interlock device in any vehicle you own or operate for not less than (3) months, that you may not drive any vehicle unless it is equipped with such a device until relieved of this requirement by the Court.
9. **Counseling:** You will be required to attend counseling throughout your participation in the Felony DUI Court. The Court will determine the minimal requirements for counseling and may adjust accordingly during your supervision. You must notify Specialty Courts of any changes or rescheduling of counseling sessions.
10. **Fees:** You are responsible for all fees and costs associated with your participation in the Felony DUI Court. Delinquency in the payment of those fees and fines constitute grounds for removal from the program.
11. **Search:** You shall submit your person, place of residence, vehicle or areas under your control to search at any time, with or without a warrant or warrant of arrest to determine the presence of alcohol and/or controlled substances or any violation of the conditions set forth by the Court, Specialty Court Officer, its agent(s) or any Peace Officer upon request.
12. **Travel:** You shall not leave the state without first obtaining permission from Specialty Courts. There will be no travel within the first 90 days of participation in Felony DUI Court.
13. **Courtroom Etiquette:** You must wear proper attire to court appearances. Spaghetti strap or tank top shirts, shorts, flip-flop or thong sandals are not considered appropriate & could result in being dismissed from the courtroom prior to your appearance. Chewing gum is not allowed. No hats or sunglasses are permitted.
14. **Additional Special Conditions:** _____

15. You understand and agree that, in addition to the above, you must comply with any other conditions that the Court deems necessary.

While participating in the Felony DUI Court, I am released on my Own Recognizance. I agree to appear at all scheduled court appearances. I agree to comply with the standard O/R conditions as well as all special conditions contained in this contract. Failure to follow the conditions of this contract will result in revocation of my Own Recognizance release and an order will be issued that may be served at

anytime/anywhere by any Peace Officer or Specialty Court Officer and I will be taken into custody to be brought before the court at the next available date.

I hereby do waive extradition to the State of Nevada from any jurisdiction in or outside the United States where I may be found and also agree that I will not contest any effort by any jurisdiction to return me to the State of Nevada. I will also be responsible for paying restitution for all extradition costs incurred in returning me to Washoe County.

Pursuant to NRS 239B.030, this document does not contain social security numbers.


Defendant's Signature


Specialty Court Officer

9-13-18
Date

IT IS SO ORDERED:

DATED this 18 day of September, 2018.


SENIOR DISTRICT JUDGE

12/21/2018

Dear members of the Board of Veterinary Medical Examiners,

I would like the opportunity to appear before you at the next board meeting on January 24, 2019. At that time, having surpassed a full year of sobriety, I want to share with you the progress I have made toward a life free from alcohol and fully focused on self improvement and a return to my chosen professional path.

I find myself now eager and ready to return to veterinary medicine, which is my passion and my calling in life, and I will be appealing to you to support my continued recovery by granting me the opportunity to resume a role as a productive citizen working in a field that I trained for long and hard, a field that brings me great joy.

I appeal for the restoration of my license to practice now fully confident in my ability to succeed, and, in advance of your January 24 meeting, I hope you will take some time to read my story, and the coping mechanisms I have learned and now utilize.

You are likely all aware of my struggle with alcoholism and depression. After I was given an order of abeyance two and a half years ago, I felt a deep sense of uselessness, and, unfortunately, turned back to what was at that time my only known coping mechanism: alcohol. Eventually, after a series of life struggles, I was arrested for DUI in December of 2017.

That DUI seems to have saved my life. I found the willingness to be admitted into a long-term intensive inpatient treatment program through Step 2 here in Reno, where I spent three months. Words cannot express my gratitude for what Step 2 gave me. For the first time after graduating from their intensive residential treatment, I did not and continue not to have a desire to drink, even through troubling times.

I am fully aware that this is a lifelong illness, and that I will need to be forever vigilant. Upon leaving Step 2, I went through intensive outpatient counseling at Wellcare along with counseling through Carol Schaye. Alcoholics Anonymous has become a vital piece of my recovery as well, and I currently have a service position with the answering service. I take inbound calls every Saturday night to provide resource information for people in the Northern Nevada region.

Additionally, in the interest of full transparency, I would like to share that I now take monthly Vivitrol injections, which have been shown to significantly reduce alcohol cravings. These were initiated prior to leaving residential treatment, and I continue them today. Currently, I am under the care of a primary healthcare professional as well as a psychiatric care professional who started me on a new antidepressant last year. I am very satisfied with the results I have experienced with this medication along with the Vivitrol.

The DUI last year opened the door for me to be in specialty court diversion. This program includes intensive treatment and monitoring that continues for three years. Through this court diversion, I am engaged in counseling three times a week and attend regular AA meetings. I am monitored by random testing and average two to three tests a week for alcohol as well as any controlled substance. At this time I have a SCRAM ankle monitor on that would measure alcohol in my system immediately if I were to relapse. An ignition interlock has been installed in my vehicle and will remain there for the duration of this three year program. Due to intensive treatment and monitoring, combined with my heartfelt desire to live a stable, sober life, there is no risk of my drinking without immediate legal consequences. I hope this brings you some peace of mind. It certainly brings me the level of support and accountability I need to continue my success.

In closing, please rest assured that I am well aware of the stressors associated with veterinary medicine. I have worked hard to get to a place where I am confident of my ability to cope with these stressors without alcohol. Currently I work two jobs in addition to meeting all my recovery and court needs. I have developed a strong support system with AA, my sponsor, my counselor, as well as medical professionals and renewed relationships with family and friends. I sincerely appreciate your consideration and hope you see the changes in me that I see in myself. I am ready to resume a role as a productive, sober citizen, and eager to return to providing high quality care for animals.

Thank you for your time and consideration.

Sincerely,

Carrie Lambert, DVM



Carols Counseling, Specializing in Licensed Professionals

Certified by the Substance Abuse and Prevention Treatment Agency (SAPTA) NAC Chapter 458.2882, N RS Chapter 4, 5,209 (AB305) (SB 277), 453,458 et al

Referred by Larry Esperdero LADC, PRN

Date 2-21-2020

To Whom It May Concern,

Re: Carrie Lambert DVM

From; Carol Schaye RNC, LADC

Diagnosis: Alcohol Use Disorder severe in sustained late remission

Doctor Lambert has been in treatment at this agency for two years. She has maintained total abstinence from all mood altering substances as evidenced by random observed urine drug screens. She attended group two times a week and one individual per week initially. She has been down stepped to one group session a week. She is in the maintenance stage of change.

Doctor Lambert has no substance use history other than the above diagnosis. She has met all requirements for treatment, returned to work as a veterinarian and is an outstanding group member. A monthly update will be sent to the board.

Thank you for trusting me with this client's care

Carol Schaye
Carol Schaye RNC, LADC, Director

Bible Way #40, Reno, NV 89502, (775) 240-5251 methodvideo2@att.net

10B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

What types of drugs will you be dispensing?

☐ Controlled Substances☐ Dangerous Drugs☒ BothDo you, as a dispensing practitioner or in conjunction with other practitioners, wholly own your practice? Yes ☐ No ☐
If no, please complete the Application for Non-Practitioner Dispensing Site Owners as required by NAC 639.742 (2).

Personal Information

First: MelissaMiddle: AnnLast: Tyson

Date of Birth: _____

SSN: _____

Sex: ☐ M or ☒ F

Email Address: _____

mail.comDegree: DVMPractitioner License #: 2626

(You MUST be licensed with your respective BOARD before we will process this application.)

Practice Information (Submit addresses for all other dispensing sites on a separate sheet.)

Practice Name (if any): _____

Practice Address: 37 Olympia Hills Circle Las Vegas State: NV Zip: 89141

(This must be a Nevada practice address. A license will not be issued to a home or a PO Box address.)

Work Telephone: 626.666.7864 Work Fax: _____

Personal and Professional History

Yes No

1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? ☐ ☒2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? ☐ ☒3. Have you been the subject of an administrative action whether completed or pending in any state? ☒ ☐4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? ☐ ☒

If you marked YES to any of the number questions (2-4) above, include the following information and provide documentation:

Board Administrative Action:	State:		Date:		Case #:	
	CALIFORNIA		01/08/2018		4602017000560	
Criminal Action:	State:	Date:	Case #:	County:	Court:	

Payment: Submit with this application a fee of \$150 by providing your credit or debit card information below or by submitting a check for \$150 made payable to Nevada State Board of Pharmacy

Credit Type: ☐ Visa ☐ Mastercard ☐ Discover ☐ American Express Exp Date: ____/____/____ (MM/YY) Amount Charge: \$150

Credit Card #: _____ CVV (3 digits on back of card): _____ Billing Zip: _____

I hereby certify that the answers given in this application are true and correct to the best of my knowledge. I understand that the approval of this application provides me alone with the authority to dispense controlled substance or dangerous drugs or both to my own patients at the address stated on the application. I further understand that I may not delegate this authority to any other person. I further agree to abide by all statutes, rules or regulations governing practitioner dispensing and understand that a violation of any such statute, rules or regulations may be grounds for suspension or revocation of this permit of authorization.

Original Signature, no copies or stamps accepted.

Date

12.25.19

Board Use Only Received: _____ Amount: _____

RAY NEWMAN
Law Offices of Ray Newman
236 West Mountain Street, Unit 119
Pasadena, California 91103
(626) 440-9433
sbcglobal.net

December 23, 2019

Nevada State Board
Of Veterinary Medical Examiners
4600 Kietzke Lane
Building O-#265
Reno, Nevada 89502

Re: Dr. Melissa Ann Tyson, License No. 2626

Dear Sir/Madame:

I am submitting this letter to clarify a mistake in Dr. Melissa Ann Tyson's renewal application. Dr. Tyson became embroiled in a dispute with the California Department of Food and Agriculture whereby the aforesaid state agency filed a lawsuit against her in the Los Angeles County Superior Court. As her attorney in the California action, I filed a motion to dismiss the action for failure to state a valid cause of action. The matter was eventually dismissed by the aforementioned California state agency.

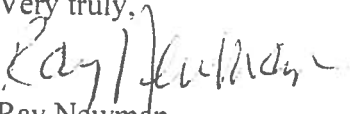
Sometime later, the state of California decided to file different charges, requesting an administrative hearing to avoid the legal requirements imposed by a superior court filing. At the time Dr. Tyson filed her application, I had advised her that the matter would be quickly dismissed. Acting under that impression caused by my erroneous advice, Dr. Tyson was under the impression that this matter would be quickly dismissed like the previous action so she checked the box "no action pending" under a misapprehension of her legal situation caused by me.

Dr. Tyson is extremely sorry for any confusion her mistaken answer may have caused. The appeal of that matter is presently pending.

I would also like to point out that none of the California state actions filed against Dr. Tyson had anything to do with medical knowledge or ability as a veterinarian

If I can be of further assistance please feel free to contact me

Very truly,


Ray Newman

**BEFORE THE
VETERINARY MEDICAL BOARD
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

**MELISSA ANN TYSON, DVM,
Veterinary Medical License No. VET 13995,**

and

CROWN CITY VETERINARY MEDICAL GROUP, INC.,

MELISSA ANN TYSON, DVM, Managing Licensee,

Premises Permit No. HSP 5890,

Respondents

Agency Case No. 4602017000560

OAH No. 2018051074

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby accepted and adopted by the Veterinary Medical Board as its Decision in the above-entitled matter, except that, pursuant to

Government Code section 11517, subdivision (c)(2)(B), the prosecution costs totaling \$20,410 are reduced by \$5,102.50 to reflect Respondents' successful challenge to the second cause for discipline under Business and Professions Code section 4883, subdivisions (d), (g), and (j), reducing the total amount of prosecution and investigative costs ordered to be paid by Respondents from \$26,043.75 to \$20,941.25, and, pursuant to Government Code section 11517, subdivision (c)(2)(C), the following minor and technical errors are corrected:

1. Page 2, second paragraph, first line, after "General," insert "Office of the Attorney General, Department of Justice, State of California,"; and remove and replace "complainant" with "Jessica Sieferman, in her official capacity as Executive Officer (complainant) of the Veterinary Medical Board (Board), Department of Consumer Affairs, State of California."
2. Page 21, paragraph 54.B., first line, remove and replace "tum" with "turn".

This Decision shall become effective on November 22, 2019.

IT IS SO ORDERED on October 23, 2019.



A handwritten signature in blue ink, appearing to read "Jaymie Noland", is written over a horizontal line.

Jaymie Noland, DVM, President
VETERINARY MEDICAL BOARD
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



**BEFORE THE
VETERINARY MEDICAL BOARD
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

MELISSA ANN TYSON, DVM

CROWN CITY VETERINARY MEDICAL GROUP, INC.

Veterinary Medical License No. VET 13995

CROWN CITY VETERINARY MEDICAL GROUP, INC.

MELISSA ANN TYSON, DVM, Managing Licensee

Premises Permit No. HSP 5890

Respondents

Agency Case No. 4602017000560

OAH No. 2018051074

PROPOSED DECISION

Eric Sawyer, Administrative Law Judge (ALJ), Office of Administrative Hearings (OAH), State of California, heard this matter on November 26-29, 2018, and May 20-24, 2019, in Los Angeles.¹

Gillian E. Friedman, Deputy Attorney General, represented complainant.

Ray Newman, Attorney at Law, represented respondents Dr. Melissa Tyson and Crown City Veterinary Medical Group, Inc.

The record was held open after the hearing for the submission of closing briefs from the parties in the other consolidated matter. The events that transpired while the record was held open are described in the ALJ's orders marked for identification as exhibits 17 and 18.

The record was closed and the matter submitted for decision on August 27, 2019.

¹ This matter was consolidated for hearing with OAH case number 2018051076, a matter before the California Department of Food and Agriculture. At the parties' request in both matters, separate proposed decisions are being issued. (Cal. Code Regs., tit. 1, § 1016, subd. (d).)

SUMMARY

It was clearly and convincingly established that Dr. Melissa Tyson (respondent Tyson) knowingly violated a quarantine order issued by the California Department of Food and Agriculture due to an outbreak of Equine Herpes Myeloencephalopathy (EHM), a potentially deadly neurologic disease associated with the highly contagious Equine Herpes Virus-1 (EHV-1), by removing a horse, Emmy, from the Los Angeles Equestrian Center (LAEC). At the time of her removal, Emmy was exhibiting signs of EHM; a nasal swab test taken earlier that day was later confirmed positive for EHV-1.

Thereafter, respondent Tyson obstructed the efforts of the California Department of Food and Agriculture (CDFA) to locate Emmy. Respondent Tyson failed to disclose the horse's location, had documents falsified, and perjured herself in declarations filed in court. Respondent Tyson eventually euthanized Emmy, who had by that time recovered from her EHV-1 infection, in order to cover up the false statements in her declarations filed in court.

Respondents' actions were unprofessional and deceptive, in violation of the Business and Professions Code, and constitute grounds to discipline respondents' licenses. Respondents' various denials and defenses to the charges of the Accusation were unpersuasive. Respondent Tyson showed little rehabilitation and no remorse for her misconduct. Under the circumstances, revocation of respondents' licensing rights is warranted, as well as an order that they reimburse the Board its reasonable costs in investigating and prosecuting this matter in the amount of \$26,043.75. However, an additional \$5,000 fine against respondents is unwarranted.

FACTUAL FINDINGS

Parties and Jurisdiction

1. Annemarie Del Mugnaio, then the Executive Officer of the Veterinary Medical Board (Board), brought the Accusation on January 8, 2018, in her official capacity. When the matter came to hearing, Jessica Sieferman was the Board's Executive Officer. Both individuals are referred to herein as complainant.

2. On or about January 16, 2018, respondents filed a Notice of Defense, which requested a hearing to contest the Accusation.

3. On May 25, 2000, the Board issued Veterinary Medicine License Number VET 13995 to respondent Tyson. The license was in full force and effect at all times relevant and will expire on October 31, 2020, unless renewed.

4. On November 24, 2003, the Board issued Premises Permit Number HSP 5890 to Crown City Veterinary Medical Group, Inc., with respondent Tyson as the managing licensee (respondent Crown City). The permit was in full force and effect at all times relevant and will expire on May 31, 2020, unless renewed.

Respondents' Background Information

5. Respondent Tyson is from a well-respected family that has lived in the Pasadena area for many years. Her father was a long-time physician and heavily involved in the civil rights movement. Her two sisters and brother are medical doctors. She is married and has four young children.

6. Respondent Tyson received veterinarian degrees from Washington State University and Oregon State University. She has no prior history of discipline by the Board.

7. Respondent Tyson is also accredited by the United States Department of Agriculture (USDA) as an Animal and Plant Health Inspection Services (APHIS) veterinarian. (Ex. 221.) As such, respondent Tyson received training and authorization to be involved in the National Animal Health Surveillance System, including efforts to prevent, control or eliminate equine diseases. (Ex. 222.)

8. Respondent Crown City is owned and operated by respondent Tyson. It is located in Pasadena in an award winning architecture design building. In 2016, just before the events in question, respondent Crown City employed six to nine people, and also provided opportunities for a number of interns and volunteers.

9. Respondent Crown City worked in partnership with the Asper de Tyson Foundation and Sanctuary (the Foundation), which is a non-profit organization dedicated to providing a safe haven for rare and neglected animals, including service dogs and horses. The Foundation is supported almost exclusively by respondent Tyson and her husband. (Ex. 211.)

10. Respondent Tyson has a love of horses which began with a riding career at the Eaton Canyon Stables in Pasadena from an early age until she went away to college. Her love of horses is one reason she became a veterinarian. Respondent since has owned many horses. She has been a member of various riding clubs throughout Southern California for most of her life.

11. Respondent Tyson and her family were formerly members of the Flintridge Riding Club, located in La Canada-Flintridge, adjacent to Pasadena. They

joined the club sometime in 2015. In May 2016, Respondent Tyson and her four children filed a lawsuit against the Flintridge Riding Club and two of its employees after an incident that occurred at the club on September 5, 2015. Respondent Tyson alleged she and her family were traumatized, subjected to emotional distress, discriminated against, and had their civil rights violated by club members on the basis of their race. (Ex. 200.) The club reached an undisclosed, confidential settlement with the family in or around September 2016, and the case was dismissed. (*Ibid.*) The relevance of these events is explained in respondents' mitigation argument below concerning her subsequent diagnosis of post-traumatic stress disorder.

The Los Angeles Equestrian Center

12. On a date not established, respondent Tyson had her horses stabled at LAEC, located in Burbank.

13. LAEC is a large equestrian club, with up to 600 horses stabled there. LAEC boards horses for private owners and trainers, including show horses and those involved in polo matches. There are six barns, known as Barns A through F. Each barn can accommodate many horses. For example, during the events in question, Barn C stabled 76 horses. LAEC holds horse shows and events open to the public; it also rents out its facilities for private parties and classes.

14. In October 2016, respondent Tyson wrote a letter to LAEC, on respondent Crown City's letterhead, complaining about a number of husbandry, health and maintenance concerns in the stable and barn areas. (Ex. 201.) Respondent Tyson concluded that her concerns could become health risks if not managed correctly. (*Ibid.*) However, respondents failed to show factual support for respondent Tyson's concerns noted in the complaint letter. In fact, of the other witnesses who testified

about LAEC, including three people involved in the horse community but otherwise unaffiliated with LAEC (Christopher Slauson, Kathleen Baker, Kathleen Hobstetter), none had any negative comments. Moreover, several CDFA veterinarians, who were at LAEC frequently during the events in question, did not offer any criticism about the cleanliness of LAEC or safety of the horses boarded there.

15. A. On September 11, 2016, Christopher Slauson, a horse sales agent in Bakersfield, sold a four-year-old bay filly named "Emma" to respondent Tyson for \$1,500. (Ex. 152, p. 4.) The horse was thereafter referred to as "Emmy." Respondent Tyson also bought another horse from Mr. Slauson for \$8,600. (Ex. 215.)

B. Emmy and the other horse were ostensibly purchased by respondent Tyson on behalf of her sister Maureen Tyson, who in turn would give them to respondent Tyson's two daughters. However, respondent Tyson was the only person who negotiated with Mr. Slauson, signed the purchase contract, took possession of Emmy, and made all the decisions regarding Emmy's care. In fact, it was not established that Maureen Tyson or respondent Tyson's daughters ever saw Emmy.

C. Respondent Tyson decided to stable Emmy at LAEC; she was boarded in Barn C in November 2016. She advised LAEC staff that she was Emmy's veterinarian. (Reporter's Transcript (RT), Vol. VIII, 48:19-20; ex. 114, p. 3.)

Outbreak of Equine Herpes Virus-1 at LAEC

16. EHV-1 is a highly contagious disease that can spread quickly among horse populations. (Ex. 138, p. 2.) EHV-1 is spread through direct horse-to-horse contact and indirectly through objects contaminated with the virus, such as clothing; human hands, tack, trailers, feed, and wash rags. (Ex. 138, p. 2.) Horses that become infected with EHV-1 usually develop a fever. They may also develop EHM, a neurologic

disease condition that may lead to death. (Ex. 155, p. 2.) Neurologic signs of EHM include decreased coordination, lethargy, and weakness. (*Ibid.*)

17. Because there is no vaccine to prevent EHM, immediate separation and isolation of horses suspected to be infected with EHV-1 and implementation of appropriate biosecurity measures are key elements of disease control. (Ex. 138, p. 2; ex. 155, p. 2.)

18. On November 3, 2016, two horses in Barn A at LAEC were confirmed positive for EHV-1 and diagnosed with EHM. (Ex. 138, p. 2.)

Legal Powers to Quarantine Animals

19. Food and Agricultural Code section 9562 gives the State Veterinarian broad authority to impose a quarantine whenever she reasonably suspects a population of domestic animals carries a potentially deadly contagious disease that could spread if those animals are not moved, segregated, isolated, held in place, or destroyed.

20. Pursuant to Food and Agricultural Code section 9564, if it is necessary to restrict the movements of animals pursuant to Food and Agricultural Code section 9562, the State Veterinarian may fix and proclaim the boundaries of a quarantine area in lieu of separate, individual orders issued to each owner pursuant to section 9562. While the boundaries are in force, it is unlawful for any person to move or allow to be moved any animals from or within the boundaries of the quarantine area, unless that person is authorized by the State Veterinarian.

21. When the State Veterinarian quarantines a population of domestic animals pursuant to Food and Agricultural Code section 9562, she is required to issue

a written notice of required action pursuant to quarantine (quarantine order) and serve that quarantine order upon the legal owner of the population of animals, the legal owner's agent, a person with immediate control over the population of animals, or a person with immediate control over the premises at which the population of animals is or has been located. (Cal. Code Regs., tit. 3, §§ 1301, subd. (o), 1301:1.)

22. Under Food and Agricultural Code sections 9563 and 9691, it is unlawful for any person to remove any animal from any premises that has been quarantined pursuant to Food and Agricultural Code section 9562 without the State Veterinarian's permission.

23. Pursuant to Food and Agricultural Code section 9695, it is unlawful for any person to hide or conceal any animal that is suffering from, or has been exposed or potentially exposed to, any disease subject to a quarantine order or to fail to disclose the whereabouts of that animal.

The Quarantine at LAEC

24. In light of the confirmed cases of EHM, on November 3, 2016, CDFA equine veterinarian Katherine Flynn, the designee of Dr. Annette Jones, the State Veterinarian, issued a quarantine order for all horses stabled in LAEC's Barn A, pursuant to Food and Agricultural Code section 9562. (Ex. 109, p. 1; ex. 138, pp. 2-3.)

25. The quarantine order required that enhanced biosecurity measures be implemented for all horses stabled in Barn A, including taking their temperatures twice daily, testing febrile horses (those with a fever) for EHV-1, and isolating any horse exhibiting signs of EHM before receipt of the EHV-1 test results. (Ex. 109, pp. 2-3.) George Chatigny, in his capacity as general manager of LAEC, signed and accepted

service of the quarantine order for Barn A. (Ex. 109, p. 1.) There was no appeal from this or any other quarantine order issued to LAEC.

26. On November 4, 2016, respondent Tyson traveled to LAEC to vaccinate Emmy. The following day, Emmy's trainer, Renee Baker, informed Dr. Flynn that Emmy had developed a fever. Dr. Flynn called respondent Tyson to confirm the vaccination as a potential cause of fever and the two discussed their differing opinions on whether to vaccinate horses in the face of an EHM outbreak. (Ex. 128, p. 3.)

27. On November 8, 2016, a horse in Barn B tested positive for EHV-1 and a horse in Barn C became febrile. In light of the ease of movement between the two barns, Kent Fowler, a veterinarian, CDFA's Animal Health Branch Chief, and a designee of State Veterinarian Annette Jones, issued an order that expanded the quarantine order to cover all horses stabled in Barns B and C, which included Emmy. (Ex. 110, p. 1; ex. 111, p. 25.) Mr. Chatigny signed and accepted service of the quarantine order for Barns B and C. (Ex. 110, p. 1.) The febrile horse from Barn C (not Emmy) later tested positive for EHV-1. (Ex. 111, p. 29.)

28. The CDFA and LAEC informed LAEC clients and the general public about the quarantine, including sending e-mails with quarantine updates to horse owners who stabled horses there, holding informational meetings with interested parties, and publishing updates on the CDFA's website. In addition, there were signs, caution tape, barricades, notices and warnings in, on, and around all of the barns that were under quarantine. (Exs. 111 & 113.)

29. Specifically with respect to respondent Tyson, LAEC sent the quarantine updates to the e-mail address on her boarding agreements. (RT, Vol. II, 204:9-23, 207:11-19; exs. 112 & 173.) As of November 22, 2016, there were numerous signs and

warnings posted at LAEC that Barn C was under quarantine. (Ex. 138, p. 2; ex. 139, p. 2.) The CDFA also prominently posted the quarantine order for Barns B and C on the side of Barn C.

30. On November 22, 2016, Emmy developed a fever and exhibited mild to moderate neurologic signs consistent with EHM. In the presence of Dr. Alisha Olmstead, an equine veterinarian with the CDFA, Dr. Michael Peralez confirmed Emmy had a fever. Dr. Peralez is an experienced independent equine veterinarian with extensive experience diagnosing horses with EHM, whom the CDFA had previously authorized to evaluate symptomatic horses pursuant to its regulatory authority. Dr. Peralez performed a neurologic assessment of Emmy, collected a blood sample, and nasal swabbed Emmy for testing for EHV-1. (Ex. 118, p. 1; ex. 155, p. 3.) Both Dr. Peralez and Dr. Olmstead testified that Emmy was uncoordinated, lethargic, and very weak during the neurologic exam, behavior symptomatic of EHM. (RT, Vol. II, 59:2-10; RT, Vol. III, 116:6-23, 120:14-25.) Consequently, the CDFA decided to place Emmy into isolation pending the EHV-1 test results. (Ex. 122, p. 1.)

Respondent Tyson Removes Emmy from Quarantine at LAEC

31. Before the CDFA placed Emmy into isolation that day, November 22, 2016, Emmy's trainer, Renee Baker, advised Dr. Olmstead that respondent Tyson, once she learned of the isolation decision, would "push back" and so should be contacted. (RT, Vol. II, 57:22-58:1; ex. 122, p. 1.) Dr. Olmstead then asked Animal Health Branch Chief, Dr. Fowler, to call respondent Tyson.

32. Dr. Fowler reached respondent Tyson on her cellphone as she was driving to LAEC on November 22, 2016. Respondent Tyson had already intended to remove Emmy from LAEC before embarking on that trip; she had a horse trailer

attached to the truck she was driving. Dr. Fowler informed respondent Tyson that Emmy had displayed a fever and mild to moderate neurologic signs consistent with EHM; that she had been nasal swabbed and blood sampled for EHV-1; and that she would be moved to the isolation stall pending the results of testing. (Ex. 126, p. 1; ex. 138, p. 2.) Respondent Tyson responded that she was on her way to remove Emmy from LAEC, was familiar with the current status of the quarantine efforts at LAEC, was going to implement her own quarantine of Emmy (which she stated superseded that of the state), and was willing to pay a fine for violating the quarantine at LAEC. (RT, Vol. I, 122:2-8, 123:6-11; ex. 126, p. 1, ex. 220, p. 3.)

33. Respondent Tyson testified that Dr. Fowler was abusive toward her during this call. The telephone call was put on a speaker by Dr. Fowler so Dr. Flynn, who was in the room with him, could hear. While the conversation became contentious, it was respondent Tyson who turned it in that direction. For example, when Dr. Fowler told respondent Tyson the number of horses already placed in isolation, respondent Tyson told him, "You do not know what you are talking about. . . ." (Ex. 126, p. 1.) Dr. Fowler responded, "You cannot count, there has never been more than 12 horses in isolation and currently there are 10 horses in isolation." (*Ibid.*) At that point, respondent Tyson accused Dr. Fowler of being "abusive," which was not the case.

34. After that conversation, Dr. Fowler called Dr. Olmstead and instructed her to contact law enforcement, since respondent Tyson had threatened to violate the quarantine order. Dr. Olmstead saw respondent Tyson arrive and watched her go to Emmy's stall in Barn C without complying with the quarantine's biosecurity measures. (Ex. 155, p. 3.) In fact, when told of the biosecurity measures, respondent Tyson told Dr. Olmstead that she would not comply "with your silly little rules." Dr. Olmstead told

respondent Tyson that Emmy was under quarantine. Respondent Tyson told Dr. Olmstead that she, respondent Tyson, was a state veterinarian; she was going to put Emmy in her own quarantine; her quarantine superseded the CDFA's quarantine; and she was going to remove Emmy from LAEC and take her home to be with her other horses. (RT, Vol. II, 62:10-15, 70:4-6; ex. 122, pp. 2-3.)

35. Without permission to do so, respondent Tyson then walked Emmy out of Barn C without complying with biosecurity measures, moved quarantine barricades out of the way, and loaded Emmy into the horse trailer attached to her truck.

36. A. Respondent Tyson testified that she removed Emmy from LAEC because she felt threatened by "a mob" of onlookers during an onsite evaluation of Emmy she did in the aisle-way outside Emmy's stall in Barn C. She therefore decided to evaluate Emmy off-site. (RT, Vol. VII, 117:3-8, 117:17-22.)

B. But her testimony is contradicted by Dr. Olmstead's testimony that respondent Tyson never attempted to perform a neurologic evaluation of Emmy at LAEC, there was no one threatening her when she was in Barn C, and there were no bystanders until respondent Tyson had already left Barn C and was loading Emmy into her trailer in the parking lot. (RT, Vol. II, 62:18-23, 63:23-25.)

C. Respondent Tyson's testimony is also contradicted by a declaration she signed in the civil case brought against her by the CDFA, discussed in more detail below. Under penalty of perjury, she described performing an evaluation of Emmy in Barn C, but wrote nothing about being harassed or confronted there by a mob or any individual. (Ex. 141, p. 2.)

D. Respondent Tyson's testimony is also contradicted by Dr. Fowler's testimony and written notes indicating respondent Tyson told Dr. Fowler she planned

to remove Emmy during his conversation with her before she arrived at LAEC on November 22, 2016.

E. Finally, respondents' medical records for Emmy indicate that, prior to arriving at LAEC on November 22, 2016, respondent Tyson already had told Emmy's trainer, Ms. Baker, that she would take Emmy to respondent Crown City's clinic if she found her to be febrile upon arrival; and told Caryn McDaris, an employee of LAEC, that "Emmy would be leaving the property today." (Ex. 220, p. 3.)

F. Under these circumstances, respondent Tyson's version of events is not credited.

37. Videos taken after respondent Tyson loaded Emmy into her trailer in the parking lot show respondent Tyson confronted by a handful of bystanders, who were telling her she was violating the quarantine order. (Ex. 121.) During that exchange, one bystander told respondent Tyson she was "breaking quarantine;" would be subject to a fine; and asked if she had talked to Dr. Fowler. (*Ibid.*) Respondent Tyson said that she had talked to Dr. Fowler, the bystanders should keep their horses under quarantine, but that, as a state veterinarian, she could and would quarantine Emmy at her facility. (*Ibid.*) Respondent Tyson drove away from LAEC with Emmy. Park rangers arrived just as respondent Tyson was leaving LAEC, but did not intercede.

38. A. During the hearing, respondent testified that the group who confronted her in the parking lot (different from the group who she said confronted her in Barn C) was also an angry mob of people, who shouted expletives and tried to block her truck. Respondent Tyson's testimony is not credited, mainly because the videos described above do not demonstrate any such activity. (Ex. 121.)

B. For example, the videos show, at most, five people in the area, who generally kept their distance from respondent Tyson. (Ex. 121.)

C. On the other hand, respondent Tyson was aggressive and vocal with bystanders. She can be seen leaning toward one woman, telling her in a loud and confrontational way, "so don't give me any of your craziness!" (*Ibid.*)

D. Respondent Tyson also clearly can be heard telling bystanders, "are you kidding me?"; "don't tell me about your quarantine"; "according to state law, as a state veterinarian, I can quarantine my horse"; and "so don't get in my face and tell me what's going to happen to this horse." (*Ibid.*)

39. A. Respondent Tyson also contends she was unaware of the quarantine order on Barn C when she arrived at LAEC, which would explain, in part, why she did not knowingly violate the order. She points out that the actual quarantine order was received and signed for by the General Manager of LAEC, Mr. Chatigny, and there was no proof she or her sister Maureen Tyson received it.

B. However, respondent Tyson did not need to be personally served in order to violate the quarantine order. As explained above, under California Code of Regulations, title 3, sections 1301, subdivision (o), and 1301.1, the CDFA could personally serve the quarantine order for Barns B and C on the person with immediate control over those barns, which in this case was Mr. Chatigny. Thus, the Barn C quarantine order was valid, and under Food and Agricultural Code sections 9691 and 9695, it was unlawful for anyone, including respondent Tyson, to remove Emmy from quarantine.

C. In any event, and as discussed above, it is clear that by the time respondent Tyson arrived at LAEC on November 22, 2016, she was well aware of

quarantine orders issued for LAEC and Barn C. There were also various signs and notices on the premises concerning the quarantine that she had to pass to reach and enter Barn C. In addition, Drs. Olmstead and Fowler, as well as the bystanders in the parking lot, told respondent Tyson of the quarantine.

Respondent Tyson Hides Emmy

40. On November 23, 2016, the day after respondent Tyson removed Emmy from quarantine at LAEC, Dr. Beate Crossley of the California Animal Health and Food Safety Laboratory in Davis, California, received the nasal swab Dr. Peralez collected from Emmy the previous day. The nasal swab was tested, and confirmed that Emmy was positive for EHV-1. Dr. Crossley informed Dr. Fowler of Emmy's positive test result. (Ex. 132, pp. 1-2.)

41. On November 23, 2016, Dr. Fowler texted respondent Tyson that Emmy had tested positive for EHV-1, was a confirmed case of EHM, and demanded that respondent Tyson inform the CDFA where Emmy was located so that the CDFA could issue a quarantine order for that location. (Ex. 124, pp. 1-2.) Respondent Tyson did not respond to Dr. Fowler's demand. (Ex. 124, pp. 2-4.)

42. As a result of respondent Tyson removing Emmy from LAEC and not disclosing the horse's whereabouts, on November 23, 2016, the CDFA issued and served on respondent Tyson a quarantine order covering respondent Tyson's residence and the Crown City clinic. Respondent Tyson's attorney at that time, Carl Douglas, made a timely written request for an informal hearing to contest that quarantine order pursuant to California Code of Regulations, title 3, section 1301.3, subdivision (a). CDFA failed to timely provide respondents a hearing on their appeal.

The quarantine order against respondent Tyson's residence and clinic was therefore rescinded.

43. On November 24, 2016, respondent Tyson left a voicemail for Dr. Olmstead, in which she stated that she had euthanized Emmy. (RT, Vol. IV, 52:3-9.) Dr. Flynn then spoke to respondent Tyson. During that conversation, Dr. Flynn expressed condolences and requested that respondent Tyson tell her where Emmy's remains were located. Respondent Tyson told Dr. Flynn that she did not have "the horse named Emmy," that Emmy was not located in Pasadena, and that the CDFA needed to find Emmy and Emmy's owner to protect the Pasadena horse community. (RT, Vol. IV, 34:2-3, 37:4-10, 38:12-22; ex. 128, pp. 1-2.) The latter part of this response was disingenuous, because, as discussed above, respondent Tyson at all times exerted control and possession of Emmy.

44. Later on November 24, 2016, Dr. Fowler requested that respondent Tyson provide proof of euthanasia. (Ex. 124, pp. 4-5.) Respondent Tyson failed to do so and instructed Dr. Fowler to direct all future requests to her attorney, Mr. Douglas. (Ex. 124, pp. 5-6.)

45. On November 27, 2016, Kathleen Baker sent respondent Tyson the text, "Shame on you for breaking quarantine and endangering other horses. What kind of professional are you?" (Ex. 135, p. 1.) Ms. Baker was a third party who had learned about Emmy being removed from quarantine on Facebook. Respondent Tyson texted Ms. Baker (not to be confused with Emmy's trainer Renee Baker) back, writing, among other things, "The horse remains disease free." (RT, Vol. II, 188:1-4, 188:25-189:6, 190:6-13, 191:13-16, 191:23-192:1; ex. 135, pp. 1-2.) During the hearing, respondent Tyson did not deny or otherwise refute that she had informed Ms. Baker that Emmy was alive as of November 27, 2016.

46. A. On or about November 28, 2016, respondent Tyson had a telephone conversation with Kathleen Hobstetter, a journalist covering the horse community, who had learned about Emmy being removed from quarantine. Respondent Tyson told Ms. Hobstetter that Emmy was her horse, that Emmy was alive, that Emmy was no longer at her clinic, and that she had taken Emmy somewhere safe. (RT, Vol. II, 165:12-17, 168:17-22, 170:18-171:18, 175:23-176:7.)

B. On or about November 29, 2016, respondent Tyson and Ms. Hobstetter spoke again. During that conversation, respondent Tyson again confirmed that Emmy was alive. (RT, Vol. II, 174:4-910.)

C. Respondents' medical chart for Emmy documents one of these telephone conversations with Ms. Hobstetter, in which respondent Tyson characterized Ms. Hobstetter as being aggressive and accusatory. (Ex. 220, p. 9.) However, there is nothing in the note that contradicts any part of Ms. Hobstetter's testimony. In any event, respondent Tyson's testimony did not deny or refute that she told Ms. Hobstetter that Emmy was still alive during both conversations.

47. Between November 22, 2016, and December 8, 2016, neither respondent Tyson nor her attorneys disclosed Emmy's location to the CDFA.

The CDFA's Civil Action Against Respondent Tyson

48. Because of respondent Tyson's failure to disclose Emmy's location after removing her from quarantine at LAEC, on December 8, 2016, the CDFA obtained a preliminary injunction against respondent Tyson (Civil Action) from the Superior Court of the State of California, Los Angeles County (Superior Court), requiring that respondent Tyson disclose Emmy's location. (Ex. 140, pp. 1-3.)

49. A. Respondent Tyson's attorney, Mr. Douglas, filed in the Civil Action two declarations that respondent Tyson signed under penalty of perjury, one filed on December 11, 2016, the second on December 14, 2016. (Exs. 141 & 148.)

B. In her December 11, 2016 declaration, respondent Tyson averred that, on November 22, 2016, she instructed her staff to contact Christopher Slauson, the man who sold her Emmy, and that Mr. Slauson sent his agent, Armando Perez, to the Crown City clinic to pick up Emmy. (Ex. 141, p. 2.) In both declarations, respondent Tyson also averred that she returned to the clinic and euthanized Emmy per Mr. Perez's request on the morning of November 23, 2016. Attached as exhibits were copies of alleged records showing transfer of ownership to Mr. Perez, request for euthanasia by Mr. Perez, and a controlled substances log for the euthanasia. (Ex. 141, pp. 2, 3, 11, 13; ex. 148, pp. 1, 2, 4, 5, 7.)

C. In the December 11, 2016 declaration, respondent Tyson declared that Heritage Disposal picked up Emmy's remains from the Crown City clinic at 4:00 a.m. on November 23, 2016; an alleged receipt for that pickup was attached to the declaration. (Ex. 141, pp. 3, 15.) Respondent Tyson also declared that Emmy's remains were picked up from Heritage Disposal by Stiles Animal Removal on November 25, 2016, and that the receipt attached as exhibit 6 was a true and accurate copy of the receipt for that pickup. (Ex. 141, pp. 3, 17.) Finally, respondent Tyson declared that she had no other information regarding the location of Emmy or her remains. (Ex. 141, p. 3.)

50. As described in more detail below, the CDFA filed declarations from Mr. Slauson, Mr. Stiles, and Francis Gonzalez (an employee of Stiles Animal Removal), indicating that statements in respondent Tyson's declarations were false.

Based on that information, on December 21, 2016, the Superior Court issued an Inspection Warrant pursuant to Code of Civil Procedure section 1822.50, authorizing the CDFA to enter both respondent Crown City's clinic and respondent Tyson's residence (which included the Foundation's animal sanctuary) to search for Emmy. (Ex. 156, pp. 1-2.)

51. On December 23, 2016, the CDFA attempted to find Emmy at respondent Tyson's residence and the Foundation's animal sanctuary. (RT, Vol. I, 143:10-15.) After respondent Tyson and her new attorney (her counsel in this matter, Mr. Newman) arrived, respondent Tyson, through Mr. Newman, suggested the address of the Foundation's animal sanctuary was different than that on the warrant and refused to allow the CDFA to inspect it. (RT, Vol. I, 144:6-20.) No one from the CDFA entered her property at that time. (RT, Vol. I, 144:25-145:1; RT, Vol II, 19:4-7.) The CDFA did not find Emmy at the Crown City clinic. (RT, Vol. I, 144:21-24.)

52. On December 30, 2016, respondent Tyson, through her attorney Mr. Newman, allowed the CDFA to come back to the address on the Inspection Warrant to search the Foundation's animal sanctuary. (RT, Vol. II, 83:14-18; ex. 159, p. 1.) Emmy was not at the sanctuary on that date, but an empty stall at the sanctuary had evidence of recent occupancy by a horse. (RT, Vol. II, 83:14-84:1; ex. 159, pp. 1-2.) Respondent Tyson refused to allow Dr. Olmstead to nasal swab the horses in other stalls at the sanctuary or perform neurologic exams for signs of EHM. (RT, Vol. II, 84:14-20, 84:23-85:9; ex. 159, p. 2.)

53. On January 11, 2017, respondent Tyson informed the CDFA that Emmy's carcass would be at the Crown City clinic the next day. (RT, Vol. VII, 177:19-21.)

54. A. On January 12, 2017, CDFA veterinarian Ann Ikelman, Dr. Olmstead, and CDFA employee Esteban Escobedo, traveled to respondent Crown City's clinic. They had understood from prior communications by respondent Tyson and her attorney that the carcass would be released to them. (RT, Vol. II, 90:2-13; RT, Vol. VII, 23:11-18; ex. 162, p. 1.)

B. Respondent Tyson refused to turn over Emmy's carcass, but allowed the CDFA staff members to take blood and tissue samples. (RT, Vol. VII, 35:3-10; ex. 162, p. 2.) As they were taking samples from the various bags containing the carcass, Dr. Olmstead observed that the carcass appeared fresh and that the bags contained shavings that were similar to those she had observed at the Foundation's animal sanctuary. (RT, Vol. II, 94:10-20, 99:10-24, 140:22-143:5; ex. 164, pp. 2-3.)

C. Respondent Tyson also refused to allow Drs. Ikelman and Olmstead to leave with the samples they collected, insisting instead that Stiles Animal Removal pick up the samples and transport them. (RT, Vol. VII, 37:5-10; ex. 162, p. 2.) The samples were then delivered to the California Animal Health and Food Safety Laboratory in Ontario, California. (RT, Vol. VII, 40:20-23; ex. 162, p. 4.)

D. A DNA test on the samples later confirmed that the horse carcass was Emmy. (RT, Vol. I, 153:6-10; RT, Vol. IV, 74:14-18.)

55. At the CDFA's request, Dr. Francisco Carvallo-Chaigneau of the California Animal Health and Food Safety Laboratory in San Bernardino performed a necropsy on the tissue samples. (RT, Vol. V, 19:25-20:2; exs. 167 & 168.) As Dr. Carvallo-Chaigneau testified at the hearing, and as reflected in his necropsy report, the tissue samples did not show the signs a pathologist would normally observe in the carcass of a horse that had been euthanized many weeks before or had been frozen or refrigerated. (RT, Vol. V, 24:5-16, 25:10-12, 35:23-36:4, 54:22-24; exs. 167 & 168.) Accordingly, he concluded that the samples were fresh; it was likely Emmy had only recently been euthanized; and it was highly unlikely that Emmy had been frozen or refrigerated for an extended period of time. (RT, Vol. V, 41:10-42:14.)²

Respondent Tyson Perjured Herself in the Civil Action

56. Respondent Tyson declared in the Civil Action that Mr. Slauson, and his purported agent Armando Perez, had requested her to euthanize Emmy on November 22, 2016. As explained in his declaration filed in the Civil Action and his testimony at the hearing, Mr. Slauson never spoke with respondent Tyson on or after November 22, 2016; Mr. Slauson did not send anyone to pick up a horse from respondent Tyson on November 22, 2016; Mr. Slauson did not instruct anyone to

² While he could not pin-point a time of death for Emmy, Dr. Carvallo-Chaigneau testified that tissue samples, even if refrigerated continuously post-mortem, still show signs of decomposition within five or six days after death; Emmy's tissue samples showed no such signs.

euthanize Emmy; and Mr. Slauson does not know anyone named Armando Perez. (RT, Vol. I, 175:11-25; ex. 152, p. 2.)

57. A. Similarly, respondent Tyson had declared in the Civil Action that Stiles Animal Removal picked up Emmy's remains from Heritage Disposal early on the morning of November 23, 2016, and she attached documentation of that alleged pickup. However, it was established that there was no such pickup by Stiles Animal Removal on November 23, 2016. (RT, Vol. IV, 94:15-23; ex. 154, p. 3.)

B. Instead, Stephen Stiles, the Vice President of Stiles Animal Removal, persuasively testified that on December 7, 2016, he received a series of calls from a telephone number identified as belonging to "Crown City Med. Group." (RT, Vol. IV, 85:22-25; ex. 154, pp. 2, 5.) The caller identified herself as "Dr. Melissa Tyson." (RT, Vol. IV, 86:1-4; ex. 154, p. 2.) During those phone calls, respondent Tyson asked Mr. Stiles if he would (a) provide her with a receipt even if he did not pick up a dead horse from her, (b) provide her with a blank receipt, and (c) tell any attorney that calls that he picked up a dead horse even if he did not. (RT, Vol. IV, 87:3-9, 87:20-88:2; ex. 154, p. 2.) Mr. Stiles told respondent Tyson that he would not provide her with a false or blank receipt, and he would not lie to any lawyer that called him. (RT, Vol. I, 87:10-15, 88:3-5; ex. 154, p. 2.) Respondent Tyson then told Mr. Stiles she had bags of animal parts that needed to be picked up. (RT, Vol. IV, 88:15-20; ex. 154, p. 2.) After Mr. Stiles asked her why she had bags of animal parts, respondent Tyson did not respond and the conversation ended. (RT, Vol. IV, 88:19-89:3; ex. 154, p. 2.) At this point, Mr. Stiles "suspected something illegal was going on." (Ex. 154, p. 2.)

58. A. Respondent Tyson had also declared in the Civil Action that Heritage Disposal had picked up Emmy's remains from the Crown City clinic early on the morning of November 23, 2016.

B. In reality, respondent Tyson had not contacted Heritage Disposal about such a transaction until December 7, 2016, two weeks later. On that date, respondent Tyson called Michael Arutunian, a family friend and Operations Manager and Vice President of Heritage Disposal, and told him she wanted paperwork indicating that his company had previously disposed of a dead horse. (RT, Vol. IV, 124:9-12; ex. 171, p. 1.) When Mr. Arutunian told her that his company did not do that type of work and could not provide that paperwork, she suggested he call Stiles Animal Removal. (RT, Vol. IV, 124:1-7; ex. 171, p. 2.) He did. (RT, Vol. IV, 125:8-11; ex. 171, p. 2.) During that conversation, Mr. Arutunian asked Mr. Stiles to pick up bags of animal parts. (RT, Vol. IV, 90:1-7; ex. 154, p. 2, ex. 171, p. 2.) Mr. Stiles agreed that his company would come to Heritage Disposal to pick up those bags of animal parts.

C. On December 7, 2016, Heritage Disposal, Mr. Arutunian's company, picked up bags of animal parts from respondent Crown City's clinic, in order to give them to Stiles Animal Removal. (RT, Vol. IV, 126:17-127:8.) Respondent Tyson or her employee, Herbert Ramirez, instructed Mr. Arutunian to obtain a blank copy of a Stiles Animal Removal receipt that they could falsify to reflect the pickup of a horse on November 25, 2016. (RT, Vol. IV, 128:12-129:25, 130:6-15; ex. 171, pp. 2-3.)

59. On the morning of December 8, 2016, Francis Gonzalez, a driver for Stiles Animal Removal, picked up bags of animal parts from Heritage Disposal's Alhambra location. (RT, Vol. IV, 91:15-92:16, 127:15-21.) The bags of animal parts were provided by respondent Tyson, but did not contain Emmy's remains. (RT, Vol. IV, 126:17-127:8; RT, Vol. VII, 20:22-21:7.) At the end of the transaction, at Mr. Arutunian's request, Mr. Gonzalez gave Mr. Arutunian both copies of a receipt (Dead Slip) that was blank except for the pickup location of 704 S. Date Avenue, Alhambra, CA. (RT, Vol. IV, 131:8-16.)

60. At respondent Tyson's or Mr. Ramirez's direction, Mr. Arutunian then filled out a receipt falsely indicating that Heritage Disposal had picked up a dead horse named Emmy at respondent Tyson's clinic on November 23, 2016, and filled out the Dead Slip falsely indicating that Stiles Animal Removal had picked up Emmy at Heritage Disposal on November 25, 2016. (RT, Vol. IV, 131:9-16, 135:10-12, 137:25-138:5; ex. 147, p. 15, ex. 147, p. 17, ex. 171, p. 2, ex. 171, p. 3.) Mr. Arutunian then met with respondent Tyson and gave her the receipt from Heritage Disposal and Dead Slip from Stiles Animal Removal, and those documents were included as exhibits 5 and 6 to the declaration of respondent Tyson filed in the Civil Action on December 11, 2016. (RT, Vol. IV, 138:20-139:4; ex. 147, p. 15, ex. 147, p. 17, ex. 171, p. 2.)

61. Mr. Arutunian was subsequently contacted by an investigator from CDFA. He hired an attorney and began cooperating with CDFA's investigation of this matter. In a declaration he signed on April 24, 2017, and in his testimony at the hearing, Mr. Arutunian admitted the work order and receipt from Heritage Disposal he created were false and back-dated at the request of respondent Tyson.

62. Respondent Tyson admitted during the hearing that her declarations contained falsehoods, and she did not deny that she requested others to help her falsify records.

The Virus Outbreak at LAEC Ends

63. The initial quarantine was placed at LAEC on November 3, 2016. Dr. Crossley testified it was one of the larger outbreaks she had seen. A total of 330 exposed horses were under quarantine at the peak of the outbreak. A total of 15 horses were confirmed positive for EHV-1 and eight horses were diagnosed with EHM; the other seven horses were febrile but had no signs of neurologic disease.

Only one of the horses diagnosed with EHM was euthanized due to the severity of clinical signs. (Vol. I, 94:24-95:4; ex. 111, p. 81.) After respondent removed Emmy from LAEC, three horses tested positive for EHV-1; two of these horses were stalled in Barn C. (Ex. 111, pp. 56, 63, 65.)

64. Emmy was never diagnosed with EHM: Although Emmy tested positive for EHV-1 by the nasal swab, her blood sample tested negative. (Ex. 132.) Dr. Crossley persuasively testified that this was not unusual. The nasal swab test is more sensitive since it can detect the virus for a period of up to 10 days, but a blood test will only show signs of the virus when the host is still viremic (characterized by the presence of a virus in the blood), which is a very short period. The tissue samples received by Dr. Carvallo-Chaigneau on January 12, 2017, were negative for any sign of EHV-1, meaning Emmy had recovered from the virus by the time she had been euthanized. (Ex. 167.) Respondents' expert pathologist, Dr. David W. Gardiner, similarly testified that the tissue samples of Emmy he received and tested when he conducted his own necropsy in January 2017 were disease-free.

65. A. Respondent Tyson never provided a coherent explanation for euthanizing Emmy and the exact date of her death was not established.

B. Her initial contention was false that Emmy had been euthanized on November 23, 2016, as explained above. Moreover, as discussed above, respondent Tyson told Ms. Baker and Ms. Hobstetter, after November 23, 2016, that Emmy was still alive. Finally, Dr. Carvallo-Chaigneau persuasively opined that Emmy had only recently been euthanized when he performed the necropsy on January 12, 2017, suggesting Emmy's death was only five or six days before.

C. Respondent Tyson testified she euthanized Emmy because, when she called her sister Maureen for advice after leaving LAEC with Emmy on November 22, 2016, her sister told her to "just get rid of the horse." While Maureen Tyson corroborated that conversation in her testimony during the hearing, she testified she meant for her sister to either sell Emmy or euthanize her. However, it is unclear why respondent Tyson decided to have Emmy euthanized before trying to sell her. If respondent believed Emmy never had the EVH-1 virus or EHM, it is also perplexing why she decided to euthanize Emmy instead of simply releasing Emmy to the Foundation animal sanctuary, where retired service dogs and unwanted horses and other animals are kept.

D. Based on these circumstances, it was established that respondent Tyson ultimately decided to euthanize Emmy, on a date not established but a significant period after November 23, 2016, and relatively close to January 12, 2017, in order to cover up the false statements in her declarations filed in the Civil Action that Emmy had been euthanized on November 23, 2016.

66. A. As established by the declarations and testimony of Drs. Fowler, Olmstead and Flynn, as well as the testimony of the Board's expert witness Dr. Lisa Franz-Weiss, respondent Tyson's removing Emmy from quarantine, exposing her to other horses, and hiding her location from the CDFA, put at risk the horse population in California. Emmy could have infected any horse she came in contact with, who then could have spread the disease to other horses.

B. Respondent Tyson's behavior also increased the chances that other owners and trainers would violate quarantine orders at LAEC and elsewhere. While CDFA and LAEC staff tried to keep respondent Tyson's quarantine violation from public knowledge, the fact that third parties such as Kathleen Baker and Kathleen

Hobstetter found out about it indicates that some members of the public learned of the violation.

C. As described by Dr. Flynn in her testimony, after respondent Tyson removed Emmy from quarantine, some of the LAEC owners and trainers had become concerned about the situation and questioned whether they also had to keep their horses under quarantine. Dr. Flynn had to reassure those individuals at a number of meetings that CDFA had the situation under control, which made enforcement efforts at LAEC more difficult. (RT, Vol. IV, 44:3-11, 46:8-17, 47:4-6.)

Respondents' Defenses

LACK OF KNOWLEDGE OF THE BARN C QUARANTINE

67. A. In addition to respondents' contentions described above, they offered several other defenses for their actions.

B. For example, respondent Tyson testified she did not know about the quarantine order for Barn C, and argues her lack of knowledge is evidenced by the fact she immediately appealed the quarantine order placed on her residence and clinic. Respondents argue it is reasonable to infer that, had respondent Tyson known of the quarantine order for Barn C, she would have similarly requested a hearing to contest it, as she did with the November 23, 2016 quarantine order.

C. Respondents' argument is unconvincing for several reasons. First, as discussed above, respondent Tyson was probably aware of the quarantine order covering Barn C where Emmy was stabled by the time she arrived at LAEC on November 22, 2016, and certainly aware of it by the time she removed Emmy. Second, respondent Tyson had no remedy regarding the quarantine order covering her

residence or clinic other than appealing it; as to the quarantine covering Barn C, it is clear that she decided it was easier to remove Emmy from LAEC than leave her there and resort to an appeal. Third, respondent Tyson may have realized, on November 23, 2016, that the CDFA was serious about enforcing its quarantines, which she may not have thought was the case the day before when she removed Emmy from LAEC. Finally, respondent Tyson's testimony on this point is self-serving and uncorroborated; in light of her acts of perjury discussed above, her credibility here is suspect.

RESPONDENT TYSON WAS NOT TOLD ABOUT A MOVEMENT PERMIT

68. A. Respondents point to the fact that a horse theoretically could be removed from a quarantine for medical care under proper circumstances. (RT, Vol. II, 118:23-25.) All that would be required was a "movement permit." (RT, Vol. II, 120:1-2.) To obtain such a permit, one only had to contact Dr. Olmstead. (RT, Vol. II, 118:19-22.) Respondents complain that Dr. Olmstead was present and met with respondent Tyson on November 22, 2016, but that Dr. Olmstead failed to advise respondent Tyson about a movement permit.

B. This argument is also unconvincing. Respondent Tyson's status as an APHIS veterinarian makes it hard to believe she did not know about being able to request a movement permit for a medical situation. Next, as demonstrated by her statements to Renee Baker, Caryn McDaris, and Dr. Fowler, it is clear that respondent Tyson fully intended to remove Emmy regardless of the circumstances. It strains credulity to believe she would have stopped and asked Dr. Olmstead to fill out a movement permit. In any event, it was very unlikely that Dr. Olmstead would have given such a permit to respondent Tyson, given that Emmy was exhibiting symptoms of EHM, respondent Tyson was not cooperating, and the CDFA had a practice only to issue movement permits for horses that are safe to travel to an approved location and

will be quarantined at that location. Respondent Tyson demonstrated nothing indicating she would disclose Emmy's location once removed or otherwise cooperate with CDFA efforts to monitor her situation.

EMMY NEVER HAD A DISEASE

69. A. Respondents have always maintained that Emmy was not suffering from a disease on or after November 22, 2016. In support, respondents refer to the fact that after she had removed Emmy from LAEC, respondent Tyson sent a text to State Veterinarian Dr. Jones stating that she did not believe Emmy had been exposed to the virus because no horse within 30 feet of her had a positive nasal swab for more than three weeks. (Ex. 208, p. 4.) Respondent Tyson also testified Emmy did not exhibit any signs of a virus when she saw her at Emmy's stable. Respondent Tyson also points to the fact that Dr. Crossley testified a nasal swab sample of Emmy taken by respondent Tyson on November 23, 2016, tested negative for EHV-1. Respondent Tyson also testified that she believed the negative blood test result indicated Emmy did not have EHV-1. Respondent Tyson also pointed to her prior concerns about equine husbandry and maintenance of the LAEC stables, which she previously expressed in her October 2016 complaint letter to LAEC.

B. First, whether or not respondent Tyson believed Emmy was infected with EHV-1 at the time she removed Emmy from quarantine is irrelevant to whether respondent Tyson violated the quarantine order. As established by the testimony of Drs. Fowler, Olmstead, Flynn, and Franz-Weiss, an apparently healthy horse that has been exposed to EHV-1 could develop and spread that disease. Regardless, there are no exceptions from a quarantine order under the Food and Agricultural Code simply because a licensed veterinarian believes an animal under quarantine is nonetheless disease-free.

C. Second, the evidence respondents rely upon fails to call into question Dr. Peralez's diagnosis of EHM or the positive EHV-1 test result on Emmy's nasal swab. As discussed above, Dr. Crossley testified that testing nasal swabs for EHV-1 is more reliable than testing blood because it has a longer window in which positive results may be observed. (RT, Vol. III, 178:4-179:8.) Similarly, none of the results of other tests discussed by Dr. Tyson are reliable. They do not indicate whether Emmy had EHV-1 at the time she was removed because those results related to the body's immune response to EHV-1 and not the presence of the virus itself; they post-dated Emmy's removal from quarantine by a substantial period of time; and were obtained from tests performed by unaccredited laboratories on samples that were collected and stored in less than desirable media (like gel). (See, e.g., RT, Vol. V, 58:3-9; RT, Vol. VI, 27:4-24; ex. 220, pp. 10-11.) In addition, a total of 15 horses at LAEC were confirmed positive for EHV-1, including three in Barn C, and respondent Tyson never provided a theory regarding what was causing the horses at LAEC to become ill. (Vol. I, 94:24-95:4; ex. 111, pp. 29, 63, 65, 81.)

D. As discussed above, respondent Tyson failed to corroborate the validity of her expressed concerns regarding the care Emmy was receiving at, or the general condition of, LAEC. Respondent Tyson also undercut her purported concern about Emmy when she testified that she had no qualms over euthanizing Emmy simply because she had nowhere to stable her. (RT, Vol. VIII, 41:7-12.)

DR. PERALEZ IS ACCUSED OF A FALSE DIAGNOSIS

70. A. Respondents also contend Dr. Peralez erroneously reported that Emmy had a fever when he examined her on November 22, 2016. Respondents contend Dr. Peralez must have submitted a contaminated nasal swab, because the blood he submitted from Emmy tested negative for EHV-1. Respondents also point

out that Dr. Perez would have been going between barns and isolation, and therefore surmise that he somehow carried the virus with him and infected the nasal swab.

B. Respondents also contend Dr. Perez erroneously claimed Emmy had neurologic movement problems, because they claim that videos showed otherwise as Dr. Tyson loaded Emmy into the trailer.

C. At the time of these events, Dr. Perez had two or three clients at the Flintridge Riding Club, which respondent Tyson had sued. (RT, Vol. III, 143:5-7.) Dr. Perez learned of the events that took place at the Flintridge Riding Club involving respondent Tyson sometime in 2017. (RT, Vol. III, 143:18-24.) From these facts, respondents suggest Dr. Perez may have been motivated to falsely claim Emmy was symptomatic of EHV-1 so he could place her in isolation.

D. This defense involving Dr. Perez is sheer conjecture and completely lacking in merit. The only two videos in evidence (ex. 121) start when Emmy was already in respondent Tyson's trailer. Dr. Perez was not the only witness who diagnosed Emmy as having symptoms compatible with EHM; Dr. Olmstead reached the same conclusion. As an equine specialist with a great deal of experience examining horses in a quarantine setting, Dr. Perez testified that he followed biosecurity measures to prevent the spread of the virus, or the contamination of the nasal swab. (RT, Vol. II, 58:23-59:10, 143:18-144:6; RT, Vol. III, 108:11-14, 113:4-22, 115:10-15, 117:13-25.) Moreover, it is not clear how his knowledge of the events concerning the Flintridge Riding Club lawsuit would create any animus toward respondents when he only learned about those events well after the events that occurred at LAEC.

THE RESCINDED NOVEMBER 23, 2016 QUARANTINE

71. A. Respondents argue there was no valid quarantine that was violated because the CDFA rescinded the November 23, 2016 quarantine order placed on respondent Tyson's residence and clinic. Respondents also point out that the Civil Action was ultimately dismissed by CDFA without any further action, other than as described above, on April 28, 2017, after Mr. Newman filed a Demurrer in that case.

B. The fact that the November 23, 2016 quarantine order was rescinded had no impact on the earlier quarantine placed on Barn C, which was still in effect when respondent Tyson removed Emmy.

C. The fact that the Civil Action was dismissed without prejudice by the CDFA has no collateral estoppel or other legal impact on this proceeding, as was explained previously in the ALJ's Order dated October 15, 2018, denying respondents' Demurrer and Request for Dismissal filed in this case. There were no issues necessarily decided in the prior matter, and no final judgment on the merits. Without such, issue preclusion does not apply. (*Ronald F. v. State Dept. of Developmental Services* (2017) 8 Cal.App.5th 84; *Shor v. Department of Social Services* (1990) 223 Cal.App.3d 70.)

LACK OF KNOWLEDGE THAT THE CDFA WAS LOOKING FOR EMMY

72. A. Respondent Tyson testified that she did not know the CDFA was looking for Emmy after she removed Emmy from LAEC. Respondent Tyson's testimony is fanciful in light of the overwhelming contrary evidence.

B. For example, in the days after she removed Emmy from quarantine, respondent Tyson had multiple conversations and text exchanges with

CDFA staff, who each time requested that she disclose Emmy's location and submit proof of euthanasia. On November 23, 2016, respondent Tyson was served with a quarantine order for her residence and clinic, which her attorney appealed. After respondent Tyson told the CDFA to contact her attorney instead of her, the CDFA directed requests to her attorneys for Emmy's location. The CDFA thereafter obtained a preliminary injunction order requiring respondent Tyson to disclose Emmy's location and then an Inspection Warrant to search her residence and clinic. Respondent Tyson signed two declarations in the Civil Action. Even assuming arguendo that she did not read her own declarations before signing them, respondent Tyson must have known the CDFA was looking for Emmy after she was served with process in the Civil Action and therefore had to hire legal counsel.

C. The fact that respondent Tyson concocted a scheme to lie about Emmy being euthanized on November 23, 2016, and enlisted Mr. Arutunian to help her, also corroborates her knowledge that the CDFA was still looking for Emmy. Finally, respondent Tyson was present when the CDFA tried to execute the Inspection Warrant at her residence on December 23, 2016, and again when she allowed the Department to inspect the Foundation's animal sanctuary on December 30, 2016.

MR. DOUGLAS IS BLAMED FOR THE FALSE DECLARATIONS

73. A. Respondent Tyson conceded in her testimony that there were many false statements in her declarations filed in the Civil Action. However, she denies having committed perjury; she testified instead that Mr. Douglas was responsible for writing them, which she signed without reading. Respondents therefore argue that it was Mr. Douglas who made the false statements to the court in the Civil Action, not respondent Tyson. Respondents conclude that because CDFA

elected not to pursue any contempt proceedings in the Civil Action, which they argue was the proper venue to contest the truth of the declarations, respondent Tyson has never had an opportunity to defend against any such claims.

B. It became clear from the evidence and respondent Tyson's testimony that she is an intelligent, well-educated woman, who would not allow herself to be bullied or forced to do something she did not want to do; and that she would not sign an important legal document without reading it. She testified she did not know what perjury is, did not know it was a crime to lie under oath, and did not know that it was wrong to lie under oath. (RT, Vol. VIII, 120:13-15, 121:7-15, 121:19-23.) This testimony is not credible and greatly undermined her credibility in this case.

C. Moreover, it is not clear how her prior attorney would have obtained the detailed information contained in the declarations unless it was provided to him by respondent Tyson, including the names of those involved (Messrs. Stiles, Arutunian, and Slauson) and the documents attached to them. As explained in great detail above, the evidence clearly demonstrated that it was respondent Tyson who contacted Mr. Stiles and Mr. Arutunian to solicit them to help her generate false documents. Respondent Tyson had an opportunity in this case to defend herself against claims that she committed perjury, but she chose not to, other than her claim against Mr. Douglas.

Expert Opinions on Professionalism

74. Complainant presented the expert witness testimony of Lisa Franz-Weiss, a licensed veterinarian with over 30 years' experience in California who, for the past several years, has also served as a medical consultant and hospital inspector for

the Board. Dr. Franz-Weiss reviewed summaries of interviews with various witnesses, statements, and other documents concerning the events in question. She wrote a detailed report describing the information she reviewed and her understanding of the events. (Ex. 15.) In her report, and during her testimony at hearing, Dr. Franz-Weiss offered several opinions about respondent Tyson's conduct as compared with veterinary professional standards in this state. Her opinions were persuasive, well-supported, and virtually unopposed by respondents, who offered no competing expert opinion evidence other than respondent Tyson's testimony.

75. Specifically, it was established by Dr. Franz-Weiss's persuasive report and testimony that respondent Tyson acted unprofessionally by violating the mandatory quarantine in place on Barn C at LAEC on November 22, 2016. She removed Emmy, after the horse had exhibited clinical signs of a contagious disease and had been designated for isolation, without consent from the State Veterinarian. By doing so, respondent Tyson violated state law, without good reason or justification, and presented a significant risk of spreading the virus to other horses on and off the premises. (Ex. 15, p. 298-299.)

76. It was also established by Dr. Franz-Weiss's persuasive report and testimony that respondent Tyson acted unprofessionally when she failed to comply with enhanced biosecurity measures in place at LAEC on November 22, 2016. By doing so, respondent Tyson presented a significant risk of spreading the virus to other horses on and off the premises. (Ex. 15, pp. 298-299.)

77. For the same reason, it was established by Dr. Franz-Weiss's persuasive report and testimony that respondent Tyson acted unprofessionally by causing more than a 30-day delay in the containment of the spread of the EHV-1 virus and the potential spread of the virus to other horses, by using deception to hide Emmy's whereabouts, and by refusing to disclose Emmy's location to the CDFA.

Evidence of Mitigation, Aggravation and Rehabilitation

78. Respondent Tyson had six or seven other horses stabled at LAEC, but Emmy was the only horse she removed. She argues this shows she is not likely to commit similar misconduct in the future. This evidence has little probative value because there is no evidence suggesting any of the other horses were suspected of having a disease. If there had been such a suspicion about any of her other horses, the evidence indicates that respondent Tyson would have removed them.

79. Respondent Tyson testified that at all times Emmy was kept isolated from her other animals. For example, she drove Emmy alone in an enclosed trailer to her clinic, where she kept Emmy in isolation. However, respondent Tyson presented no corroboration. The fact she has consistently stated Emmy was not sick, and that she took affirmative steps to keep Emmy's location hidden from the CDFA, calls into question whether Emmy in fact was kept in isolation.

80. A. Respondent Tyson began seeing clinical psychologist Barbara Janetzke in January 2017. Respondent Tyson reported to Dr. Janetzke feelings of stress and depression stemming from the events at the Flintridge Riding Club in September 2015 and from LAEC in November 2016. Dr. Janetzke saw respondent

Tyson periodically through May 2019. Dr. Janetzke ultimately diagnosed respondent Tyson with post-traumatic stress disorder (PTSD).

B. Dr. Janetzke testified that, because of the events respondent Tyson experienced at the Flintridge Riding Club, she was hyper-aroused, hyper-vigilant, and extremely distrustful of other people by the time she became embroiled in the events at LAEC. As a result of respondent Tyson's suffering from PTSD on and after November 22, 2016, Dr. Janetzke believes respondent Tyson's cognitive and rational skills were so compromised that she did not intend to deceive CDFA when she refused to disclose Emmy's location. Respondents argue that Dr. Janetzke's observations help explain why respondent Tyson would hide Emmy from the CDFA and thereafter signed declarations her attorney prepared containing false information.

C. While the validity of Dr. Janetzke's diagnosis of respondent Tyson's PTSD is not necessarily called into question, the possible effects of the disorder Dr. Janetzke attributes to respondent Tyson's actions are contradicted by the weight of the evidence and therefore not convincing. For example, Dr. Janetzke's opinion was based solely on information that respondent Tyson and her attorney Mr. Newman provided to her. (RT, Vol. VI, 70:10-13, 74:10-14, 83:22-84:10.) This is important because Dr. Janetzke was not aware that respondent Tyson, with the help of Mr. Arutunian, had executed her intricate plan to deceive the CDFA with false declarations and documents purporting to show Emmy had been euthanized and picked up for rendering on November 23, 2016.

D. Dr. Janetzke's opinion also conflicts with other evidence. For example, instead of avoiding potential conflict, as one would suspect someone suffering from PTSD would do, respondent Tyson returned to LAEC to take nasal swabs of other horses on November 30, 2016. (RT, Vol. VIII, 118:23-119:1.) Moreover,

respondent Tyson testified that she continued to practice as a veterinarian, a stressful job, in the months after she removed Emmy from quarantine, and that during that time she knew the difference between right and wrong. (RT, Vol. VIII, 119:6-11, 121:16-18 [respondent Tyson]; see also RT, Vol. VI, 85:10-15 [Dr. Janetzke].)

E. Dr. Janetzke's records show she only met with respondent Tyson three times in January 2017, three times in 2018, and twice in 2019. (Ex. 227, p. 2.) This sparse treatment regimen is not indicative of a pervasive condition. To the contrary, the progress notes for those visits consistently record that respondent Tyson's "[j]udgment is good." (*Ibid.*) Those notes suggest respondent Tyson's cognitive and rational thinking skills were not impacted as badly as depicted by Dr. Janetzke during the hearing.

F. Interestingly, Dr. Janetzke's January 18, 2017 note indicates respondent Tyson "verbalizes awareness of problems, but blames on [sic] others." (Ex. 227, p. 8.) During the January 31, 2018 session, respondent Tyson told Dr. Janetzke, "She feels she is ready to have her license taken and that she will shift her focus to other projects involving horses. She is more angry about the possibility of having to pay the CA board's legal fees." (*Id.*, p. 10.) These notes show a confluence of the following thoughts: respondent Tyson blames others for the events in question; demonstrates no remorse for her own conduct, but instead is angry that she may be required to reimburse the legal fees and costs incurred as a result of her actions; and she realizes on some level that her actions were serious enough to make revocation of her license a distinct possibility.

81. Respondents presented character reference letters from veterinarian Valerie Talleyrand, who had worked several years for respondents, as well as Sara Shatford Layne and MaryMichael Swenson, both long-time clients who take their pets

to respondents. (Ex. 225.) All three also testified. They described respondent Tyson as an honest, caring and expert practitioner, and they offered their unflinching support of her in this matter. However, the probative value of their opinions concerning respondent Tyson's character is greatly diminished by their imperfect understanding of the details behind respondent Tyson's violation of the LAEC quarantine and their complete lack of knowledge that she perjured herself in the Civil Action. In a sense, these character witnesses crystalize perhaps the most perplexing aspect of this case: how someone as talented and able as respondent Tyson could act so unprofessionally and deceptively with so little to gain by such actions.

82. Other than her treatment with Dr. Janetzke, respondent Tyson offered no evidence of rehabilitation. Dr. Janetzke testified that respondent Tyson's treatment has concluded, her PTSD is now in remission, and she is safe to practice as a veterinarian at this time.

83. In aggravation, her sister Maureen testified that respondent Tyson has never shown remorse for euthanizing Emmy. As discussed above, respondent Tyson offered no remorse or contrition about her conduct when treating with Dr. Janetzke. During the hearing, respondent Tyson did not appear to be remorseful or contrite in the least for her actions. As chronicled above, she still blames others for her misfortunes and it is apparent she has never accepted any responsibility.

84. In aggravation, it became clear from respondent Tyson's testimony on cross-examination that respondent Crown City's staff members had little supervision

or oversight. Rather they had almost unfettered access to controlled substances, and were not required to maintain comprehensive or accurate controlled substances logs.

Costs

85. A. The Board submitted evidence of having incurred the following costs in this matter totaling \$30,733.50:

B. Investigative costs totaling \$4,071 investigating the complaint in its case number 17-10947-VM. That was a complaint the Board had received about respondent Tyson purportedly falsely impersonating a state officer when she visited LAEC to take nasal swab samples from other horses on November 30, 2016. (Ex. 4.)

C. Investigative costs totaling \$5,015 investigating the complaint in its case number 17-10899-VM. That was a complaint the Board had received from CDFA's attorneys who prosecuted the Civil Action against respondent Tyson for violating the quarantine at LAEC. (Ex. 5.)

D. Expert witness costs totaling \$1,237.50 associated with Dr. Franz-Weiss's review of materials pertaining to the two complaints described above. (Ex. 15.)

E. Prosecution costs totaling \$20,410 representing the attorneys' fees billed to the Board by the Office of the Attorney General (AGO) in this matter.

86. A. The investigative costs related to the CDFA's complaint to the Board concerning respondent Tyson's violation of the quarantine (Board case no. 17-10899-VM), as well as the attorney fees billed by the AGO in this matter, are reasonable.

B. The Board ultimately decided to not file charges against respondent Tyson concerning the complaint that she had impersonated a state officer at LAEC on November 30, 2016, concluding there was insufficient evidence. (Ex. 4, p. 150.) Dr. Franz-Weiss reached the same conclusion. (Ex. 15, p. 297.) Thus, the costs related to that complaint are not reasonable. They do not demonstrate that respondents violated any part of the Veterinary Medicine Practice Act. Since Dr. Franz-Weiss did not provide a break-down of her total review costs, it is concluded that half of her costs were devoted to reviewing the complaint concerning the events of November 30, 2016. Under these circumstances, a reduction of \$4,689.75 from the Board's total costs is warranted.

87. Based on the above, the Board incurred reasonable costs in investigating and prosecuting this matter totaling \$26,043.75.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. The burden of proof in this licensing disciplinary matter is on complainant. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 855-856.)

2. A. The standard of proof for disciplining a professional license is clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance, supra*, 135 Cal.App.3d at pp. 855-856.) Respondent Tyson's license is a professional one warranting this standard, a point of which the parties agree.

B. The parties do not specifically address whether the clear and convincing standard also applies to respondent Crown City, but neither argued the lower preponderance of the evidence standard applies. While the ALJ is not concluding a veterinarian premises permit is a professional license, the clear and convincing standard is nonetheless also applied to respondent Crown City because all of the factual findings herein were established using the higher standard.

C. The clear and convincing standard has been defined as meaning proof that is clear, explicit, and unequivocal; so clear as to leave no substantial doubt and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.)

Cause for Discipline Against Respondents

3. A. Business and Professions Code section 4883, subdivision (g),³ allows the Board to revoke, suspend, or assess a fine against a license for unprofessional conduct. As discussed above in Factual Findings 19-23, Food and Agricultural Code sections 9562, 9563, 9564 and 9691 provide the CDFA with legal authority to issue and enforce quarantines over animals suspected of having serious, contagious diseases.

B. Respondents Tyson and Crown City are subject to disciplinary action under section 4883, subdivision (g), in conjunction with Food and Agricultural Code sections 9562, 9563, 9564 and 9691, in that it was clearly and convincingly established that respondent Tyson acted unprofessionally by violating a mandatory quarantine issued by the CDFA for LAEC on November 22, 2016, when she removed

³ Unspecified statutory references are to the Business and Professions Code.

the horse Emmy from mandated quarantine premises after Emmy had exhibited clinical signs of a contagious disease. Respondent Tyson further engaged in unprofessional conduct when she failed to comply with enhanced biosecurity measures on November 22, 2016, before and after entering Barn C at LAEC to remove Emmy from the premises. (Factual Findings 1-39, 67-73 & 74-77.)

C. Respondents unconvincingly argue section 4883, subdivision (g), only provides discipline for unprofessional conduct when a licensee has been convicted of a drug-related crime (subd. (g)(1)), has used a drug or controlled substance improperly (subd. (g)(2)), or otherwise violated a state or federal rule or law pertaining to dangerous drugs or controlled substances (subd. (g)(3)), because those are the only acts specifically described in subdivision (g). However, section 4883, subdivision (g), also provides that unprofessional conduct "includes, but is not limited to" what is described in subdivision (g)(1) through (g)(3). The phrase "is not limited to" means unlisted conduct may still be "unprofessional conduct" subject to discipline. (*Gillis v. Dental Bd. of California* (2012) 206 Cal.App.4th 311, 320, disapproved of on other grounds by *Dhillon v. John Muir Health* (2017) 2 Cal.5th 1109.) This is because it is a general rule of statutory construction that use of the language "including, but not limited to" in the statutory definition is a phrase of enlargement rather than limitation. (*People v. Arias* (2008) 45 Cal.4th 169, 182.)

4. A. In addition to the aforementioned section 4883, subdivision (g), the Board may also discipline a license for "[f]raud or dishonesty in applying, treating, or reporting on tuberculin or other biological tests" (§ 4883, subd (d)); and "[a]iding or abetting in any acts that are in violation of any of the provisions of this chapter" (§ 4883, subd. (j)).

B. It was not established that respondents are subject to disciplinary action under section 4883, subdivisions (d), (g) and (j), in that it was not clearly and convincingly established that on November 22, 2016, respondent Tyson acted unprofessionally by misrepresenting that Emmy did not have a fever and was not displaying signs of illness in connection with her removal of Emmy from Barn C at LAEC. While Drs. Peralez and Olmstead, in their capacity as CDFA designees, had concluded Emmy had such signs of illness and suspected she may have been infected with EHV-1, such matters are subject to professional differences, and it is entirely possible that respondent Tyson believed otherwise. Thus, while the evidence clearly established that Emmy had a fever and had displayed signs of neurological deficits consistent with EHV-1, it was not clearly and convincingly established that respondent knew otherwise and purposely misrepresented Emmy's condition when she removed her from LAEC. (Factual Findings 1-39, 67-73 & 74-77.) As explained above, respondents' misconduct consisted of knowingly violating a quarantine order and thereafter hiding Emmy from the CDFA.

5. A. Respondents Tyson and Crown City are subject to disciplinary action under section 4883, subdivisions (g) and (j), in conjunction with Food and Agricultural Code section 9695 (see Factual Finding 23), in that it was clearly and convincingly established that respondent Tyson acted unprofessionally by failing to disclose the location of Emmy, an infected horse, after the horse was unlawfully removed from LAEC mandatory quarantine on November 22, 2016.

B. More specifically, when the CDFA requested several times that respondent Tyson provide Emmy's location, she failed and refused, even after the CDFA obtained a court-ordered preliminary injunction and then an Inspection Warrant under Code of Civil Procedure section 1822.50. Respondent Tyson's actions caused

more than a 30-day delay in the containment of the EHV-1 virus and the potential exposure of the virus to other horses. (Factual Findings 1-39, 40-55, 67-73 & 74-77.)

C. Respondent Tyson argues she was suffering from PTSD during the events in question and therefore did not understand the CDFA was looking for Emmy after she removed Emmy from LAEC, and that, in any event, it was not proven that she actually knew before January 2017 that the CDFA was still looking for Emmy. But respondents did not prove those two contentions as a matter of fact. (See, e.g., Factual Findings 72 & 80.)

6. A. In addition to the aforementioned section 4883, subdivision (j), the Board may discipline a license for "[v]iolation or attempting to violate, directly or indirectly, any of the provisions of this chapter" (§ 4883, subd. (c)); and for "[f]raud, deception, negligence, or incompetence in the practice of veterinary medicine" (§ 4883, subd. (i)).

B. Respondents are subject to disciplinary action under section 4883, subdivisions (c), (i) and (j), in that it was clearly and convincingly established that respondent Tyson engaged in deception with the CDFA when she failed to disclose the true circumstances relating to the date and time of the euthanasia of Emmy after respondent Tyson had unlawfully removed Emmy from the mandatory quarantine. In fact, respondent Tyson committed acts of perjury in proceedings before the Superior Court by falsely stating that she had euthanized Emmy on November 23, 2016, when, in fact, she had euthanized Emmy significantly later, though the precise date was not established. (Factual Findings 1-39, 40-55, 56-66 & 67-73.)

C. Respondents argue section 4883, subdivision (i), was not violated because respondent Tyson's acts of deception were related to her perjured declarations in court filings, which did not involve "the practice of veterinary medicine" as is required by subdivision (i). However, respondent Tyson's acts of deception were tightly intertwined with her actions as Emmy's veterinarian, i.e., vaccinating and caring for Emmy before the quarantine, evaluating Emmy for signs of EHM before removing her from LAEC, removing Emmy from LAEC purportedly to protect her health, her decision to place Emmy in her own quarantine at another location, and her later decision to euthanize Emmy. The relationship between respondent Tyson's acts of deception and her care for Emmy as a veterinarian show her deception was indeed related to her practice of veterinary medicine.

Disposition

7. A. The purpose of licensing statutes is to protect the public. (*Clerici v. Department of Motor Vehicles* (1990) 224 Cal.App.3d 1016.)

B. In determining the level of discipline to be imposed in this case, the ALJ considered the Board's *Disciplinary Guidelines* [effect. July 2012] (Guidelines). For the violations established in this case, i.e., section 4883, subdivisions (g), (i), (j), and (c), the Guidelines recommend revocation as the maximum discipline, and a stayed revocation under probation for two years with various terms as the minimum discipline.

C. In this case, revocation is clearly warranted by respondent Tyson's egregious misconduct. She knowingly violated a quarantine designed to protect the health of animals, something a state-licensed and APHIS-accredited veterinarian should know not to do. Respondent Tyson thereafter hid Emmy and purposely

confounded the CDFA's ability to find Emmy and enforce its quarantine. She thereafter committed several acts of perjury in the Superior Court by falsely declaring that Emmy was euthanized on November 23, 2016, which in fact did not occur. Respondent Tyson ultimately euthanized a healthy animal, Emmy, when she did not have to, simply to cover up her prior acts of perjury. Killing a healthy animal should be anathema to a veterinarian. And yet, respondent Tyson has exhibited no remorse for that action.

D. Respondents presented some evidence of mitigation, namely many years of unblemished service as a licensed veterinarian and many happy customers. The Foundation has apparently also done good works for animals. However, the severity of respondent Tyson's conduct and aggravating facts greatly outweigh the mitigation. For example, respondent Tyson has demonstrated no remorse for any of her acts in this case. Inasmuch as all of her denials and defenses were either not established or patently unbelievable, it is apparent that respondent Tyson has never accepted any responsibility for her misconduct. Her actions also made the CDFA's enforcement efforts to contain the EHM outbreak at LAEC much more difficult and expensive. She presented little evidence of rehabilitation, other than limited treatment for PTSD with Dr. Janetzke. Under these circumstances, public protection warrants revocation of her license. (Factual Findings 1-84; Legal Conclusions 1, 2, 3, 5 & 6.)

E. When a licensee operates its licensed business through employees and agents, the licensee must be responsible to the licensing authority for the employees' and agents' conduct in the exercise of the license. (*Mantzoros v. State Bd. of Equalization* (1948) 87 Cal.App.2d 140, 144.) In this case, respondent Crown City is owned and controlled by respondent Tyson, and therefore is responsible for the actions of respondent Tyson. No argument was advanced that respondent Crown City

should be disciplined differently than respondent Tyson. **Therefore, its premises permit also should be revoked.** (Factual Findings 1-84; Legal Conclusions 1, 2, 3, 5 & 6.)

8. Section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation of her governing licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case. Here, it was established that respondents violated provisions of the Veterinary Medicine Practice Act, and that the reasonable costs incurred by the Board in investigating and prosecuting this matter are \$26,043.75. (Factual Findings 85-87; Legal Conclusions 3, 5 & 6.)

9. Section 4883 allows the Board to assess a fine, as provided in section 4875, for a violation of any subdivision of section 4883. Under section 4875, the Board has the authority to assess a fine not in excess of \$5,000 against a licensee for any of the causes specified in section 4883, and that such a fine may be assessed in lieu of, or in addition to, a suspension or revocation. In light of the revocation of their licenses, assessing an additional \$5,000 fine against respondents is not necessary to protect the public and therefore not warranted.

ORDER

Veterinary Medical License Number VET 13995, issued to respondent Melissa Ann Tyson, is revoked.

Premises Permit Number HSP 5890, issued to respondent Crown City Veterinary Medical Group, Inc., is revoked.

Respondents Melissa Ann Tyson and Crown City Veterinary Medical Group, Inc., jointly and severally, are ordered to pay the Veterinary Medical Board the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3, in the amount of \$26,043.75.

DATE: September 12, 2019

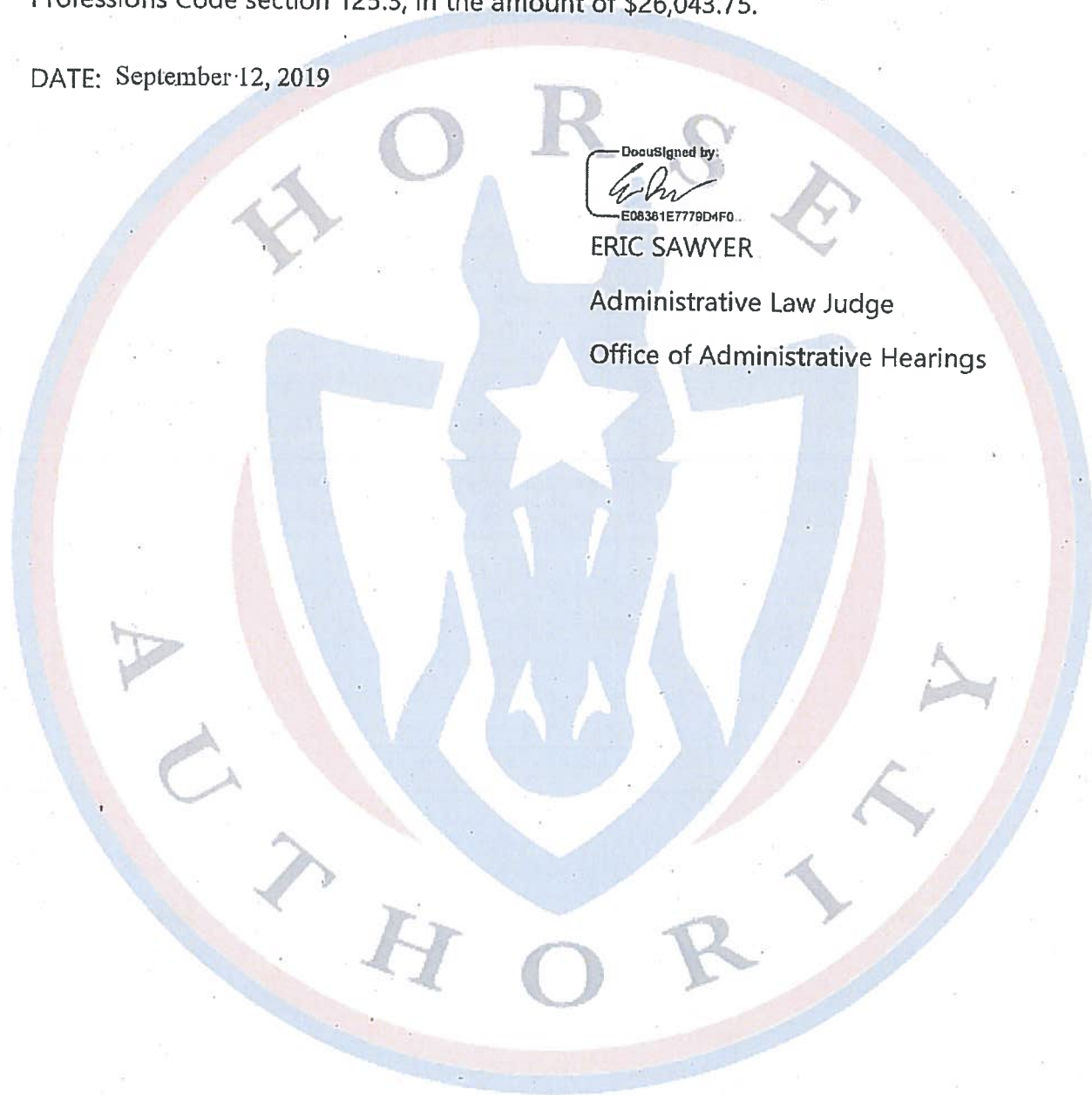
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ERIC SAWYER

Administrative Law Judge

Office of Administrative Hearings



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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ **Ownership Change** (Provide current license number if making changes: **PH 02716**)

Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,7

☐ Partnership – Pages 1,2,5,7

☒ Non Publicly Traded Corporation – Pages 1,2,4,7

☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Drug Depot, LLC d/b/a APS Pharmacy

Physical Address: 34911 Us Hwy. 19 N., Suite 600

Mailing Address: Same as physical address.

City: Palm Harbor State: Florida Zip Code: 34684

Telephone: 727-787-4137 Fax: 727-781-7361

Toll Free Number: 855-787-4137 (Required per NAC 639.708)

E-mail: info@apsmeds.com/ Website: www.apsmeds.com

nmarling@apsmeds.com

Managing Pharmacist: George Chrysakis License Number: PS36009 (PIC)

PH 20986 (Pharmacy)

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

☒ ☐ Retail

☐ ☒ Hospital (# beds)

☐ ☒ Internet

☐ ☒ Nuclear

☐ ☒ Ambulatory Surgery Center

☒ ☐ Community

☐ ☒ Other:

All boxes must be checked

For the application to be complete

Yes/No

☐ ☒ Off-site Cognitive Services

☐ ☒ Parenteral **

☐ ☒ Parenteral (outpatient)

☐ ☒ Outpatient/Discharge

☒ ☐ Mail Service

☐ ☒ Long Term Care

☒ ☐ Sterile Compounding **

☒ ☐ Non Sterile Compounding

☒ ☐ Mail Service Sterile Compounding **

☒ ☐ Other Services: Veterinary

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
**Please see attached supplemental response.
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jaime Rios
Print Name of Authorized Person

Date

Page 2

Board Use Only

Date Processed: 4/20/2020

Amount: 500-

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: To be supplementedParent Company if any: See attached ownership informationMailing Address: 34911 US Hwy. 19 N., Suite 600City: Palm Harbor State: Florida Zip: 34684Telephone: 727-787-4137 Fax: 727-781-7361Contact Person: George Chrysakis, Pharmacist In Charge

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A See attached Corporate Information and Structure Chart

Name

Address

b)

Name

Address

c)

Name

Address

d)

Name

Address

2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 8:30 am 5:00 pmSaturday N/A am _____ pmSunday N/A am _____ pm24 Hours N/AA Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

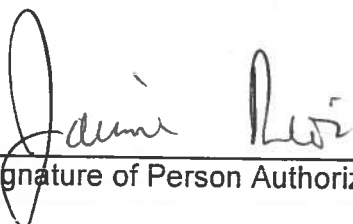
I, Jaime Rios

Responsible Person of Drug Depot, LLC d/b/a APS Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Jaime Rios
Print Name of Authorized Person

3/23/20
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Ohio)
) ss.
Franklin COUNTY)

I, Jaime Rios, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Corporate President for Drug Depot, LLC d/b/a APS (the Pharmacy

Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

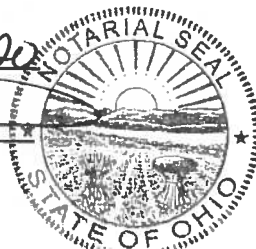
5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Jaime Rios, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
 before me, a notary public this
23 day of March, 2020

NOTARY PUBLIC



Name

Jaime Rios
 WILLIAM BRAUN
 Notary Public, State of Ohio
 My Commission Expires 12-22-2020

C#8637985

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/09/2018	PH 20986	104254

he PHARMACY

named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

DRUG DEPOT INC

PS PHARMACY

4911 US 19 N, SUITE 600

ALM HARBOR, FL 34684

QUALIFICATION(S):

SCHEDULE II & III

COMMUNITY PHARMACY

3:1 PHARMACY TECHNICIAN RATIO APPROVED

STATE OF FLORIDA	AC#	8637985
DEPARTMENT OF HEALTH		
DIVISION OF MEDICAL QUALITY ASSURANCE		
DATE	LICENSE NO.	CONTROL NO.
11/09/2018	PH 20986	104254

The PHARMACY
named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

DRUG DEPOT INC



Rick Scott
GOVERNOR



Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

QUALIFICATION(S):
Schedule II & III
Community Pharmacy
3:1 Pharmacy Technician Ratio Approved

EXPIRATION DATE: **FEBRUARY 28, 2021**

Your license number is PH 20986. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

Medical Quality Assurance has a new and improved Online Services Portal. In the new system, you have the ability to renew your license, update your mailing and practice location addresses, request a name change, request a duplicate license and update your profile information all from the convenience of your online account.

1. Go to www.FLHealthSource.gov.
2. Click on "Provider Services" and select "Manage Your License."
3. Select your profession and license type and click "Submit."
4. The question "Have you Registered in Our New Online Service System?" will display.
 - a. Click on "No" if you have not registered for an account in the new system and follow the instructions provided for new user registration.
 - b. Click on "Yes" if you are a returning user. Enter the user ID and password you selected during the registration process, then select "Sign In" to access your MQA Online Services Portal account.

IMPORTANT ANNOUNCEMENTS

Are You Renewal Ready?

The Department of Health will now review
your continuing education records at the
time of license renewal.

To learn more, please visit
www.FLHealthSource.gov/AYRR

Grounds for Discipline

You should be familiar with the Grounds for
Discipline found in Section 456.072(1),
Florida Statutes, and in the practice act for
the profession in which you are licensed.
Florida Statutes can be accessed at
www.leg.state.fl.us/Statutes

AC# 8637986

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/09/2018	PH 27903	104257

The PHARMACY

named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

DRUG DEPOT, INC

PS Pharmacy

4911 US HWY 19N

SUITE 600

ALM HARBOR, FL 34684

QUALIFICATION(S):

SPECIAL STERILE COMPOUNDING

3:1 PHARMACY TECHNICIAN RATIO APPROVED

STATE OF FLORIDA	AC#	8637986
DEPARTMENT OF HEALTH		
DIVISION OF MEDICAL QUALITY ASSURANCE		
DATE	LICENSE NO.	CONTROL NO.
11/09/2018	PH 27903	104257

The PHARMACY
named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

DRUG DEPOT, INC



Rick Scott
GOVERNOR



Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

QUALIFICATION(S):
Special Sterile Compounding
3:1 Pharmacy Technician Ratio Approved

EXPIRATION DATE: **FEBRUARY 28, 2021**

Your license number is PH 27903. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

Medical Quality Assurance has a new and improved Online Services Portal. In the new system, you have the ability to renew your license, update your mailing and practice location addresses, request a name change, request a duplicate license and update your profile information all from the convenience of your online account.

1. Go to www.FLHealthSource.gov.
2. Click on "Provider Services" and select "Manage Your License."
3. Select your profession and license type and click "Submit."
4. The question "Have you Registered in Our New Online Service System?" will display.
 - a. Click on "No" if you have not registered for an account in the new system and follow the instructions provided for new user registration.
 - b. Click on "Yes" if you are a returning user. Enter the user ID and password you selected during the registration process, then select "Sign In" to access your MQA Online Services Portal account.

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Florida Statutes, and in the practice act for
the profession in which you are licensed.

Florida Statutes can be accessed at
www.leg.state.fl.us/Statutes



Department of Health



License Verification

DRUG DEPOT INC APS PHARMACY

Printer Friendly Version

License Number: PH20986

Data As Of 2/20/2020

License Information	Secondary Locations	Discipline/Admin Action	Supervising Practitioners	Subordinate Practitioners
Profession	Pharmacy			
License	PH20986			
License Status	CLEAR/			
Qualifications	Schedule II & III Community Pharmacy			
License Expiration Date	2/28/2021			
License Original Issue Date	11/23/2004			
Address of Record	34911 US 19 N, SUITE 600 PALM HARBOR, FL 34684			
Discipline on File	Yes - <i>Click on Discipline/Admin Action tab to see more details</i>			
Public Complaint	Yes - <i>Click on Discipline/Admin Action tab to see more details</i>			

[Back](#)

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.



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Department of Health



License Verification

DRUG DEPOT, INC APS Pharmacy

Printer Friendly Version

License Number: PH27903

Data As Of 2/20/2020

License Information	Secondary Locations	Discipline/Admin Action	Supervising Practitioners
Profession	Pharmacy		
License	PH27903		
License Status	CLEAR/		
Qualifications	Special Sterile Compounding		
License Expiration Date	2/28/2021		
License Original Issue Date	03/22/2014		
Address of Record	34911 US HWY 19N SUITE 600 PALM HARBOR, FL 34684		
Discipline on File	No		
Public Complaint	No		

Back

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.



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Nevada State Board of Pharmacy

Within the last five (5) years:

3) Has the corporation, any owner(s), shareholder(s), partner(s), with any interest, ever been the subject of an administrative action, board citation, site fine, or proceeding relating to the pharmaceutical industry?

First, the applicant, Drug Depot, LLC d/b/a APS Pharmacy (*"Applicant"*), wishes to clarify that, as a new entity, it has never been the subject of an administrative action, board citation, site fine or another other type of proceeding by any board or agency in any jurisdiction. Out of an abundance of caution, we have elected to disclose the below disciplinary history for the predecessor entity, Drug Depot, Inc. d/b/a APS Pharmacy (*"Predecessor Entity"*). Copies of all materials related to the below are enclosed for your reference.

We wish to note that in 2018 the Pennsylvania Board of Pharmacy granted the Predecessor Entity's renewal application, but subjected its license to an indefinite period of probation due to sister-state administrative actions from 2012-2017. The Pennsylvania Board initially chose not to list the probation on its website as a disciplinary action, nor was there language in the Proposed Order characterizing the probation as a discipline. Accordingly, the Predecessor Entity was under the impression that the Pennsylvania Board did not consider the probation to be a discipline and did not report the event as a discipline. Nevertheless, we are reporting it here out of an abundance of caution.

- **Alabama** - In September 2015, the Alabama Board of Pharmacy (*"Alabama BOP"*) entered a Consent Order directing the Predecessor Entity to pay a fine of \$500. The Predecessor Entity paid the fine and its license remains in good standing today.
- **Oklahoma** - In February 2016, the Oklahoma Board of Pharmacy (*"Oklahoma BOP"*) placed the Predecessor Entity's license on probation for three years and imposed a fine and Plan of Correction. The Oklahoma BOP released the Predecessor Entity's license from probation in February 2019 and that license remains in good standing today.
 - **Kansas (sister-state action)** - In January 2017, the Kansas Board of Pharmacy (*"Kansas BOP"*) placed the Predecessor Entity's license on probation for a period not to exceed five years as a result of the 2016 Oklahoma Consent Order. The Predecessor Entity is nevertheless permitted to dispense into the state.
 - **Michigan (sister-state action)** - In February 2017, the Michigan Board of Pharmacy (*"Michigan BOP"*) entered a Consent Order against the Predecessor Entity in a sister-state action for disciplinary actions from Iowa (2016, below) and Oklahoma (2016, above). The Predecessor Entity was ordered to pay a fine of \$2500 and its license was placed on probation for a period of six months. The Predecessor Entity paid the fine, its license is no longer under probation, and it remains in good standing today.
 - **California (sister-state action)** - In July 2017, the California Board of Pharmacy (*"California BOP"*) brought a sister-state action against the Predecessor Entity based on disciplinary actions from Iowa (2016, below) and Oklahoma (2016, above). The California BOP received a citation and issued a fine. The Predecessor Entity's California license remains in good standing today.
 - **Oregon (sister-state action)** - In March 2018, the Oregon Board of Pharmacy (*"Oregon BOP"*) entered a Consent Order that placed the Predecessor Entity's license

on probation for the duration of the Oklahoma probation. The Oregon BOP released the Predecessor Entity's license from probation in May 2019 and it remains in good standing today.

- **Oklahoma Bureau of Narcotics (sister-agency action)** – In April 2018, the Oklahoma Bureau of Narcotics assessed a fine against the Predecessor Entity's controlled substance registration as a result of the Oklahoma probation. The Predecessor Entity's controlled substance registration remains in good standing today.
- **Iowa** - In March 2016, the Iowa Board of Pharmacy ("*Iowa BOP*") issued a citation and ordered a fine against the Predecessor Entity. The Predecessor Entity's Iowa license remains in good standing today.
- **Colorado** – In October 2016, the Colorado BOP issued a Letter of Admonition for the 2015 Alabama discipline and failure to report said action.
- **Texas** - In November 2016, the Texas BOP issued a fine against the Predecessor Entity for failure to report the 2012 Colorado disciplinary action on a 2014 renewal application. The Texas BOP further initiated a sister-state action based on the Colorado (2012), Iowa (2016), and Oklahoma (2016) disciplinary actions. The Predecessor Entity's Texas license remains in good standing today.
- **Colorado** - In December 2016, Colorado BOP placed the Predecessor Entity's license on indefinite probation for the Oklahoma (2016) and Iowa (2016) disciplinary actions and for failure to timely report said actions. The Predecessor Entity's license is active and it is permitted to dispense into the state.
- **Louisiana** - In April 2017, the Louisiana Board of Pharmacy ("*Louisiana BOP*") issued a Letter of Reprimand and ordered a fine against the Predecessor Entity for failure to report disciplinary actions from Alabama (2015), Colorado (2012, 2016), and Texas (2012). The Predecessor Entity's Louisiana license remains in good standing today.
- **Michigan** - In December 2017, the Michigan BOP issued a fine and suspended the Predecessor Entity's license as a result of the 2015 Alabama disciplinary action and failure to timely report said action. The Predecessor Entity's Michigan license was reinstated in January 2018 and remains in good standing today.
- **Minnesota** - In January 2018, the Minnesota Board of Pharmacy ("*Minnesota BOP*") issued a reprimand and ordered a fine against the Predecessor Entity. The Predecessor Entity's Minnesota license remains in good standing today.
- **Alabama (sister-state action)** - In January 2018, the Alabama BOP issued a fine against the Predecessor Entity in a sister-state action for disciplinary actions from Colorado (2016), Iowa (2016), Oklahoma (2016), and Texas (2018). The Predecessor Entity's Alabama license remains in good standing today.

- **Pennsylvania (sister-state)** - In August 2018, the Pennsylvania Board of Pharmacy ("*Pennsylvania BOP*") granted the Predecessor Entity's application for a non-resident pharmacy permit, but subjected the license to an indefinite period of probation due to out-of-state disciplinary actions from 2012-2017. The Predecessor Entity's Pennsylvania license remains active and it is permitted to dispense into the state.
- **Texas** – In November 2018, the Texas BOP issued a fine against the Predecessor Entity. The Predecessor Entity's Texas license remains in good standing today.
- **Maryland** - In January 2019, the Maryland Board of Pharmacy ("*Maryland BOP*") entered an order against the Predecessor Entity for allegedly dispensing into the state without proper licensure and also initiated a sister-state action based on disciplinary actions from Michigan (2018), Oklahoma (2016), Iowa (2016), Alabama (2015), and Florida (2010). The Predecessor Entity paid a fine and its Maryland license remains in good standing today.
- **Illinois (sister-state action)** - In September 2019, the Illinois Board of Pharmacy reprimanded the Predecessor Entity in a sister-state action for disciplinary actions from Iowa (2016), Oklahoma (2016), Texas (2016), Colorado (2016), California (2017), Kansas (2017), Louisiana (2017), Michigan (2017), and Alabama (2018). The Predecessor Entity's Illinois license remains in good standing today.
- **Missouri (sister-state action)** – In February 2020, the Missouri Board of Pharmacy ("*Missouri BOP*") entered an order against the Predecessor Entity in a sister-state action based on disciplinary actions from Oklahoma (2016), Colorado (2016), Iowa (2016), Texas (2016), Kansas (2017) California (2017), Michigan (2017), Alabama (2018), Minnesota (2018), and Oregon (2018). Missouri BOP placed the Predecessor Entity's license on probation for a period of three years. The Predecessor Entity's license remains active and it is permitted to dispense into the state.

IN THE MATTER OF:)	BEFORE THE ALABAMA STATE
)	
DRUG MEDICAL INC; dba APS PHARMACY)	
Non- Resident Pharmacy)	BOARD OF PHARMACY
Permit #114007/202063)	

CONSENT ORDER

THIS case came before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against DRUG MEDICAL INC; dba APS PHARMACY (hereinafter referred to as "APS") relating to engaging in the selling, offering for sale, compounding or dispensing drugs during the year 2015 without first receiving your permit from the Board required by Code of Alabama (1975) §34-23-30 in violation of Code of Alabama (1975), §34-23-33(7) as more specifically set forth in Exhibit "A" hereto:

Prior to a hearing in this case, APS pled guilty to violating Code of Alabama (1975) §34-23-33(7), based upon engaging in the selling, offering for sale, compounding or dispensing of drugs during the year 2015 without first having your permit with the Board by evidenced by your execution of Exhibit "A". Accordingly, pursuant to Code of Alabama (1975) §§ 34-23-33 and 41-22-12(e), the matters at issue have been resolved informally by the parties and the parties have agreed that this Consent Order can be entered and include the following terms:

1. That APS is guilty of violating Code of Alabama (1975) §34-23-33 (7) by engaging in the selling, offering for sale, compounding or dispensing drugs during the year 2015 without first having renewed your permit with the Board in violation of Code of Alabama (1975) §34-23-30.
2. That APS shall pay to the Board simultaneously with the

AUG 18 2015

SEP 24 2015

execution of this Consent Order a fine in the amount of Five Hundred Dollars (\$500.00). This obligation of payment to the Board shall not be dischargeable in bankruptcy and APS shall not attempt to discharge the same in any bankruptcy proceeding.

3. By execution of this Consent Order APS hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and complaint.

4. That APS expressly waives their rights pursuant to the Alabama Pharmacy Practice Act, Code of Alabama (1975) §34-23-1 et seq., and the Alabama Administrative Procedure Act, Code of Alabama (1975) §41-22-1 et seq., including but not limited to Code of Alabama (1975) §§§§§34-23-34, 34-23-92(7) and (12), 34-23-94, 41-22-12 and 41-22-20, and including but not limited to a statement or notice of charges and the opportunity for a hearing before the Board in connection with any charges against APS. APS further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975) §41-22-18.

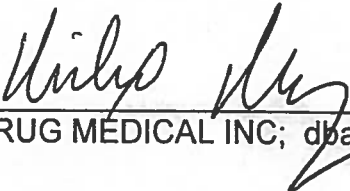
5. That APS agrees that any future violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against their license.

AUG 18 2015

SEP 24 2015

6. That APS acknowledges, stipulates and agrees that they have read this Consent Order and that they fully understand the terms, conditions and contents of the same. APS acknowledges, stipulates and agrees that they voluntarily and of their own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress or threats or pursuant to any promises.

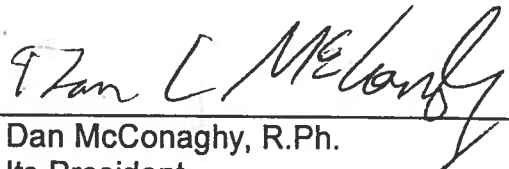
DONE this the 17 day of August, 2015.



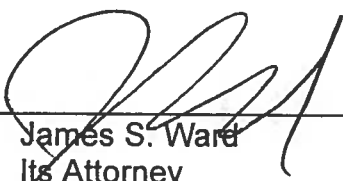
DRUG MEDICAL INC; dba APS PHARMACY

DONE this the 17 day of Sept, 2015.

ALABAMA STATE BOARD OF
PHARMACY

BY: 

Dan McConaghy, R.Ph.
Its President

BY: 

James S. Ward
Its Attorney

WARD & WILSON, LLC
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205)871-5404

AUG 18 2015

SEP 24 2015

**BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA**

IN THE MATTER OF THE COMPLAINT AGAINST: APS Pharmacy (99-7398) 34911 US Highway 19 N, Ste 600 Palm Harbor, FL 34684))))))	Case No. 1390
--	----------------------------	----------------------

**AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW
AND FINAL ORDER**

This matter came for hearing on February 24, 2016, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Dudley, Spoon, Wilson, Adams, and Whitehead were present. President Spoon presided. Brinda K. White, Assistant Attorney General, served as prosecutor for the Board. Respondent was represented by legal counsel Beauchamp M. Patterson.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondent hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondent has been advised of its right to contest the allegations against it, to cross-examine witnesses, and to present witnesses and evidence in its own defense. Respondent hereby knowingly and voluntarily waives these rights. In addition, Respondent understands and acknowledges that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondent agrees that neither the presentation of the Order to the Board nor the Board's consideration of the Order will be deemed to have unfairly or illegally

prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent is licensed in the State of Oklahoma as a non-resident pharmacy and is located at 34911 US Highway 19 N, Ste 600, Palm Harbor, FL 34684.

2. In March of 2015, the Board received information that the Drug Enforcement Administration ("DEA"), the Oklahoma Bureau of Narcotics and Dangerous Drugs ("OBNDD"), and the Oklahoma State Board of Medical Licensure and Supervision ("Medical Board") (collectively, "The Agencies") had investigated an Oklahoma business called Enhance Spa. Based on their respective findings of fact, The Agencies determined that employees of Enhance Spa, one of whom was a nurse: (i) examined the patients and drew blood for blood chemistry tests; (ii) interpreted the lab results; (iii) made diagnoses and prescribed medication; and (iv) sent prescriptions for the patients, including CDS prescriptions with stamped signatures, to Respondent who filled and shipped the prescriptions to Enhance Spa based on their apparent content. The Agencies further determined that the nurse at Enhanced Spa implanted the pellets under the skin of the patients, and that Dr. Darnell Blackmon, whose name was on the scripts, neither saw the patients nor authorized their prescriptions.

3. The Medical Board, OBNDD, and DEA seized all of the testosterone at Enhance Spa because Dr. Blackmon was not registered with the DEA at that address. Subsequently, the Board determined that

Respondent was not permitted to mail patient-specific drugs to any address other than to the patient's home or place of employment. An audit by The Agencies showed that Enhance Spa had 24 vials of Testosterone pellets, 22 of which were labeled for specific patients.

4. On September 24, 2015, Dr. Blackmon was disciplined by the Medical Board. Dr. Blackmon's license was suspended for a period of 20 days, he was fined \$50,000, he was not permitted to dispense controlled substances for a period of 5 years and he was limited to practicing orthopedic medicine for a period of 5 years.

5. Because Respondent was not continuously licensed by the Board during the entire time in which Respondent was shipping drugs to Enhance Spa, the Board subpoenaed Respondent's dispensing records in June of 2015 for the period October 1, 2013 through May 31, 2015. The records produced by Respondent showed that during this period of time, Respondent filled and shipped 1952 prescriptions of which 1002 were for controlled substances. The majority of prescriptions filled consisted of medications that were sterile products such as testosterone or estradiol pellets and testosterone or HCG injections. During the October 1, 2013 through May 31, 2015 time frame, Respondent continued to submit CDS prescriptions to Oklahoma's Prescription Monitoring Program ("PMP").

6. Respondent's dispensing records showed that it compounded HCG injection in 11,000 units; this drug is available commercially in 10,000 units. Respondent's dispensing records showed that it compounded Cyanocobalamin Injection 1mg/ml which is available commercially in that strength. Respondent's dispensing records showed that it compounded Testosterone Cypionate 200mg/ml and Testosterone Enanthate 200mg/ml

which are both available commercially in that strength. However, Respondent did not use the same oil that is used in commercially available drugs. Respondent used sesame and grapeseed oils.

7. On August 11, 2015, the Board received a Non-Resident Pharmacy application from Respondent. The Board issued Respondent's license on August 19, 2015.

8. In Section G of the license application, Applicant History, Respondent answered "No" to Question 4:

Has any sanction or disciplinary action been taken regarding any license permit or registration issued to the applicant, officers, directors, partners or stockholders involving the practice of pharmacy? (If the applicant is a business entity, you need not include members, partners or stockholders in this question unless they currently serve as managers, officers or directors of the applicant business, or own more than twenty percent (20%) of the business entity.)

Respondent included in its application a copy of the pharmacy license it was issued by the State of Florida Department of Health Division of Medical Quality Assurance, license number PH 20986.

9. On October 30, 2015, the Board received a Parenteral Permit Application from Respondent. Respondent never received approval for the application. The application stated that John Ford, Oklahoma licensed DPh number 13183, is the PIC. Since March 20, 2015, John Delano Ford, DPh 13183, has been and still is the PIC at H & G Home Medical & Infusion (pharmacy license number 9-4296), 112 NE Washington Blvd in Bartlesville, Oklahoma. Ford is not licensed as a pharmacist in Florida; therefore, Ford could not be Respondent's PIC.

10. The State of Florida Department of Health has disciplined

Respondent. On July 2, 2009, the State of Florida Department of Health filed an Administrative Complaint in Case No. 2008-16712 against Respondent. The complaint contained 9 counts and these counts included violations for wholesaling drugs without a permit, dispensing prescription drugs without prescriptions, failing to properly maintain compounding records, purchasing prescription drugs from an unauthorized vendor, receipt of prescription drugs from a wholesaler without receipt of pedigree papers, mislabeling of drugs, having outdated drugs in the pharmaceuticals active stock, having an improper generic drug sign and improperly storing prescription drugs (the "Florida 2009 Complaint").

11. On January 7, 2010, Respondent entered into a Settlement Agreement in Case No. 2008-16712 with the State of Florida Department of Health. On May 11, 2010, the State of Florida Department of Health issued a Final Order Approving Settlement Agreement. Respondent was fined \$2500.00 in addition to administrative costs associated with the investigation and prosecution of this matter which was determined to be \$2534.31. Also, the prescription department manager was required to successfully complete a 12 hour laws and rules CE course approved by the Florida Department of Health or successfully take the MPJE within 1 year after the date the Final Order was filed (the "Florida Settlement Agreement").

12. Respondent disclosed both the Florida 2009 Complaint and the corresponding Florida Settlement Agreement to the Board in connection with Respondent's 2011 non-resident license application, which the Board granted.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the

Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondent has admitted violating 59 O.S. § 353.18(A)(1) by selling at retail, or offering for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and drugs or accepting prescriptions for the same, without first procuring a license from the Board for the period of October 1, 2013 through May 31, 2015, as set forth in Count 1 of the Complaint.

4. Respondent has admitted violating OAC 535:15-3-9(b)(1) by failing, as a non-resident pharmacy, to make application and receive an annual non-resident pharmacy license at a fee set by the Board for the period October 1, 2013 through May 31, 2015, as set forth in Count 2 of the Complaint.

5. Respondent neither admits nor denies violating 59 O.S. § 353.24(A)(4) by entering into an arrangement whereby prescription orders are received, or prescriptions are delivered, at a place other than the pharmacy in which they are filled, compounded or dispensed, as set forth in Count 3 of the Complaint.

6. Respondent does not dispute that the Board has found that it violated OAC 535:15-10-53(a) by compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product, as set forth in Count 4 of the Complaint.

7. Respondent neither admits nor denies violating OAC 535:15-3-2(c)(4) by failing to establish and maintain effective controls against the

diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules, as set forth in Count 5 of the Complaint.

8. Respondent neither admits nor denies violating OAC 475:30-1-4(a) and OAC 535:10-3-1.2(1) by filling a written prescription that was not signed by the practitioner in the same manner as he/she would sign a check or legal document, as set forth in Count 6 of the Complaint.

9. Respondent neither admits nor denies violating OAC 535:15-3-13(c) by failing to ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized prescriber acting in the usual course of the prescriber's professional practice, as set forth in Count 7 of the Complaint.

10. Respondent neither admits nor denies violating OAC 535:15-3-13(d) by dispensing a prescription drug knowing or should have known that the prescription was issued without a valid preexisting patient-prescriber relationship, as set forth in Count 8 of the Complaint.

11. Respondent has admitted violating OAC 535:25-9-4(1) by making or filing a report or record that the registrant knows or should have known to be false, intentionally or negligently failing to file a report or record required by federal, state or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to violate this rule, as set forth in Count 9 of the Complaint. Specifically, Respondent admits that it submitted a parenteral permit application that designated a Pharmacist-in-Charge who was not licensed in the State of Florida.

12. Respondent neither admits nor denies violating OAC 535:25-9-3 by directly violating (or indirectly, through actions of another), or by assisting

or abetting in the violation of, or by conspiring to violate, any provision of the Oklahoma Pharmacy Act (59 O.S. § 353 et seq.), the Federal Food, Drug and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, the Prescription Drug Marketing Act (21 U.S.C. Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C. Sec. 13 et seq.), or federal, state and local laws and rules, as set forth in Count 10 of the Complaint.

13. Respondent has admitted violating OAC 535:25-7-3(a) by failing to conduct business at all times in conformity with all federal, state and municipal laws, as set forth in Count 11 of the Complaint.

14. Respondent neither admits nor denies violating OAC 535:25-7-3(b) by failing to conduct itself at all times in a manner that will entitle it to the respect and confidence of the community in which it practices, as set forth in Count 12 of the Complaint.

15. Respondent neither admits nor denies violating OAC 535:15-3-9(c)(1) by failing to follow Oklahoma pharmacy laws and regulations in the practice of pharmacy for the Oklahoma portion of the nonresident pharmacy's practice or operation; specifically, Respondent submitted an application including a pharmacist-in-charge who was not currently licensed as a pharmacist in Florida and in Oklahoma, as set forth in Count 13 of the Complaint.

16. Pursuant to 59 O.S. §353.7(11), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, the Board has authority to levy fines not to exceed Three Thousand Dollars (\$3000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the

impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees.

17. Based on the above Agreed Findings of Fact, Respondent is subject to disciplinary action pursuant to 59 O.S. §§ 353.7 and 353.26.

AGREED ORDER

1. Respondent, APS Pharmacy, holder of non-resident pharmacy license No. 99-7398, admits to guilt on Counts 1, 2, 9, and 11. Respondent does not dispute that the Board has found it violated Count 4. Respondent neither admits nor denies guilt on the remainder of the counts.

2. Respondent is hereby placed on probation for three (3) years until February 24, 2019.

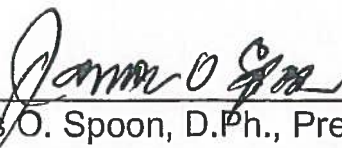
3. Respondent is hereby fined Three Thousand Dollars (\$3000.00) per count on Counts 1, 2, 4, 9 and 11 for a total fine of Fifteen Thousand Dollars (\$15,000.00). The fine is due on February 24, 2016.

4. Respondent shall develop and implement a Plan of Correction. That Plan of Correction shall be submitted on or before March 24, 2016, to the Board's Executive Director for his approval.

5. Failure of Respondent to abide by any of the terms of this Agreed Order could result in further disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

6. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".



James O. Spoon, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss.
County of Oklahoma)

Subscribed and sworn before me on this the 24th day of February, 2016.



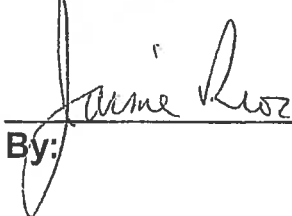
Notary Public



I am Jaime Ries of APS Pharmacy (99-7398), and, therefore, I am authorized to sign on behalf of APS Pharmacy. I have read the above Agreed Findings of Fact, Conclusions of Law and Final Order. I understand that by its terms APS Pharmacy will be waiving certain rights accorded it under Oklahoma Law. I also understand that by its terms the Oklahoma State Board of Pharmacy has placed APS Pharmacy on probation and that APS Pharmacy must comply with the terms and conditions of the Agreed Order or further discipline will be imposed on it. On behalf of APS Pharmacy, I agree to the above Agreed Order.

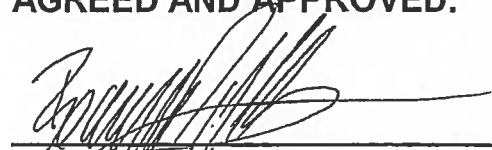
Dated this 19th day of February, 2016.

APS Pharmacy, Respondent



By:

AGREED AND APPROVED:

A handwritten signature in black ink, appearing to read 'Beauchamp M. Patterson', is written over a horizontal line.

Beauchamp M. Patterson, OBA # 19188

Patricia A. Rogers, OBA # 18353

Attorneys for Respondent



OKLAHOMA

State Board of Pharmacy

2920 N. Lincoln Blvd, Suite A • Oklahoma City, OK 73105-4211
 pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov
 Dorothy Gourley, DPh, Executive Director
 Phone: 405.521.3815 • Fax: 405.521.3758

April 30, 2019

APS Pharmacy
 34911 US Hwy 19 N, Ste. 600
 Palm Harbor, FL 34684

Re: Case No. 1390 – February 24, 2016

Dear Pharmacist:

This letter will confirm the end of the probation of the pharmacy. The completion date for the Board ordered probation of your Oklahoma pharmacy license #99-7398 was February 24, 2019. The records in the Board office will no longer show that your license is on probation.

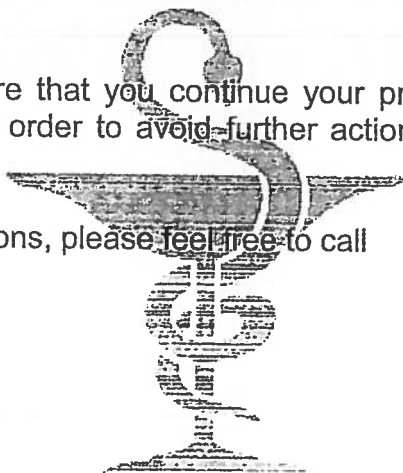
It is the Board's desire that you continue your practice in accordance with all pharmacy laws and rules in order to avoid further action against your license by the Board.

If you have any questions, please feel free to call

Sincerely,

Dorothy Gourley

Dorothy Gourley, DPh
 Executive Director



DG:rj

A Constitutional Board Established in 1907

President Kyle Whitehead, D.Ph. <i>Enid</i>	Vice-President Mark St.Cyr, .D.Ph. <i>Jones</i>	Member Greg Adams, D.Ph. <i>Clinton</i>	Member James O. Spoon D.Ph. <i>Sand Springs</i>	Member Justin Wilson, D.Ph. <i>Norman</i>	Public Member Stephen Dudley <i>Edmond</i>
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BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)

APS Pharmacy)

Registration No. 22-12906)

Case No. 16-097

1/10/2017
 10:00 AM
 BOARD OF PHARMACY

SUMMARY ORDER

NOW on this 6 day of January, 2017, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of APS Pharmacy ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-12906 which entitles Respondent to function as a non-resident pharmacy in the State of Kansas ("Respondent's Registration").

2. On or about June 30, 2016, Respondent submitted a renewal application to the Board. Respondent reported disciplinary history with other states in the renewal application and submitted the S-300 Facility History form, along with a Final Order with the Oklahoma Board of Pharmacy, on July 21, 2016.

3. The Oklahoma Order included the following offenses:

Matter of APS Pharmacy, No. 16-097 (Kan. Bd. of Pharmacy)

SUMMARY ORDER

Page 1 of 5

- (1) Respondent allowed its non-resident license to lapse.
- (2) Respondent compounded a commercially available drug.
- (3) Respondent delivered patient-specific testosterone pellets to a physician's office for surgery.
- (4) Respondent allowed inconsistent signatures from a specific physician.
- (5) Before servicing any clinic, Respondent required signed paperwork explaining the practice setting to ensure proper doctor-patient relationship, however, upon investigation, it was determined that this policy had not been satisfied.
- (6) Respondent did not have a Pharmacist in Charge licensed in Oklahoma as well as the resident state where the pharmacy is located, as required by Oklahoma law.
- (7) Respondent neither admitted nor denied guilt.

4. The Oklahoma Board placed Respondent Pharmacy on probation for three years, or until February 24, 2019, imposed a fine of \$15,000, and required Respondent to develop and implement a Plan of Correction.

5. Furthermore, the Oklahoma Order stipulated that failure to abide by any of the terms of the Order would result in further disciplinary action.

6. On September 8, 2016, an investigator for the Board called and spoke to an Oklahoma Board inspector about Respondent and the Oklahoma Order, who confirmed the above statements.

CONCLUSIONS OF LAW

7. Pursuant to K.S.A. 65-1627(a)(12), the Board may place on probationary status the registration of any pharmacy upon a finding that the pharmacy has had a registration limited or censured by the proper licensing authority of any state.

8. Respondent's discipline and probation imposed by the Oklahoma Board of Pharmacy warrants the Board to place its renewal registration on probationary status in Kansas.

ORDER

Based upon the foregoing findings of fact and conclusions of law, Respondent's Renewal is GRANTED, subject to a probationary period not to exceed five years, with bi-annual reporting of (1) patient specific prescriptions sent to Kansas patient residences, Kansas physician offices and any and all other Kansas locations, (2) any and all recalls issued by Respondent, and (3) notification to the Board of any FDA inspection. Respondent is also required to comply with state and federal laws during the probationary period.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

Matter of APS Pharmacy, No. 16-097 (Kan. Bd. of Pharmacy)

SUMMARY ORDER

Page 3 of 5

3. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

11/6/17
Date



Alexandra Blasi, J.D., M.B.A.
Executive Secretary
Kansas Board of Pharmacy

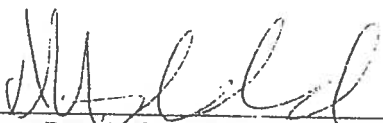
CERTIFICATE OF SERVICE

I hereby certify that I did, on the 6 day of January, 2017, deposit in the United States Mail, postage prepaid, a copy of the foregoing Summary Order, properly addressed to the following:

APS Pharmacy
34911 US Highway 19N, Ste. 600
Palm Harbor, FL 34684

and the original hand delivered to:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Ste. 1414
Topeka, KS 66612



Kansas Board of Pharmacy Staff

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

APS PHARMACY
License Number: 53-01-009652

File Number: 53-16-142843
CONSENT ORDER AND STIPULATION

CONSENT ORDER

On October 6, 2016, the Department of Licensing and Regulatory Affairs (Department) executed an Administrative Complaint (Complaint) charging APS Pharmacy (Respondent) with violating section(s) 17768(2)(d) of the Public Health Code, MCL 333.1101 et seq.

Respondent has admitted that the facts alleged in the Complaint are true and constitute violation(s) of the Public Health Code. The Disciplinary Subcommittee of the Michigan Board of Pharmacy (Board) has reviewed the Consent Order and Stipulation (Order) and agrees that the public interest is best served by resolution of the outstanding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violation of section(s) 17768(2)(d) of the Public Health Code, supra.

Accordingly, IT IS ORDERED that for the cited violations of the Public Health Code, Respondent is placed on PROBATION for six months, commencing on the effective date of this Order. The terms of probation shall be as follows:

1. ACCREDITATION DOCUMENTATION: Respondent shall submit board-accepted verification of accreditation by a national accrediting organization that assessed Respondent for compliance with U.S. Pharmacopeial Convention (USP) standards.

Respondent shall mail the verification of accreditation documentation to the **Department of Licensing and Regulatory Affairs, Legal Affairs Division, Compliance Section, P.O. Box 30670, Lansing, MI 48909.**

2. COMPLIANCE WITH THE PUBLIC HEALTH CODE: Respondent shall comply with all applicable provisions of the Public Health Code and rules promulgated thereunder.
3. COSTS: Respondent shall be solely responsible for payment of all costs incurred in complying with the terms of this Order.

IT IS FURTHER ORDERED that Respondent shall be automatically discharged from probation at the end of the probationary period, PROVIDED Respondent has paid the fine set forth below, complied with the terms of this Order and has not violated the Public Health Code.

IT IS ORDERED that for the cited violation of the Public Health Code, Respondent is FINED \$2,500.00 to be paid to the State of Michigan within 90 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Legal Affairs Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-16-142843**.

IT IS FURTHER ORDERED that if Respondent fails to comply with the terms and conditions of this Order, Respondent's license to practice as a pharmacy shall be automatically suspended for a minimum of one day. If, within six months of the suspension of the license, Respondent complies with the terms of this Order, the license shall be automatically reinstated.

IT IS FURTHER ORDERED that if Respondent's license to practice as a pharmacy remains suspended for more than six months, Respondent must apply for reinstatement of the license. In the event Respondent applies for reinstatement of the license, application for reinstatement shall be in accordance with sections 16245 and 16247 of the Public Health Code, supra.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: _____

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. The facts alleged in the Complaint are true and constitute violation(s) of section 17768(2)(d) the Public Health Code, supra.
2. Respondent understands and intends that by signing this Stipulation, Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 et seq, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.
3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 et seq; and this action will be reported to the National Practitioner Data Bank, and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

4. Patricia A. Keim, R.Ph., a member of the Michigan Board of Pharmacy, who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Order.

5. This Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the Disciplinary Subcommittee in this matter.

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent and the Department expressly reserving the right to further proceedings without prejudice should the Order be rejected.

AGREED TO BY:

Kim Gaedeke, Director
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: _____

kp

AGREED TO BY:

Michael Marling, GM
APS Pharmacy
Respondent

Dated: _____



RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

SHELLY EDGERTON
DIRECTOR

January 3, 2018

APS Pharmacy
34911 US Hwy 19 N #600
Palm Harbor, FL 34684

Re: File 53-16-142843

Dear Licensee :

You have complied with the terms of the Board of Pharmacy Disciplinary Subcommittee's Consent Order dated April 12, 2017. Effective January 3, 2018, you are discharged from probation, and the status of your license has been changed from suspended to full and unlimited.

Please be advised that in accordance with State law, this disciplinary action will remain a permanent part of your license history.

Bureau of Professional Licensing
Enforcement Division
Compliance Section


California State Board of Pharmacy

1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

July 28, 2017

DATED MATERIAL ENCLOSED

APS PHARMACY
 ATTN: JAIME ALBERTO RIOS, PRS
 34911 US HWY 19N STE 600
 PALM HARBOR, FL 34684

**RE: CI 2016 74158
 APS PHARMACY
 NRP 1286**

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- August 27, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- August 11, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- August 27, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

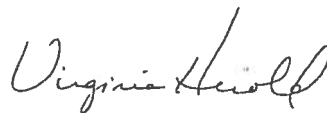
Page two
APS PHARMACY
CI 2016 74158

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Ericka Busby, Enforcement Analyst at (916) 574-7731.

Sincerely

A handwritten signature in cursive script, appearing to read "Virginia Herold".

Virginia Herold
Executive Officer
Board of Pharmacy .

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **August 27, 2017**.
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy

Attn: Ericka Busby

1625 North Market Boulevard, Suite N219

Sacramento, CA 95834-1924

(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than August 11, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than August 27, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

CITATION AND FINE

Citation Number	Name, License No
CI 2016 74158	APS PHARMACY, NRP 1286

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4301 subd. (n)	Unprofessional Conduct - Out of state disciplinary action	\$2,500.00
Bus. & Prof. Code § 4301 subd. (n)	Unprofessional Conduct - Out of state disciplinary action	\$2,500.00

CONDUCT:

Business and Professions Code section 4301(n) authorizes the Board to take action against a licensee for the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required. Specifically, on March 8, 2016, the Iowa Board of Pharmacy cited APS Pharmacy's Iowa license and ordered it to pay \$2,500 after the pharmacy shipped approximately 100 prescriptions into Iowa without an active pharmacy license from Jan. 1, 2014 through Sep. 7, 2014.

Business and Professions Code section 4301(n) authorizes the Board to take action against a licensee for the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required. Specifically, on Feb. 24, 2016, the Oklahoma Board of Pharmacy (OKBP) placed APS Pharmacy's Oklahoma license on probation for three years, until Feb. 24, 2019, and fined it \$15,000. The OKBP acted after finding that APS Pharmacy was not continuously licensed from Oct. 1, 2013, to May 31, 2015, when it shipped 1,952 prescriptions to Enhance Spa, 1,002 of which were for controlled substances; mailed patient-specific drugs to addresses other than the patient's home or place of employment; and compounded medications in strengths that were already commercially available.

CITATION ISSUED ON: July 28, 2017

TOTAL AMOUNT OF FINE(S): \$5,000.00

PAYMENT OF FINE(S) DUE BY: August 27, 2017

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

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CITATION ISSUED ON: July 28, 2017

TOTAL AMOUNT OF FINE(S): \$5,000.00

PAYMENT OF FINE(S) DUE BY: August 27, 2017

California State Board of Pharmacy**DECLARATION OF SERVICE BY CERTIFIED MAIL**

Name: APS PHARMACY, NRP 1286
Citation and Fine CI 2016 74158

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On July 28, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME


APS PHARMACY
ATTN: JAIME ALBERTO RIOS, PRS
34911 US HWY 19N STE 600
PALM HARBOR, FL 34684

CERTIFIED MAIL NO

7016 2710 0000 2970 9339

I declare under penalty of perjury that the forgoing is true and correct.

Executed on July 28, 2017, at Sacramento, California.



DECLARANT

Ericka Busby
Enforcement Analyst



Oregon

Kate Brown, Governor

Board of Pharmacy

800 NE Oregon Street, Suite 150

Portland, OR 97232

Phone: (971) 673-0001

Fax: (971) 673-0002

Pharmacy.board@oregon.gov

www.oregon.gov/pharmacy

May 6, 2019

APS Pharmacy
34911 US Highway 19 N Ste 600
Palm Harbor, FL 34684-1921

Re: Case No. 2017-0372

This letter will confirm the end of your probation. The completion date for your Board ordered probation is May 6, 2019.

It is the Board's desire that you continue your practice in accordance with all pharmacy laws and rules in order to avoid further action by the Board against your license.

Should you have any questions concerning your practice in the future, you are encouraged to call the Board office for assistance.

Sincerely,

Brianne Efremoff, Pharm.D, R.Ph.
Compliance Director

CC: Oregon Board of Pharmacy Licensing Department
National Practitioner Data Bank

BE/ko

RECEIVED

MAR 09 2018

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

OREGON BOARD OF PHARMACY

In the Matter of the)
Drug Outlet Registration of) Case No. 2017-0372
)
DRUG DEPOT INC dba:)
APS PHARMACY) CONSENT ORDER
)
Registrant)

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant admits that the facts alleged in the above-noted Notice are true, that the registrant's conduct, as admitted, violated the statutes and rules cited in the Notice, and that legal cause exists pursuant to ORS 689.405 for disciplinary action by the Board; and

WHEREAS, the registrant consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby imposes the following sanctions:

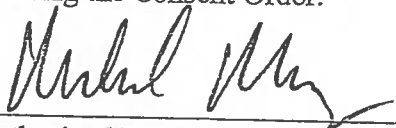
1. The respondent is placed on probation for the duration of their probation with the Oklahoma Board of Pharmacy. Terms of probation with the Oregon Board of Pharmacy:
 - a. The respondent shall comply with all terms and conditions of the Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order in Case No. 1390 (Oklahoma Order);
 - b. Respondent shall notify the Oregon Board in writing within 15 calendar days of any action related to their Oklahoma Order, including but not limited to, the completion of their probation. Respondent shall submit said written acknowledgement to the Board office by certified mail (or other method approved by the Board in writing) within 15 calendar days and retain receipt of verification of delivery to the Board office; and
 - c. The respondent shall comply with all Oregon laws and rules regarding

pharmacy practice.

2. Failure of the respondent to comply with all the requirements of this Consent Order constitutes unprofessional conduct and is grounds for revocation or any other form of discipline or sanction authorized by law.

CONSENT

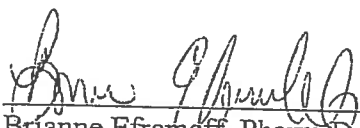
I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.


 Authorized Representative
 DRUG DEPOT INC dba:
 APS Pharmacy
 Registrant (Registration No. RP-0002770)

3/1/18
 Date

IT IS SO ORDERED.

BOARD OF PHARMACY
 FOR THE STATE OF OREGON


 Brianne Efremoff, Pharm.D., R.Ph.,
 Compliance Director

3/12/18
 Date

BEFORE THE OKLAHOMA STATE BUREAU OF
NARCOTICS AND DANGEROUS DRUGS CONTROL
STATE OF OKLAHOMA

FILED
Oklahoma State Bureau of Narcotics
and Dangerous Drug Control

APR 26 2018

Office of the General Counsel
By *[Signature]*

STATE OF OKLAHOMA, *ex rel.*
THE OKLAHOMA STATE BUREAU OF
NARCOTICS AND DANGEROUS DRUGS
CONTROL, JOHN SCULLY, Director,

Petitioner,

v.

Case No. SCH-2018-007

APS PHARMACY,
OBN REGISTRATION #52622,

Respondent.

*CORRECTION: OBND REGISTRATION
NUMBER IS 46706

STIPULATION AND AGREED ORDER

COMES NOW the parties to the above-styled and numbered cause to present this *Stipulation and Agreed Order*. The State of Oklahoma appears by and through Oklahoma Bureau of Narcotics Deputy General Counsel Sunne Riedel Day, and the Respondent, APS Pharmacy, by and through Jaime Rios and attorney Vani Singhal. The parties hereby agree to the following:

JURISDICTION

1. That John Scully is the Director of the Oklahoma Bureau of Narcotics (OBN) and is charged with the duty of administering and enforcing the provisions of the Uniform Controlled Dangerous Substances Act of the State of Oklahoma (UCDSA), 63 O.S. §§ 2-101 *et seq.*; See also 63 O.S. § 2-106;
2. That the Director has the authority to register practitioners to dispense, prescribe, administer or use for scientific purposes controlled dangerous substances (CDS) in

Schedules II through V of the UCDSA and shall register practitioners if they are authorized to carry on their respective activities under the laws of the State of Oklahoma, 63 O.S. §2-303(C);

3. That once a practitioner is a registrant pursuant to 63 O.S. §2-303, the Director has the authority to limit, condition, deny, suspend or revoke a registration upon a finding that the registrant has violated any provision of 63 O.S. §2-304(A);
4. That in lieu of or in addition to any other remedies available to the Director, if a finding is made that a registrant has committed any act in violation of federal law relating to any controlled substance, any provision of the UCDSA, or any OBN rules, the Director is authorized to assess an administrative penalty not to exceed Two Thousand Dollars (\$2,000.00) for each act, 63 O.S. §2-304(D);
5. That before the Director takes any action on an OBN registration, the Director shall serve upon the registrant an order to show cause why registration should not be denied, revoked or suspended or why the renewal should not be refused, 63 O.S. §2-305(A);
6. That the registrant is entitled to an administrative hearing on an order of show cause, wherein the State of Oklahoma must prove by clear and convincing evidence the allegations contained within the order to show cause, 63 O.S. §2-305(A);

FINDINGS OF FACT

7. That APS Pharmacy (hereinafter – *Respondent*) is licensed by the Oklahoma State Board of Pharmacy (OSBP) as a non-resident pharmacy (license number 99-7398)

owned by Drug Depot, Inc., 34911 US Hwy 19 N, Ste. 600, Palm Harbor, FL, 34684;

8. That Respondent is an OBN registrant (OBN registration number 52622 - expiration October 31, 2018) authorized to dispense, prescribe, administer or use for scientific purposes controlled dangerous substances in Schedules II through V of the UCDSA;
9. That an *Order to Show Cause and Notice of Hearing* was filed with the Oklahoma Bureau of Narcotics in an administrative action on April 3, 2018;
10. That the *Order to Show Cause and Notice of Hearing* was served on the Respondent and Respondent submits to the jurisdiction of the Director as an OBN registrant;
11. That on or about February 24, 2016, OSBP, pursuant to an agreed order, placed Respondent on probation for three (3) years until February 24, 2019;
12. That between October 1, 2013 to May 31, 2015, Respondent sold at retail dangerous drugs without first procuring a license from OSBP;

CONCLUSIONS OF LAW

13. Upon a finding that Respondent has violated a provision of 63 O.S. §2-304, the OBNDD Director may limit, condition, deny, suspend or revoke a Respondent's registration. Based on the allegations of fact contained herein, Respondent is alleged to have violated the following statutory provisions:

- 13.1 "Has had a restriction, suspension, revocation, limitation, condition, or probation placed on his or her professional license or certificate or

practice as a result of a proceeding pursuant to the general statutes" 63

O.S. §2-304(A)(6);

- 13.2 "Has violated any federal law relating to any controlled substances, any provision of the Uniform Controlled Dangerous Substances Act, or any rules of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control" 63 *O.S. §2-304(A)(11);*

- 13.3 "Except as authorized by the Uniform Controlled Dangerous Substances Act, it shall be unlawful for any person:

1. To distribute, dispense, transport with intent to distribute or dispense, possess with intent to manufacture, distribute, or dispense, a controlled dangerous substance or to solicit the use of or use the services of a person less than eighteen (18) years of age to cultivate, distribute or dispense a controlled dangerous substance" 63 *O.S. §2-401;*

STIPULATION

The parties hereby stipulate that if State's witnesses were called and sworn, that the testimony presented would be sufficient to prove by clear and convincing evidence that Respondent, as an OBN registrant, violated provisions of the Uniform Controlled Dangerous Substances Act of the State of Oklahoma, 63 *O.S. §2-101 et seq.*, as stated in paragraphs 13.1, 13.2, and 13.3 herein. By agreement of the parties, paragraph 13.1 will account for one (1) count of having had a restriction, suspension, revocation, limitation, condition, or probation placed on his or her professional license or certificate or practice in violation of 63 *O.S. §2-304(A)(6)*. Paragraphs 13.2 and 13.3 will account for one (1) count of

having violated any provision of the Uniform Controlled Dangerous Substances Act to wit: distribute, dispense, transport with intent to distribute or dispense, possess with intent to manufacture, distribute, or dispense, a controlled dangerous substance in violation of 63 O.S. §2-304(A)(11) and 63 O.S. §2-401.

AGREED ORDER

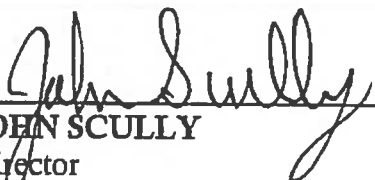
NOW on this 23rd day of April, 2018, based on the stipulations of the parties, the agreed findings of fact and conclusions of law, and under the authority of the powers granted by 63 O.S. §2-101 et. seq. as Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, I hereby find:

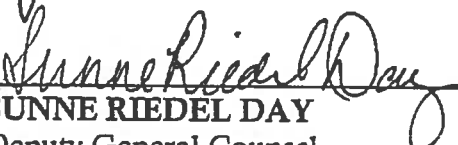
1. That APS Pharmacy, the Respondent herein, is licensed by the Oklahoma State Board of Pharmacy (OSBP) as a non-resident pharmacy (license number 99-7398) owned by Drug Depot, Inc.;
2. That Respondent is a current OBN registrant (registration number 52622) and is therefore subject to compliance with the requirements of the UCDSA and OBN rules;
3. That this administrative action is properly under the lawful jurisdiction of the Director of the Oklahoma Bureau of Narcotics;
4. That by clear and convincing evidence, Respondent has had a restriction, suspension, revocation, limitation, condition, or probation placed on his or her professional license or certificate or practice in violation of 63 O.S. §2-304(A)(6) (1 count);
5. That by clear and convincing evidence, Respondent has violated a provision of the Uniform Controlled Dangerous Substances Act to wit: distribute, dispense, transport

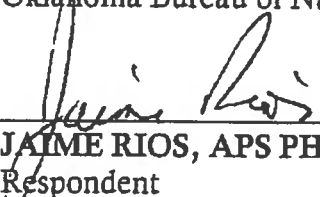
with intent to distribute or dispense, possess with intent to manufacture, distribute, or dispense, a controlled dangerous substance in violation of 63 O.S. §2-304(A)(11) and 63 O.S. §2-401 (1 count);

IT IS THEREFORE ORDERED that Respondent is hereby assessed a total administrative penalty of Three Thousand Dollars (\$3,000.00). This penalty is a cumulative assessment of One Thousand Five Hundred Dollars (\$1,500.00) for each of the counts that are the subject of this order. Respondent is ordered to pay the \$3,000 administrative penalty instant.

It is the express purpose of the parties for this Order to resolve all matters currently before the Oklahoma Bureau of Narcotics associated with the investigation of this matter.


JOHN SCULLY
Director


SUNNE RIEDEL DAY
Deputy General Counsel
Oklahoma Bureau of Narcotics


JAIME RIOS, APS PHARMACY
Respondent


VANI SINGHAL
Attorney for Respondent

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2013-4139
Nonresident Pharmacy License of)	
DRUG DEPOT, INC.)	SETTLEMENT AGREEMENT
d/b/a APS PHARMACY)	AND FINAL ORDER
License Nos. 4139 & 4375)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Drug Depot, Inc. d/b/a APS Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

The allegations contained in the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed a Notice of Hearing and Statement of Charges on January 12, 2016.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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IOWA BOARD OF PHARMACY

9. This Order shall not be binding as to any new complaints received by the Board.
10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.
11. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.
12. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.


IT IS THEREFORE ORDERED:

13. Respondent is hereby **CITED** for providing pharmacy services to Iowa residents without an active Iowa pharmacy license violating and **WARNED** that Respondent's failure to comply with the laws and rules governing the practice of pharmacy in the future could result in further discipline.

14. Respondent shall pay a **CIVIL PENALTY** in the amount of two thousand five hundred dollars (\$2,500) within thirty (30) days of Board approval of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

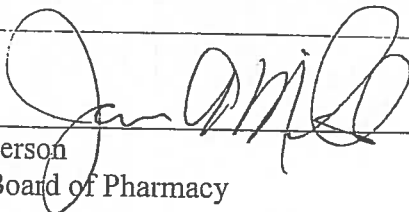
15. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 29 day of January, 2016.


 DRUG DEPOT, INC.
 APS PHARMACY
 Respondent

By this signature, Michael Marling acknowledges s/he is the General Manager for Drug Depot, Inc. d/b/a APS Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Drug Depot, Inc. d/b/a APS Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the
8th day of March, 2016.


Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

BEFORE THE STATE BOARD OF PHARMACY**STATE OF COLORADO****Case No. 2016-835**

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF DRUG DEPOT, INC., REGISTRATION NO. OSP 5618,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Drug Depot, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Number 2016-835, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).
2. Respondent Pharmacy was originally registered in the State of Colorado on or about February 22, 2012, being issued registration number OSP 5618, and has been so registered at all times relevant to this disciplinary action.
3. Respondent Pharmacy's address of record with the Board and current location is 34911 US Highway 19 N, Ste. 600, Palm Harbor, FL 34684.
4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.
5. On September 17, 2015, Respondent Pharmacy entered into a Consent Order with the Alabama Board of Pharmacy for engaging in the selling, offering for sale, compounding, and dispensing of drugs during the year 2015 without first having renewed its permit.
6. Respondent Pharmacy failed to notify the Colorado Board of the Alabama disciplinary action.
7. Respondent Pharmacy's violations of Alabama law would also constitute violations of Colorado law.

8. Respondent Pharmacy admits that its conduct, as set forth above, constitutes a violation of §§12-42.5-123(1)(c)(I)-(III), (g), and (q), C.R.S., and Rule 9.00.10(b), and provides grounds for disciplinary action against Respondent Pharmacy's Colorado registration as a prescription drug outlet.

DISPOSITION

9. **Letter of Admonition.** This Final Agency Order shall constitute a Letter of Admonition as set forth in §12-42.5-124(6)(b) and (c), C.R.S. The Board hereby admonishes Respondent Pharmacy for the acts and omissions described in paragraphs 5-7 above.
10. **Waiver of Right to Contest.** By entering into this Final Agency Order, Respondent Pharmacy agrees to waive the right provided by §12-42.5-124(6)(b) and (c), C.R.S., to contest this Letter of Admonition.
11. **Other Requirements.** Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Pharmacy shall:
- a. promptly pay all its own fees and costs associated with this Final Agency Order;
 - b. comply fully with this Final Agency Order; and
 - c. comply fully with the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceuticals and pharmacists in the State of Colorado.
12. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
13. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:
- a. To have a formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges;

c. To have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

14. **Acknowledgments.** The undersigned Authorized Representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.

18. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Pharmacy at Respondent Pharmacy's address of record with the Board, or (b) service by electronic means on Respondent Pharmacy at Respondent Pharmacy's electronic address of record. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Pharmacy

[Signature] Pharmacist In Charge Dated: 10/18/16
 Authorized Representative / Title

Subscribed and sworn to before me in the County of Pinellas,
 State of Florida, this 18th day of October, 2016, by
Cletis Koukoulakis, in his/her capacity as
 an authorized agent of Drug Depot, Inc.



REBECCA KARUKIN
 NOTARY PUBLIC
 STATE OF FLORIDA
 Comm# FF009428
 Expires 4/17/2017

[Signature]

Notary Public

My commission expires: 4/17/2017

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved,
 accepted, and hereby made an Order of the Board.

Done and effective this 19th day of October, 2016.

State Board of Pharmacy

BY: [Signature]

Chris Gassen
 Interim Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 19th day of October 2016, addressed as follows:

By electronic mail to Respondent:
Drug Depot, Inc.
Attn: Cletis Koukoulakis, PharmD
34911 US Highway 19 N, Ste. 600
Palm Harbor, FL 34684
Email: mmarling@apsmeds.com


Agent of the Board

AGREED BOARD ORDER #F-15-034

RE: IN THE MATTER OF
APS PHARMACY
(PHARMACY LICENSE #28068)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28068 issued to APS Pharmacy (Respondent), 34911 United States Highway 19 North, Suite 600, Palm Harbor, Florida 34684.

By letter dated June 23, 2016, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 565.002(a)(3), (10) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and

Section 281.8(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014), as alleged in the Counts below.

The conduct described in the disciplinary actions of the Oklahoma State Board of Pharmacy and the Iowa Board of Pharmacy is substantially similar to conduct described in:

Sections 560.001(b); and 565.002(a)(3) and (4) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and

Sections 291.32(a)(2)(H); 291.32(c)(1)(E); 291.131(d)(1)(D); and 291.133(d)(1)(D) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015).

PREVIOUS HISTORY

On or about May 8, 2012, the Texas State Board of Pharmacy entered Agreed Board Order #L-12-003 in the matter of the application for pharmacy license by APS Pharmacy. The Order was based on disciplinary action entered against the pharmacy by the Florida Board of Pharmacy on May 11, 2010, regarding various violations identified during a board inspection of the pharmacy. The Order granted the license, and imposed a reprimand.

COUNTS

- (1) On or about February 14, 2012, the Colorado State Board of Pharmacy entered a Stipulation and Final Agency Order against the application for registration as a non-resident pharmacy by APS Pharmacy. The Order was based on the disciplinary action by the Florida Board of Pharmacy described above in Previous History. The Order granted the registration, subject to probation with conditions for a period of one year.

Agreed Board Order #F-15-034

APS Pharmacy

Page 2

- (2) On or about June 23, 2014, APS Pharmacy submitted to the Texas State Board of Pharmacy an application for renewal as a nonresident pharmacy engaged in compounding sterile preparations. On the application, it was falsely indicated that the pharmacy had not been the subject of professional disciplinary action by a regulatory authority within the last 36 months, when it was disciplined by the Colorado Board of Pharmacy on February 14, 2012, as described above in Count (1).
- (3) On or about February 24, 2016, the Oklahoma State Board of Pharmacy entered an Agreed Findings of Fact, Conclusions of Law and Final Order against the Oklahoma pharmacy license number 99-7398 held by APS Pharmacy. The Order was based on findings including that between October 1, 2013, and May 31, 2015, the pharmacy shipped 1,952 prescriptions, including controlled substances, to patients in Oklahoma without a valid pharmacy license. In addition, some of these prescriptions were for compounded drugs that were essentially a copy of commercially manufactured drugs. The Order placed the license on probation for a period of three years, imposed a \$15,000 fine, and required the pharmacy to develop and implement a Plan of Correction.
- (4) On or about March 8, 2016, the Iowa Board of Pharmacy entered a Settlement Agreement and Final Order against the Iowa pharmacy license numbers 4139 and 4375 held by APS Pharmacy. The Order was based on allegations contained in a Notice of Hearing and Statement of Charges that between January 1, 2014, and September 7, 2014, the pharmacy shipped approximately 100 prescriptions to patients in Iowa after its license became delinquent and prior to submitting a new nonresident pharmacy application. The Order cited and warned the pharmacy, and imposed a \$2,500 penalty.

An informal conference was held in the Board's office on September 6, 2016. Jaime Rios, Corporate President of Drug Depot, Inc., on behalf of Respondent, was not in attendance; however, Bruce D. Lamb, Legal Counsel for Respondent, submitted a written statement. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggener, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin Arnold, General Counsel. Megan Holloway, Staff Attorney, was also in attendance.

By signing this Order, Jaime Rios and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

Agreed Board Order #F-15-034
APS Pharmacy
Page 4

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

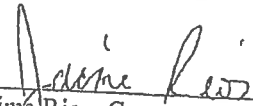
SIGNED AND ENTERED ON THIS _____ day of _____, _____.

MEMBER, TEXAS STATE BOARD OF PHARMACY

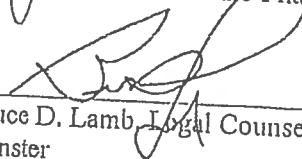
ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:



Jaime Rios, Corporate President, Drug Depot, Inc.
For and on behalf of APS Pharmacy



Bruce D. Lamb, Legal Counsel for APS Pharmacy
Gunster
401 East Jackson Street, Suite 2500
Tampa, Florida 33602

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

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BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case Nos. 2016-1848 & 2016-1913

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF DRUG DEPOT, INC., REGISTRATION NO. OSP 5618,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Drug Depot, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Numbers 2016-1848 and 2016-1913, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to provisions of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).
2. Respondent Pharmacy was originally registered in the State of Colorado on or about February 22, 2012, being issued registration number OSP 5618, and has been so registered at all times relevant to this disciplinary action.
3. Respondent Pharmacy's address of record with the Board and current location is 34911 US Highway 19 North, Suite 600, Palm Harbor, FL 34684-1921.
4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.
5. On or about February 24, 2016, the Oklahoma Board of Pharmacy issued a Final Order against Respondent Pharmacy for shipping approximately 1,952 prescriptions, 1,002 of which were controlled substances, into the State of Oklahoma from October 1, 2013 through May 31, 2015, without an active registration.
6. The Oklahoma Board placed Respondent's registration on probation for three (3) years, until February 24, 2019.

7. On or about January 1, 2016, Respondent Pharmacy entered into a Settlement Agreement with the Iowa Board of Pharmacy for shipping approximately 100 prescriptions into the State of Iowa from January 1 through September 7, 2014, without an active registration.
8. Respondent failed to report the Oklahoma and Iowa disciplinary actions to the Colorado Board.
9. Respondent Pharmacy admits that its conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Rules and provides grounds for disciplinary action against Respondent Pharmacy's Colorado registration as a prescription drug outlet:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline. (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this Article, including commission of an act declared unlawful in section 12-42.5-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs;

(g) Has had his or her license to practice pharmacy in another state revoked or suspended, or is otherwise disciplined or has committed acts in any other state that would subject him or her to disciplinary action in this state;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-124. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that the applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

12-42.5-130. Nonresident prescription drug outlet - registration. (1) Any prescription drug outlet located outside this state that ships, mails, or delivers, in any manner, drugs or devices into this state is a nonresident prescription drug outlet and shall register with the board and disclose to the board the following:

- (a) The location, names, and titles of all principal entity officers and all pharmacists who are dispensing drugs or devices to the residents of this state. The nonresident prescription drug outlet shall submit a report containing this information to the board on an annual basis and within thirty days after any change of office, officer, or pharmacist.
- (b) A verification that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident prescription drug outlet shall maintain at all times a valid, unexpired license, permit, or registration to conduct the prescription drug outlet in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident prescription drug outlet shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.
- (2) The registration requirements of this section apply only to a nonresident prescription drug outlet that only ships, mails, or delivers, in any manner, drugs and devices into this state pursuant to a prescription order.
- (3) A nonresident prescription drug outlet doing business in this state that has not obtained a registration shall not conduct the business of selling or distributing drugs in this state without first registering as a nonresident prescription drug outlet. A nonresident prescription drug outlet shall make application for a nonresident prescription drug outlet registration on a form furnished by the board. The board may require such information as it deems necessary to carry out the purpose of this section.
- (4) (a) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration for failure to comply with this section or with any rule promulgated by the board.
- (b) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration if the nonresident prescription drug outlet's license or registration has been revoked or not renewed for noncompliance with the laws of the state in which it is a resident.

Pharmacy Board Rules and Regulations

9.00.10 Reporting.

- b. All licensees or registrants shall notify the Board in writing within 30 days of any disciplinary action against them in another state. Such notification shall include the following:

1. The state;
2. The jurisdiction;
3. The case name;
4. The case number;
5. A description of the matter and a copy of the indictment or charges;
6. A copy of the discipline; and
7. Proof of completion of any requirements set forth in the order, if applicable.

10. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

DISPOSITION

11. Probation. Respondent Pharmacy's registration shall be placed on indefinite probation until Respondent Pharmacy submits documentation to the Colorado Board evidencing that its pharmacy license/registration/permit is in an active and unencumbered status with all other states in which it is registered. Credit toward satisfying the period of probation shall be given only during such periods of time that Respondent Pharmacy is in total compliance with all provisions of this Final Agency Order.

Terms of Probation

12. Other Requirements. Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent Pharmacy shall:

- a. promptly pay all its own fees and costs associated with this Final Agency Order;
- b. comply fully with this Final Agency Order; and
- c. comply fully with the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceuticals and pharmacists in the State of Colorado.

13. Violations. Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the

obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

14. Completion of Terms. Respondent must make a written request to the Board to end the terms and conditions of this Final Agency Order. In any request, it shall be Respondent's sole responsibility to establish, through written and other documentation, that Respondent has met all terms of this Final Agency Order. Respondent's probation shall continue until the Board or its designated authority has verified that Respondent has completed all terms of this Final Agency Order. The Board will consider Respondent's request during the ordinary course of business.

15. Advisements and Waivers. Through its undersigned Authorized Representative, Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

- a. To have a formal notice of hearing and charges served upon it;
- b. To respond to said formal notice of charges;
- c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and
- d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

16. Acknowledgments. The undersigned Authorized Representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

17. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
19. Board Order. This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.
20. Effective Date. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Pharmacy at Respondent Pharmacy's address of record with the Board, or (b) service by electronic means on Respondent Pharmacy at Respondent Pharmacy's electronic address of record with the Board. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Pharmacy

Michael Marling GM
Authorized Representative / Title

Dated: 12/14/16

Subscribed and sworn to before me in the County of Pinellas, State
of Florida, this 14th day of December, 2016, by
Michael Marling, In his/her capacity as an
authorized agent of Drug Depot, Inc.

Rebecca Karukin
Notary Public

My commission expires:

4/17/17




REBECCA KARUKIN
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF009426
Expires 4/17/2017

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 16 day of December, 2016.

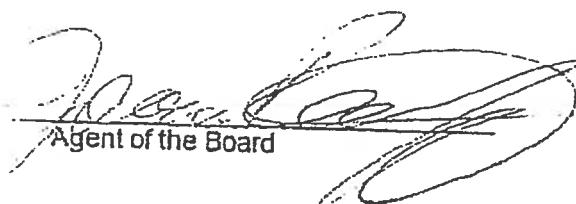
State Board of Pharmacy

BY. 
Chris Gassen
Interim Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 16th day of December 2016, addressed as follows:

Drug Depot, Inc.
Attn: Cletis Koukoulakis, PharmD
34911 US Highway 19 North, Suite 600
Palm Harbor, FL 34684-1921
Email: george@apsmeds.com and mmarling@apsmeds.com


Agent of the Board

LOUISIANA BOARD OF PHARMACY
BATON ROUGE, LOUISIANA

IN THE MATTER OF:

CONSENT ORDER

DRUG DEPOT, INC. D/B/A APS PHARMACY

LOUISIANA PHARMACY PERMIT NO. 6689

Case No. 17-0050

CONSENT AGREEMENT

WHEREAS, DRUG DEPOT, INC. D/B/A APS PHARMACY (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 6689, 34911 US Highway 19 N, Suite 600, Palm Harbor, Florida 34684, was disciplined by several Board Orders and failed to report said disciplinary action as follows:

- (1) Board Order issued by the Colorado State Board of Pharmacy on February 14, 2012 and Board Order issued by the Texas State Board of Pharmacy on May 8, 2012. Respondent failed to report these disciplinary actions to the Louisiana Board of Pharmacy ("The Board") as part of its Application for Louisiana Pharmacy Permit Located Out-of-State in 2013.
- (2) Board Order issued by the Alabama State Board of Pharmacy on September 17, 2015. Respondent failed to report this disciplinary action to the Board as part of its Application for Renewal for Year 2016.
- (3) Board Order issued by the Colorado State Board of Pharmacy on October 19, 2016. Respondent failed to report this disciplinary action to the Board as part of its Application for Renewal for Year 2017.

WHEREAS, such actions constitute a violation of the following:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1241(A)(2): Has attempted to or obtained a license by misrepresentation.

LA. R.S. 37:1241(A)(6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

DRUG DEPOT, INC. D/B/A APS PHARMACY
CONSENT AGREEMENT
Page 2 of 4

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement Respondent does not admit to violating any federal or state law. Respondent understands that the Board may be able to prove a finding of those violations, because Respondent waives its right to offer a defense at a formal administrative hearing.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. Louisiana Pharmacy Permit No. 6689 belonging to DRUG DEPOT, INC. D/B/A APS PHARMACY is issued a Letter of Reprimand.
2. DRUG DEPOT, INC. D/B/A APS PHARMACY is ordered to pay a fine of \$20,000.00 and to reimburse the Board \$250.00 for administrative costs, with total payment due the Board of \$20,250.00, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to provide the Board with the following for reporting purposes to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB):

Respondent's National Provider Identifier (NPI) Number: 1548409758

Medicare Provider Number (if in the possession of one): _____

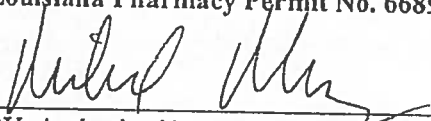
DRUG DEPOT, INC. D/B/A APS PHARMACY
 CONSENT AGREEMENT
 Page 3 of 4

I, Michael Marling, authorized to act on behalf of and acting on behalf of DRUG DEPOT, INC. D/B/A APS PHARMACY, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.


SIGNED, AGREED TO AND ENTERED ON THIS 3 DAY OF April, 2017.

DRUG DEPOT, INC. D/B/A APS PHARMACY
 Louisiana Pharmacy Permit No. 6689


 BY: Authorized Representative

JENNIFER JONES THOMAS
 Kean Miller LLP
 II City Plaza
 400 Convention Street, Suite 200
 Baton Rouge, LA 70802
 Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:


 CARLOS M. FINALET, III
 General Counsel, Louisiana Board of Pharmacy

DRUG DEPOT, INC. D/B/A APS PHARMACY
CONSENT AGREEMENT
Page 4 of 4

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF
PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on _____, 2017, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron
President and Hearing Officer for the Board

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

APS PHARMACY
License Number: 53-01-009652

File Number: 53-16-142841
CONSENT ORDER AND STIPULATION

CONSENT ORDER

On March 9, 2017, the Department of Licensing and Regulatory Affairs (Department) executed an Administrative Complaint (Complaint) charging APS Pharmacy (Respondent) with violating section(s) 17748a(5) and 17768(2)(d) of the Public Health Code, MCL 333.1101 et seq.

Respondent has admitted that the facts alleged in the Complaint are true and constitute violation(s) of the Public Health Code. The Disciplinary Subcommittee of the Michigan Board of Pharmacy (Disciplinary Subcommittee) has reviewed the Consent Order and Stipulation (Order) and agrees that the public interest is best served by resolution of the outstanding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violation(s) of section(s) 17748a(5) and 17768(2)(d) of the Public Health Code, supra.

Accordingly, IT IS ORDERED that for the cited violation(s) of the Public Health Code, Respondent is FINED \$250.00 to be paid to the State of Michigan within 60 days from the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Legal Affairs/Enforcement Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display the file number **53-16-142841**.

IT IS FURTHER ORDERED that if Respondent fails to comply with the terms and conditions of this Order, Respondent's license shall be automatically **SUSPENDED** for a minimum of one day. If, within six months of the suspension of the license, Respondent complies with the terms of this Order, the license shall be automatically reinstated.

IT IS FURTHER ORDERED that if Respondent's license remains suspended for more than six months, Respondent must apply for reinstatement of the license. If Respondent applies for reinstatement of the license, application for reinstatement shall be in accordance with sections 16245 and 16247 of the Public Health Code, supra.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____

Chairperson, Disciplinary Subcommittee

Dated: _____

10-11-17

STIPULATION

1. The facts alleged in the Complaint are true and constitute violation(s) of section(s) 17748a(5) and 17768(2)(d) of the Public Health Code, supra.

2. Respondent understands and intends that by signing this Stipulation Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 et seq., to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waiving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.

3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 et seq., and this action will be reported to the National Practitioner Data Bank, and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

4. Dhafer Almaklani, R.Ph., a member of the Board who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Order.

5. This Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the Disciplinary Subcommittee in this matter.

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent and the Department expressly reserve the right to further proceedings without prejudice should this Order be rejected.

AGREED TO BY:

Kim Gaedeke
Kim Gaedeke, Director
Bureau of Professional Licensing

Dated: 8-7-17

AGREED TO BY:

Michael Marling
Michael Marling, General Manager
APS Pharmacy
Respondent

Dated: 7/22/17

lb

**BEFORE THE MINNESOTA
BOARD OF PHARMACY**

In the Matter of
APS Pharmacy
License No. 264531

**STIPULATION AND
CONSENT ORDER**

STIPULATION

APS Pharmacy ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.
2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 13, 2017, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Joseph Stanek and Samantha Schirmer comprised the Committee. Julie K. Letwat, Esq., Faegre Baker Daniels LLP, represented Licensee. Hans A. Anderson, Assistant Attorney General, represented the Committee.

III.

FACTS

4. On or about November 26, 2012, the Board licensed Licensee as a pharmacy in Minnesota. Licensee has never been licensed by the Board as a drug wholesaler.

5. On or about June 30, 2013, Licensee's Minnesota pharmacy license expired.

6. On or about July 31, 2014, Licensee submitted an Application for a Minnesota Pharmacy License. During the review process of this application, the Board advised Licensee that a Minnesota pharmacy license only allows pharmacies to compound and dispense drug products into Minnesota pursuant to valid patient-specific prescriptions. The Board required Licensee to respond in writing, acknowledging its awareness of Minnesota law, and attesting it would limit its activities to filling only patient-specific prescriptions, or that it would apply for the required manufacturer and wholesaler licenses in the event that Licensee intended to ship products into Minnesota in any other manner.

7. On or about August 4, 2014, Licensee responded, acknowledging its awareness of Minnesota law regarding the shipping of non-patient-specific drugs, and attesting it would limit its activities to filling only patient-specific prescriptions.

8. On or about August 5, 2014, the Board again licensed Licensee as a pharmacy in Minnesota.

9. On or about February 26, 2016, in response to a Board request, Licensee provided the Board with documentation showing ten separate compounded preparations Licensee shipped to Minnesota physicians for "office use" over an eleven month period in 2015. Licensee stated that its shipment of drugs into Minnesota for "office use" was an "oversight."

10. Licensee also provided the Board with documentation showing nine additional prescriptions that were shipped by Licensee directly to medical clinics in Minnesota. Six of the

nine were filled in the name of the prescribing physician, and two were filled in the name of the physician's employee, the clinic's "Director of Operations." Those same prescriptions were billed by Licensee to the clinic, and not to the patients, resulting in wholesale transactions.

11. From January 5, 2015, through June 30, 2015, 39% of the prescriptions Licensee dispensed and shipped into Minnesota were veterinary medications. Licensee had not checked the veterinary category of licensure on its application, and was thus not licensed by the Board to dispense and ship veterinary medications into Minnesota.

IV.

LAWS

12. Licensee acknowledges the conduct described in section III. above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), Minn. Stat. § 151.34(11), Minn. Stat. § 151.47, subd. 1, Minn. R. 6800.2250, subp. 1 (H); and Minn. R. 6800.0350, and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

13. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of \$2,500.00 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

- a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.
- b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.
- c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of

the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

Jean Kroe
 APS PHARMACY
 Licensee

Dated:

1/9/18

Jan B. Ska
 Board Member

Dated:

01-16-2018

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a
CIVIL PENALTY on Licensee's license, and adopts all of the terms described above on this
16TH day of January, 2018.

MINNESOTA BOARD OF PHARMACY

Cody Wiberg
 CODY WIBERG
 Executive Director

IN THE MATTER OF:)	
)	
DRUG DEPOT INC. d/b/a APS)	BEFORE THE ALABAMA STATE
PHARMACY)	BOARD OF PHARMACY
)	
Non-Resident Pharmacy)	CASE NO: 16-L-0174
Permit Number: 114007)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Drug Depot Inc. d/b/a APS Pharmacy (Drug Depot) which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Drug Depot through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The parties stipulate that Drug Depot denies the allegations of the Statement of Charges and Notice of Hearing (SOC) and stipulates that for the purpose of this proceeding and this proceeding only the Board would meet its required burden of proof and therefore finds that Drug Depot violated the provisions of law based upon the conduct set out in Counts One, Four, Six, Seven and/or Eight. All remaining Counts shall be dismissed with prejudice.

2. Drug Depot shall pay an administrative fine in the amount of Twenty-Five Thousand Dollars (\$25,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Drug Depot attempt to discharge the

same.

3. Drug Depot expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Drug Depot further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Drug Depot hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Drug Depot acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Drug Depot's permit, including, but not limited to revocation.

6. Drug Depot acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Drug Depot acknowledges and agrees that it voluntarily and of its own free will accepts the terms and

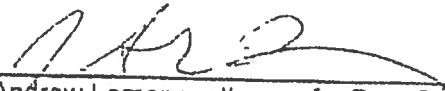
conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 5 of January, 2018.

DRUG DEPOT INC. D/B/A APS PHARMACY

BY: 

ITS: GM


J. Andrew Lemons, attorney for Drug Depot Inc.
d/b/a APS Pharmacy

DONE this the 9th of Jan, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: 

David Darby, R.Ph., President

By: 

James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY**

In the Matter of the Application	:	
for the Nonresident Pharmacy	:	Docket No. 0896-54-18
Registration of	:	File No. 18-54-03878
Drug Depot, Inc., d/b/a APS Pharmacy,	:	
Applicant	:	

PROPOSED ORDER

AND NOW, this 2nd day of **August, 2018**, upon consideration of the foregoing findings of fact, conclusions of law and discussion, it is hereby ordered that the application for nonresident pharmacy registration of Drug Depot, Inc., d/b/a APS Pharmacy ("Applicant") is **GRANTED**.

Upon the grant of a nonresident pharmacy certificate of registration ("license") to Applicant, said license **IMMEDIATELY** shall be placed on **PROBATION** for an **INDEFINITE** period of time, until such time as each and every one of Applicant's pharmacy permits, registrations, licenses, or any other authorizations to practice, in every jurisdiction in which Applicant possesses such authorizations, shall be active and unencumbered.

Said period of probation shall be subject to the following terms and conditions:

GENERAL

1. Applicant shall abide by and obey all laws of the United States, the Commonwealth of Pennsylvania and its political subdivisions and all rules and regulations and laws pertaining to the practice of the profession in this Commonwealth or any other state or jurisdiction in which Applicant holds a permit, registration, license or any other authorization to practice the profession. Summary traffic violations shall not constitute a violation of this Order.

2. Applicant shall at all times cooperate with the Bureau of Professional and Occupational Affairs and its agents and employees in the monitoring, supervision and investigation of Applicant's compliance with the terms and conditions of this Order, including requests for, and causing to be

submitted at Applicant's expense, written reports, records and verifications of actions that may be required by the Bureau of Professional and Occupational Affairs.

3. Applicant shall not falsify, misrepresent or make material omission of any information submitted pursuant to this Order.

4. Applicant shall notify the Bureau of Professional and Occupational Affairs, in writing, within five (5) days of the filing of any criminal charges against Applicant, the initiation of any legal action pertaining to Applicant's authorizations to practice of the profession, the initiation, action, restriction or limitation relating to Applicant by a professional licensing authority of any state or jurisdiction, or any violation of Applicant's term of probation imposed by any professional licensing authority of any state or jurisdiction, including but not limited to the terms of probation imposed upon Applicant by Oklahoma State Board of Pharmacy in the matter captioned *In the Matter of the Complaint Against: APS Pharmacy (99-7398), Case No 1390*, by the Agreed Findings of Fact, Conclusions of Law and Final Order dated February 24, 2016.

5. Applicant shall notify the Bureau of Professional and Occupational Affairs by telephone within 48 hours and in writing within five (5) days of any change of Applicant's business address, phone number, ownership and/or change in practice.

VIOLATION OF THIS ORDER

6. Notification of a violation of the terms or conditions of this Order shall result in the **IMMEDIATE TERMINATION** of the period of probation and **ACTIVATION** of a suspension of Applicant's license(s) to practice the profession in the Commonwealth of Pennsylvania as follows:

a. The prosecuting attorney for the Commonwealth shall present to the Board's Probable Cause Screening Committee ("Committee") a Petition that indicates that Applicant has violated any terms or conditions of this Order.

b. Upon a probable cause determination by the Committee that Applicant has violated any of the terms or conditions of this Order, the Committee shall, without holding

a formal hearing, issue a preliminary order vacating the stay of the within suspension, terminating this probation and activating the suspension of Applicant's license.

c. Applicant shall be notified of the Committee's preliminary order within three (3) business days of its issuance by certified mail and first-class mail, postage prepaid, sent to the Applicant's last registered address on file with the Board, or by personal service if necessary.

d. Within twenty (20) days of mailing of the preliminary order, Applicant may submit a written answer to the Commonwealth's Petition and request that a formal hearing be held concerning Applicant's violation of probation, in which Applicant may seek relief from the preliminary order activating the suspension. Applicant shall mail the original answer and request for hearing to the Department of State Prothonotary, 2601 North Third Street, P.O. Box 2649, Harrisburg, PA 17105, shall mail a copy to the prosecuting attorney for the Commonwealth, and shall do the same with all subsequent filings in the matter.

e. If the Applicant submits a timely answer and request for a formal hearing, the Board or a designated hearing examiner shall convene a formal hearing within forty-five (45) days from the date of the Prothonotary's receipt of Applicant's request for a formal hearing.

f. Applicant's submission of a timely answer and request for a hearing shall not stay the suspension of Applicant's license under the preliminary order. The suspension shall remain in effect unless the Board or the hearing examiner issues an order after the formal hearing staying the suspension again and reactivating the probation.

g. The facts and averments in this Order shall be deemed admitted and uncontested at this hearing.

h. If the Board or hearing examiner after the formal hearing makes a determination against Applicant, a final order will be issued sustaining the suspension of Applicant's license and imposing any additional disciplinary measures deemed appropriate.

i. If Applicant fails to timely file an answer and request for a hearing, the Board, upon motion of the prosecuting attorney, shall issue a final order affirming the suspension of Applicant's license.

j. If Applicant does not make a timely answer and request for a formal hearing and a final order affirming the suspension is issued, or the Board or the hearing examiner makes a determination against Applicant sustaining the suspension of Applicant's license, after at least one (1) year of active suspension and any additional imposed discipline, Applicant may petition the Board for reinstatement upon verification that Applicant has complied with the Board's order, abided by and obeyed all laws of the United States, the Commonwealth of Pennsylvania and its political subdivisions, and all rules and regulations pertaining to the practice of the profession in this Commonwealth.

k. Applicant's failure to fully comply with any terms of this Order may also constitute grounds for additional disciplinary action.

7. Nothing in this Order shall preclude the prosecuting attorney for the Commonwealth from filing charges or the Board from imposing disciplinary or corrective measures for violations or facts not contained in this Order.

8. At such time as each and every one of Applicant's pharmacy permits, registrations, licenses, or any other authorizations to practice, in every jurisdiction in which Applicant possesses such authorizations, shall be active and unencumbered, Applicant may petition the Board to reinstate Applicant's license to unrestricted, non-probationary status upon an affirmative showing that Applicant has complied with all terms and conditions of this Order.

The State Board of Pharmacy has announced its intention to review this Proposed Report in accordance with 1 Pa. Code § 35.226(a)(2).

BY ORDER



Ruth D. Dunnewold

Hearing Examiner

For the Applicant:

Thomas J. Weber, Esquire
CALDWELL AND KEARNS, P.C.
3631 North Front Street
Harrisburg, PA 17110

For the Commonwealth:

Monty J. Batson, Esquire
GOVERNOR'S OFFICE OF GENERAL COUNSEL
DEPARTMENT OF STATE OFFICE OF CHIEF COUNSEL
PROSECUTION DIVISION
P.O. Box 69521
Harrisburg, PA 17106-9521

Date of mailing:

8/2/18

AGREED BOARD ORDER #L-16-076

RE: IN THE MATTER OF
APS PHARMACY
(PHARMACY LICENSE #28068)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28068 issued to APS Pharmacy (Respondent), 34911 United States Highway 19 North, Suite 600, Palm Harbor, Florida 34684.

By letter dated October 10, 2018, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 560.001(b); 561.002; 561.003(b); 561.0031; 561.005; and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015); and

Section 291.14 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016), in that allegedly:

PREVIOUS HISTORY

- (1) On or about May 8, 2012, the Texas State Board of Pharmacy entered Agreed Board Order #L-12-003 in the matter of the application for pharmacy license by APS Pharmacy. The Order was based on disciplinary action entered against the pharmacy by the Florida Board of Pharmacy on May 11, 2010, regarding various violations identified during a board inspection of the pharmacy. The Order granted the license and imposed a reprimand.
- (2) On or about November 1, 2016, the Texas State Board of Pharmacy entered Agreed Board Order #F-15-034 in the matter of APS Pharmacy. The Order was based on a disciplinary action by the Oklahoma State Board of Pharmacy for shipping prescriptions, including compounded drugs that were essentially a copy of commercially manufactured drugs, to patients in Oklahoma without a valid license, a disciplinary action by the Iowa Board of Pharmacy for shipping to patients in Iowa with a delinquent license, and the pharmacy's failure to disclose a disciplinary action by the Colorado State Board of Pharmacy on a renewal application. The Order imposed a \$6,000 penalty.

COUNT

On or about June 1, 2016, through on or about August 28, 2016, APS Pharmacy, 34911 United States Highway 19 North, Suite 600, Palm Harbor, Florida 34684, was unlawfully operating in that the pharmacy shipped approximately 500 prescriptions into Texas with an expired license. On or about April 27, 2016, APS Pharmacy submitted a renewal application for

Agreed Board Order #L-16-076
APS Pharmacy
Page 2

a non-resident pharmacy engaged in compounding sterile preparations, but the pharmacy had not been inspected by a Texas State Board of Pharmacy approved vendor. The National Association of Boards of Pharmacy inspected the pharmacy on August 4 and 5, 2016, and the pharmacy's license was ultimately renewed on August 29, 2016.

By letter dated October 10, 2018, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Jaime Rios, Corporate President, Drug Depot, Inc., on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

- (1) Respondent shall pay an administrative penalty of one thousand dollars (\$1,000) due one hundred twenty (120) days after the entry of this Order.
- (2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2017), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2018).

Agreed Board Order #L-16-076
APS Pharmacy
Page 3

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of November, 2018.



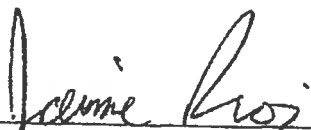
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:



Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:



Jaime Rios, Corporate President, Drug Depot, Inc.
On behalf of APS Pharmacy

APPROVED AS TO FORM:



Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

IN THE MATTER OF	*	BEFORE THE
	*	
DRUG DEPOT, INC. d/b/a	*	
APS PHARMACY	*	STATE
	*	
Respondent	*	BOARD OF PHARMACY
	*	
Permit Number: P07142	*	Case Number: 18-135

* * * * *

CONSENT ORDER

Background

In March 2016, the Maryland Board of Pharmacy (the "Board") received an application for Permit from Drug Depot, Inc., d/b/a APS Pharmacy (the "Pharmacy"), Permit P07142. The Pharmacy was previously issued Permit No. P05882 on September 24, 2012, which expired on May 31, 2014 due to non-renewal. The Board issued Permit P07142 on October 21, 2016.

On January 11, 2018, the Pharmacy sent the Board a self-report notice of disciplinary action based on a Consent Order with the Michigan Board of Pharmacy. The Michigan Board of Pharmacy took action against the Pharmacy based upon similar action taken by the Oklahoma Board of Pharmacy. These actions were taken against the Pharmacy primarily for practicing pharmacy without an active permit in those jurisdictions, and as a result the Board opened an investigation into the Pharmacy and issued a subpoena for the Pharmacy's dispensing records. These records showed that the Pharmacy dispensed over 3,800 prescriptions into the State of Maryland between May 31, 2014, and October 21, 2016 while the Pharmacy was not permitted to do so.

In lieu of instituting formal proceedings against the Pharmacy, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Drug Depot, Inc. d/b/a APS Pharmacy agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. The Pharmacy was initially issued a permit to operate as a nonresident pharmacy in the State of Maryland on or about September 24, 2012, under permit number P05882. This permit expired on May 31, 2014 due to non-renewal.
2. On or about March 17, 2016, the Pharmacy submitted a new application ("the application") for Nonresident Pharmacy Permit to the Board. On October 21, 2016, a new Nonresident Pharmacy Permit was issued to the Pharmacy under permit number P07142. This permit is scheduled to expire on May 31, 2020.
3. As part of its new application, the Pharmacy attached disciplinary actions from the Boards of Pharmacy in the States of Iowa, Alabama, and Florida.
4. On or about January 11, 2018, the Board received a self-report notice of disciplinary action from the Pharmacy based on a consent order with the Michigan Board of Pharmacy ("Michigan Board.")
5. The Board then opened an investigation into the Pharmacy.
6. On or about October 6, 2016 the Michigan Board took disciplinary action against the Pharmacy, and subsequently entered into a Consent Order based upon action

taken against the Pharmacy by the Oklahoma Board of Pharmacy ("Oklahoma Board"), and the Iowa Board of Pharmacy ("Iowa Board"), respectively.

7. The Michigan Board of Pharmacy placed the Pharmacy on a six (6) month probation, and assessed a \$2,500 fine. The Stipulation and Consent Order were agreed to by the Pharmacy on or about February 7, 2017.
8. On or about February 2, 2016, the Oklahoma Board of Pharmacy ("Oklahoma Board") issued a Final Order regarding violations committed by the Pharmacy. The Oklahoma Board and the Pharmacy agreed to findings of fact including the following grounds for discipline: The Pharmacy mailed patient-specific drugs to an address other than the patient's home or place of employment; and the Pharmacy was not continuously licensed by the Oklahoma Board during the entire time in which prescriptions were being filled. In addition, on or about August 11, 2015 the Pharmacy in its license application answered "No" to the question of having been sanctioned or disciplined regarding any license permit or registration issued to the applicant. This question was answered in the negative despite Pharmacy having entered into a Settlement Agreement with the State of Florida Board of Pharmacy ("Florida Board") on or about January 7, 2010.
9. On or about February 24, 2016, the Pharmacy was placed on a three (3) year probation by the Oklahoma Board of Pharmacy, and assessed a \$15,000 fine for operating without a license, filing false reports, and unauthorized dispensing of medication from October 1, 2013, through May 31, 2015.

10. On or about May 11, 2010, the Pharmacy entered into a Final Order with the Florida Board. Pursuant to the Final Order, the Pharmacy did not dispute allegations outlined in the Administrative Complaint including but not limited to: wholesaling drugs without a permit, dispensing prescription drugs without prescriptions, purchasing prescription drugs from an unauthorized vendor, mislabeling of drugs, and improper storage of prescription drugs. The Pharmacy was ordered to pay costs of investigation and prosecution totaling \$2,534.31.
11. On or about August 17, 2015, the Pharmacy entered into a Consent Order with the Alabama Board of Pharmacy ("Alabama Board.") Pursuant to the Consent Order the Pharmacy pled guilty to "engaging in the selling, offering for sale, compounding, or dispensing of drugs during the year 2015 without first having your permit with the Board..." The Pharmacy was ordered to pay a fine in the amount of \$500.
12. On or about March 8, 2016, the Pharmacy entered a Consent Order with the Iowa Board of Pharmacy ("Iowa Board.") Pursuant to the Consent Order the Pharmacy admitted to "providing pharmacy services to Iowa residents without an active Iowa pharmacy license." The Pharmacy was ordered to pay a civil penalty of \$2,500.
13. On or about January 12, 2018, staff from the Maryland Board subpoenaed dispensing records from the Pharmacy covering the period of May 31, 2014 through October 21, 2016, during which Pharmacy's nonresident pharmacy permit was

lapsed. The dispensing records revealed that in the period of time during which the nonresident pharmacy permit was lapsed, the Pharmacy dispensed over 3,800 prescriptions into the State of Maryland.

14. The Pharmacy has since made several administrative and personnel changes to their in-house practices in the wake of the previous violations. The Pharmacy indicates that they have added a full-time quality assurance pharmacist whose dedicated responsibilities include all regulatory matters in relation to sterile and non-sterile compounding. The pharmacy has also added another position to handle all regulatory and compliance matters at both the federal and state levels. The Pharmacy believes these changes will prevent any future compliance issues from taking place.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Pharmacy is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§ 12-313(b)(24) and (25), 12-403(c)(1), (e)(1), and (g)(1).

ORDER

Based on an affirmative vote of a majority of the Board, it is this _____ day of _____, 2019, hereby:

ORDERED that Drug Depot, Inc., d/b/a APS Pharmacy, Permit No. P07142, shall be assessed a civil fine in the amount of FIVE THOUSAND

DOLLARS (\$5,000.00), payable to the Maryland Board of Pharmacy within thirty (30) days of the date of this Order, and sent to:

Wells Fargo Bank
Attn: State of Maryland – Board of Pharmacy
Lockbox 2051
7175 Columbia Gateway Drive
Columbia, Maryland 21046
(Please include the Case Number 18-135 to ensure proper assignment.);

and it is further

ORDERED that failure to pay in full the above fine within thirty (30) days of the date of this Order shall be considered a violation of this Order, and after notice and opportunity for a show cause hearing shall subject the Pharmacy to further discipline such as suspension, revocation or further fines based on the violations cited in this Order; and it is further

ORDERED that Drug Depot, Inc., d/b/a APS Pharmacy, shall practice in Maryland at all times in accordance with the Maryland Pharmacy Act; and it is further

ORDERED that in the event that Drug Depot, Inc., d/b/a APS Pharmacy violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any disciplinary sanction it deems appropriate, including suspension, revocation,

and fines, said violation being proven by a preponderance of the evidence; and
it is further

ORDERED that this is a formal order and as such is a public document
pursuant to Md. Code Ann., General Provisions Art. § 4-301 *et seq.*

1-28-19
Date

Deena Spights-Napata
Deena Spights-Napata
Executive Director for:

Kevin Morgan, Pharm. D.
Board President

CONSENT

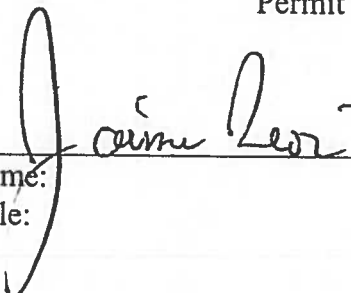
1. The Pharmacy submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, in order to avoid the cost and uncertainty of litigation and without admitting that its conduct violated any law, code or regulation.
2. By signing this Consent, the Pharmacy waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. The Pharmacy acknowledges that this is a formal order of the Board and as such is a public document.

4. The Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
5. The Pharmacy signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Pharmacy fully understands the language, meaning, and effect of this Consent Order.

Drug Depot, Inc. d/b/a APS Pharmacy

Permit No. P07142

1-17-19
Date


Name:
Title:

NOTARY

STATE OF Florida
CITY/COUNTY OF Pinellas

I HEREBY CERTIFY that on this 17th day of January,
2019, before me, a Notary Public of the foregoing State and City/County
personally appeared Jaime Rios and made oath in due form
of law that signing the foregoing Consent Order was his/her voluntary act and
deed.

AS WITNESSETH my hand and notary seal.



Rebecca Karukin
Notary Public

My commission expires:

4/17/21

**STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION**

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, DIVISION OF PROFESSIONAL REGULATION)	
of the State of Illinois,)	
v.)	
DRUG DEPOT INC.,)	
License No. 054.018831,)	
Complainant,)	No. 2018-01718
Respondent.)	

CONSENT ORDER

The Department of Financial and Professional Regulation of the State of Illinois, Division of Professional Regulation, by and through Brandon R. Thom, Enforcement Attorney of Health-Related Prosecutions, and Drug Depot Inc., Respondent, hereby agree to the following:

STIPULATIONS

Drug Depot Inc. (hereinafter "Respondent") is the holder of a pharmacy license in the State of Illinois, License No. 054.018831. Said license is currently in active status. At all times material to the matter set forth in this Consent Order, the Department of Financial and Professional Regulation of the State of Illinois, Division of Professional Regulation (hereinafter the "Department") has had jurisdiction over the subject matter and parties herein.

On or about March 8, 2016, Respondent entered into a Settlement Agreement and Final Order with the Iowa State Board of Pharmacy. Respondent's Iowa pharmacy license was disciplined for shipping approximately one hundred (100) prescriptions into Iowa without an active registration issued by the Iowa State Board of Pharmacy. Respondent was assessed a fine of two thousand five hundred dollars (\$2,500.00) by the Iowa Board of Pharmacy.

On or about February 19, 2016, Respondent entered into an Agreed Order with the Oklahoma State Board of Pharmacy. Respondent's Oklahoma pharmacy license was disciplined for shipping pharmaceuticals into Oklahoma without an active registration issued by the Oklahoma State Board of

ja

Pharmacy. Respondent was placed on probation for a period of three (3) years and was assessed a fine of fifteen thousand dollars (\$15,000.00) by the Oklahoma Board of Pharmacy.

On or about November 1, 2016, Respondent entered into an Agreed Board Order with the Texas State Board of Pharmacy. Respondent's Texas pharmacy license was disciplined for failing to disclose prior sister state discipline on an application for renewal of Respondent's Texas Pharmacy License. Respondent was assessed a fine of six thousand dollars (\$6,000.00) by the Texas Board of Pharmacy.

On or about December 14, 2016, Respondent entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy. Respondent's Colorado pharmacy license was disciplined due to adverse actions in Iowa and Oklahoma. Respondent was placed on an indefinite probation by the Colorado Board of Pharmacy. Respondent's Colorado probation has since been terminated.

On or about July 28, 2017, Respondent was disciplined by the California State Board of Pharmacy. Respondent's California pharmacy license was cited and issued a fine of five thousand dollars (\$5,000.00) due to adverse actions taken in Iowa and Oklahoma.

On or about January 6, 2017, Respondent was disciplined by the Kansas State Board of Pharmacy. Respondent's Kansas pharmacy license was disciplined due to adverse action in Oklahoma. Respondent was placed on probation by the Kansas Board of Pharmacy. Respondent's Kansas probation has since been terminated.

On or about April 3, 2017, Respondent entered into a Consent Order with the Louisiana Board of Pharmacy. Respondent's Louisiana pharmacy license was disciplined for failing to report prior sister state disciplines to the Louisiana Board of Pharmacy. Respondent was assessed a fine of twenty thousand dollars (\$20,000.00) by the Louisiana Board of Pharmacy.

On or about October 11, 2017, Respondent entered into a Consent Order with the Michigan Board of Pharmacy. Respondent's Michigan pharmacy license was disciplined for failing to report

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prior sister state complaints to the Michigan Board of Pharmacy. Respondent was assessed a fine of two hundred fifty dollars (\$250.00) by the Michigan Board of Pharmacy.

On or about January 9, 2018, Respondent entered into a Consent Order with the Alabama Board of Pharmacy. Respondent's Alabama pharmacy license was disciplined for failing to report prior sister state disciplines to the Alabama Board of Pharmacy. Respondent was assessed a fine of twenty-five thousand dollars (\$25,000.00) by the Alabama Board of Pharmacy.

The aforementioned conduct, if proven to be true, would constitute grounds for disciplinary action against Respondent's pharmacy license on the authority of 225 ILCS 85/30(a)(8).

Respondent has been advised of the right to have the pending allegations reduced to written charges, the right to a hearing, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person. Respondent acknowledges that the Department attorney may be requested to communicate with the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation in furtherance of the approval of this Consent Order.

Respondent and the Department have agreed that Respondent be permitted to enter into this Consent Order with the Department, providing for the imposition of disciplinary measures which are fair and equitable in these circumstances and which are consistent with the best interest of the people of the State of Illinois.

CM

CONDITIONS

WHEREFORE, the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation through Brandon R. Thom, Enforcement Attorney of Health-Related Prosecutions, and Drug Depot Inc., Respondent, agree:

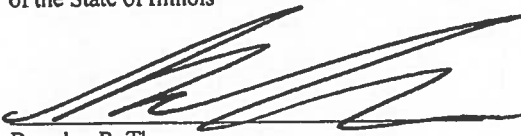
- A. Respondent's Illinois Pharmacy License, license No. 054.018831, shall be REPRIMANDED.
- B. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes, including the National Association of Boards of Pharmacy. This Consent Order will be available to the general public;
- C. This Consent Order shall become effective upon signing and approval by the Director of the Division of Professional Regulation of the Department of Financial and Professional Regulation.
- D. The above-named Respondent consents to electronic service of the Final Director's Order in lieu of service by certified mail. Service shall be made upon Respondent and Respondent's Attorney's email addresses of record with the Department.
- E. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Signatures on the following page.

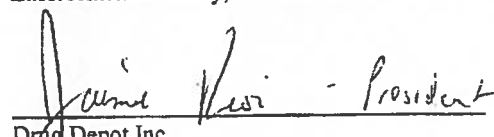
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DIVISION OF PROFESSIONAL REGULATION
of the State of Illinois

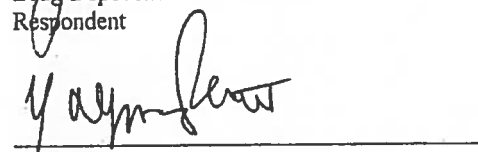
8-23-19
DATE


Brandon R. Thom
Enforcement Attorney, Health-Related Prosecutions

8/12/19
DATE


Jaime Keri - President
Drug Depot Inc.
Respondent

8/23/2019
DATE


Y. Alphonse
Member-
Illinois State Board of Pharmacy

This Consent Order is approved in full.

DATED THIS 23rd DAY OF September, 2019.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY DEBORAH HAGAN


Acting Director Cecilia Abundis
Division of Professional Regulation

Case No. 2018-01718
License No. 054.018831

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

IN RE:)
)
DRUG DEPOT, INC.)
d/b/a APS PHARMACY)
34911 US Highway 19 N, Ste. 600)
Palm Harbor, FL 34684)
Permit No. 2012034117)

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND
DRUG DEPOT, INC. d/b/a APS PHARMACY**

COME NOW Drug Depot, Inc. d/b/a APS Pharmacy ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Petitioner" or "Board") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate as a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial Administrative Hearing Commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board, at which time it may present evidence in mitigation of

discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the AHC, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For purposes of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and further stipulates that Respondent's permit as a pharmacy, numbered 2012034117, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. Petitioner is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo,¹ for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent, located at 34911 US Hwy. 19 N, Ste. 600, Palm Harbor, FL 34684, is permitted by the Board as a pharmacy under permit number 2012034117. Respondent's permit was at all times relevant herein current and active.

3. On or about July 10, 2017, Petitioner learned that the Kansas Board of Pharmacy entered a Summary Order dated January 6, 2017, placing Respondent's renewal registration on probation for a period not to exceed five (5) years ("Kansas Order"). The Kansas Order states

¹ All statutory references are to the Revised Statutes of Missouri 2016, as amended, unless otherwise stated.

that the discipline imposed by Kansas was based on discipline and probation imposed by the Oklahoma State Board of Pharmacy.

4. The Oklahoma Board of Pharmacy and Respondent entered into Agreed Findings of Fact, Conclusions of Law, and Final Order on or about February 24, 2016, placing Respondent on probation for three (3) years and imposing a fine of \$15,000.00 (Fifteen Thousand and 00/100 Dollars) (the "Oklahoma Order"). The Oklahoma probationary period has ended.

5. The Oklahoma Board alleged, among others, that Respondent violated Oklahoma law by shipping prescriptions, including controlled substance prescriptions, into the State of Oklahoma without a valid license; by compounding a commercially available drug; by dispensing prescriptions when it knew or should have known that they were issued without valid pre-existing patient-prescription relationships; and by failing to conduct its business in conformity with all federal, state and municipal laws.

6. Respondent admitted it violated Oklahoma law by shipping prescriptions, including controlled substance prescriptions, into the State of Oklahoma without a valid license and by failing to conduct its business in conformity with all federal, state and municipal laws. Respondent neither admitted nor denied that it dispensed prescriptions when it knew or should have known that they were issued without valid pre-existing patient-prescription relationships.

7. Respondent has also been disciplined in Alabama, California, Colorado, Iowa, Michigan, Minnesota, Oregon, and Texas.

8. On or about March 8, 2016, the Iowa State Board of Pharmacy and Respondent entered into a Settlement Agreement and Final Order wherein the Iowa Board imposed a

\$2,500.00 (Two Thousand Five Hundred and 00/100 Dollars) civil penalty upon Respondent for providing pharmacy services to Iowa residents without an active Iowa pharmacy license.

9. On or about November 1, 2016, the Texas State Board of Pharmacy and Respondent entered into an Agreed Board Order imposing an administrative penalty of \$6,000.00 (Six Thousand and 00/100 Dollars) on Respondent for providing false information on its nonresident pharmacy application for renewal and based for violations cited in the Oklahoma and Iowa Orders.

10. On or about December 16, 2016, the Colorado State Board of Pharmacy and Respondent entered into a Stipulation and Final Agency Order placing Respondent's registration as a non-resident prescription drug outlet on indefinite probation until it had submitted documentation to the Colorado Board showing unencumbered status in all other states in which it is registered ("Colorado Order"). Respondent admitted that its failure to report the Oklahoma and Iowa Orders to the Colorado Board constituted unprofessional conduct and violations of Colorado law, including its reporting requirements.

11. On or about April 12, 2017, the Michigan Board of Pharmacy entered a Consent Order and Stipulation placing Respondent's pharmacy license on probation for six (6) months and imposing a \$2,500.00 (Two Thousand Five Hundred and 00/100 Dollars) fine as a result of the Oklahoma and Iowa Orders.

12. On or about July 28, 2017, the California Board of Pharmacy issued a citation and imposed a fine of \$5,000.00 (Five Thousand and 00/100 Dollars) on Respondent for unprofessional conduct as a result of the discipline issued under the Oklahoma and Iowa Orders.

13. On or about January 9, 2018, the Alabama State Board of Pharmacy and Respondent entered into a Consent Order imposing a \$25,000.00 (Twenty-Five Thousand and

00/100 Dollars) administrative fine on Respondent's non-resident pharmacy permit for unprofessional conduct based on the entry of and/or certain allegations in the Oklahoma, Iowa, Colorado and California and Texas Orders.

14. On or about January 16, 2018, the Minnesota Board of Pharmacy and Respondent entered into a Stipulation reprimanding Respondent's pharmacy license and imposing a \$2,500.00 (Two Thousand Five Hundred and 00/100 Dollars) civil fine for shipping compounded preparations into Minnesota without patient-specific prescriptions under a pharmacy license, dispensing legend drugs without valid prescriptions, making wholesale transactions in Minnesota without a wholesaler license, and dispensing and shipping veterinary medications into Minnesota without the appropriate licensure, all in violation of Minnesota law.

15. On or about March 12, 2018, the Oregon Board of Pharmacy and Respondent entered into a Consent Order placing Respondent on probation for the duration of the probation imposed by the Oklahoma Board of Pharmacy for the violations contained in the Oklahoma Order which violated acceptable standards of practice and unprofessional conduct in Oregon. The Oregon probation has been completed.

16. On or about September 9, 2019, the Department of Financial and Professional Registration of the State of Illinois, Division of Professional Registration and Respondent entered into a Consent Order agreeing that Respondent's Illinois pharmacy license is reprimanded for conduct described above which would constitute grounds for disciplinary action in Illinois.

17. Respondent is subject to discipline in Missouri because Respondent has been the subject of disciplinary action in multiple states on grounds for which denial/discipline is authorized in Missouri under Section 338.055.2(8), RSMo.

JOINT CONCLUSIONS OF LAW

17. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under Section 338.055.2(8) and (15), RSMo, which states, in pertinent parts:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the Disciplinary Order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

1. Respondent's pharmacy permit numbered 2012034117 shall be placed on **PROBATION** for a period of **THREE (3) YEARS** ("Disciplinary Period"). The terms of discipline shall be as follows:

A. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

- B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
 - C. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by Respondent, and the individuals' current home addresses and telephone numbers.
 - D. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
 - E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.
 - F. Respondent shall not serve as an intern training facility for Missouri interns.
 - G. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the Disciplinary Period. Respondent will be notified and given sufficient time to arrange these meetings.
 - H. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.
 - I. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.
2. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C.

§1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ **REQUESTS**

_____ **X** _____ **DOES NOT REQUEST**

THE AHC TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.

Respondent understands that it may, either at the time the Settlement Agreement is signed by all parties, or within fifteen (15) days thereafter, submit the Settlement Agreement to the AHC for determination that the facts agreed to by the parties constitute grounds for disciplining Respondent's permit. If Respondent desires the AHC to review this Agreement, it may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

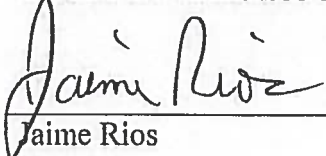
If Respondent has not requested review by the AHC, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director ("Effective Date").

[Remainder of page left blank intentionally – signature page follows]

RESPONDENT

DRUG DEPOT, INC.
d/b/a APS PHARMACY

By:


Jaime Rios

President

As Authorized Agent for
DRUG DEPOT, INC.
d/b/a APS PHARMACY

Date:

12/2/2019

PETITIONER

MISSOURI BOARD OF
PHARMACY

By:

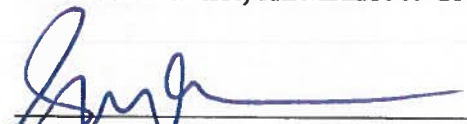

Kimberly Grinston
Executive Director

Date:

12/7/20

GREENSFELDER, HEMKER & GALE, P.C.

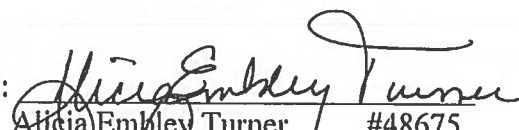
By:


Sanja Ord #67340
10 S. Broadway, Suite 2000
St. Louis, MO 63102
Telephone: (314) 345-5448
Fax: (314) 516-2693
sord@greensfelder.com

Attorneys for Drug Depot, Inc.
d/b/a APS Pharmacy

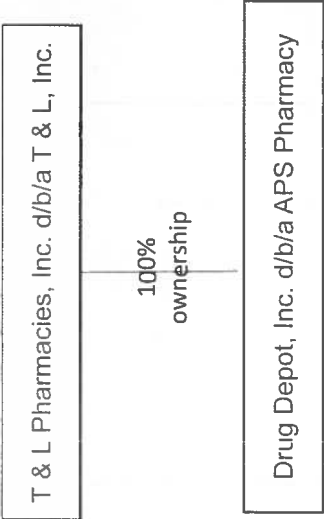
NEWMAN, COMLEY & RUTH P.C.

By:

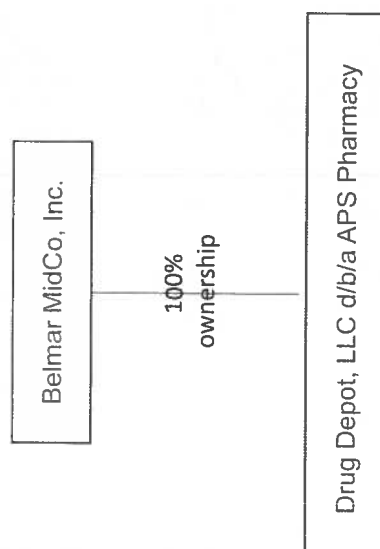

Alicia Embley Turner #48675
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: (573) 634-2266
Fax: (573) 636-3306
turnera@ncrpc.com

Attorneys for Missouri Board of
Pharmacy

Old Structure



New Post-Closing Structure



Ownership Information for Drug Depot, LLC d/b/a APS Pharmacy

Drug Depot, LLC
d/b/a APS Pharmacy
34911 US Highway 19 N, Ste. 600
Palm Harbor, FL 34684
Ph: 888-787-4137
Fx: 866-739-4750

Officers of Drug Depot, LLC:

- Jaime Rios, President
Lafferre Lane
Hilliard, OH 43026
(
- Michael A. Marling, Vice President
16 Canopy Dr.
Tampa, FL 33626
- David Malm, Secretary and Treasurer
Boylston Street, # 9009
Boston, MA 02116

Drug Depot, LLC will be wholly owned by Belmar MidCo, Inc.

Belmar MidCo, Inc.
c/o Webster Equity Partners
1000 Winter Street
Waltham, MA 02451
(781) 419-1515

Officers and Directors of Belmar MidCo, Inc.:

- David W. Hill, CEO and President
- Robert Kilgore, VP and CFO
- David P. Malm, Secretary and Treasurer; Director

Drug Depot, LLC is Manager-Managed by Belmar Holdings, Inc.

ReedSmith

Driving progress
through partnership

David T. Hartmann

Direct Phone: +1 312 207 6556

Email: dhartmann@reedsmith.com

Reed Smith LLP
10 South Wacker Drive
Chicago, IL 60606-7507
+1 312 207 1000
Fax +1 312 207 6400
reedsmith.com

April 10, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206,
Reno, NV 89521

Re: Drug Depot, LLC d/b/a APS Pharmacy [Permit#PH02716]

Dear Sir or Madam:

On behalf of the Applicant, Drug Depot, LLC d/b/a APS Pharmacy ("APS"), please accept the attached Change of Ownership Application for review and approval. Also enclosed is a cashier's check made out to Nevada State Board of Pharmacy in the amount of \$500.

By way of background, on or about **May 14, 2020**, APS will undergo a reorganization and change of ownership wherein the current licensee, Drug Depot, Inc. d/b/a APS Pharmacy, will be converted from a corporation to a limited liability company, and its equity will be contributed to a new parent entity, Belmar Midco, Inc. APS Pharmacy will, thereafter, operate as Drug Depot, LLC d/b/a APS Pharmacy. The location and operations will otherwise remain unchanged. For ease of reference, please see the pre- and post-closing organization structure charts enclosed with this application.

Please feel free to contact me at 312-207-6556, or my paralegal, Silvia Somoza, at 312-651-1620, with any questions during the application review process.

Very truly yours,

David T. Hartmann

David. T. Hartmann

11B

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ **New Pharmacy** or ☐ **Ownership Change** (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership – Pages 1,2,5,7
☐ Non Publicly Traded Corporation – Pages 1,2,4,7 ☒ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Carolina Infusion
 Physical Address: 95 Bees Creek rd Ridgeland, SC 29936
 Mailing Address: 95 Bees Creek rd
 City: Ridgeland State: SC Zip Code: 29936
 Telephone: 843-547-1188 Fax: 843-547-1189
 Toll Free Number: 888-274-3563 (Required per NAC 639.708)
 E-mail: _____ Website: carolinainfusion.com
 Managing Pharmacist: Romeo Abangan License Number: 13439

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☒ ☐ Other: Compounding

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☒ ☐ Sterile Compounding **
☒ ☐ Non Sterile Compounding
☒ ☐ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

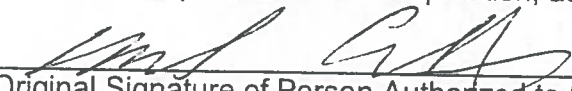
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Melissa Etheridge
Print Name of Authorized Person

2/26/20
Date

Page 2

Board Use Only

Date Processed: 4-6-2020

Amount: \$500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Melissa Etheridge

Business Name: Carolina Infusion

Current Business Address: 95 Bees Creek rd

City: Ridgeland State: SC Zip Code: 29936

Telephone: 843.547.1188 Fax: 843.547.1189

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm

Saturday N/A am N/A pm

Sunday N/A am N/A pm

24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

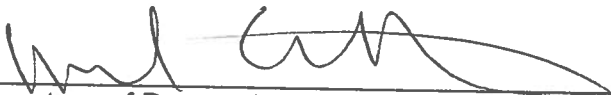
I, Melissa Etheridge

Responsible Person of Caroline Infusion

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Melissa Etheridge
Print Name of Authorized Person

2/26/20
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF SC)
Jasper) ss.
COUNTY)

I, Melissa Etheridge, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner for Carolina Infusion (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Melissa Etheridge, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Troy M Lowther
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
27 day of February, 2020.

[Signature]
NOTARY PUBLIC

[Print this page](#)**South Carolina Board of Pharmacy**

CAROLINA INFUSION
95 BEES CREEK RD
RIDGELAND, SC 29936

License number: 13447
License type: Pharmacy
Status: Active
First Issue Date: 08/21/2011
Expiration: 06/30/2020

Supervised By
Romeo Saclolo Abangan Jr - (PH)

Supervises
AMBER LYNN LANGLEY - (PHT)
STEVIE RAE ETHINGTON - (PHT)
LACY DANAE WOOD - (PHT)
Melissa Jennifer Etheridge - (PH)

[File a Complaint against this licensee](#)

No disciplinary action taken by the Board. This certifies that the above licensee is in good standing.

Board Public Action History:[View Orders](#)[View Other License for this Person](#)

No Orders Found

11C

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
 Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership – Pages 1,2,5,7
☒ Non Publicly Traded Corporation – Pages 1,2,4,7 ☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Hunt Valley Pharmacy, LLC dba Hunt Valley PharmaLAB

Physical Address: 10 Warren Road, Ste. 220, Cockeysville, MD 21030

Mailing Address: 623 Highland Colony Parkway, Ste. 100

City: Ridgeland State: MS Zip Code: 39157

Telephone: (601) 988-1700 Fax: (877) 415-4050

Toll Free Number: (888) 502-6162 (Required per NAC 639.708)

E-mail: licensingHVA@aiscaregroup.com Website: www.hvpcc.com

Managing Pharmacist: Brian Trentler License Number: 12535

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☐ ☒ Mail Service
☐ ☒ Long Term Care
☒ ☐ Sterile Compounding **
☒ ☐ Non Sterile Compounding
☒ ☐ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

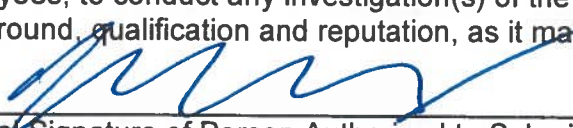
- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

See attached

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Ford, COO
Print Name of Authorized Person

3-24-2020
Date

Page 2

Board Use Only

Date Processed: 4-2-2020

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: MarylandParent Company if any: Advanced Infusion Solutions AcquisitionMailing Address: 623 Highland Colony Parkway, Ste. 100City: Ridgeland State: MS Zip: 39157Telephone: (601) 988-1700 Fax: (877) 415-4050Contact Person: Sarah Tew, Compliance Manager

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Addressb) N/A
Name Addressc) N/A
Name Addressd) N/A
Name Address2) Provide the number of shares issued by the corporation. N/A3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: Anish Patel, MD%: 0%

(Dr. Patel is the chair of the medical advisory board and also services as the company's chief medical officer. Dr. Patel has ownership potential as a member of the executive leadership team but currently has no ownership value in the company. Ownership potential will not vest unless and until such time the company is liquidated)

Name: N/A%: N/A**Hours of Operation for the pharmacy:**

*Pharmacist is on-call with record access 24/7/365

Monday thru Friday 9:00 am 6:00 pmSaturday 9:00 am 12:00 pmSunday CLOSED am CLOSED pm

24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

2020 CHOW Application

Dear Sir/Madame:

Out of an abundance of caution, Hunt Valley provides the following information regarding the non-disciplinary Virginia Order.

On or around July 30, 2018, Hunt Valley voluntarily surrendered its North Carolina non-residency pharmacy license solely for business reasons. Shortly after Hunt Valley voluntarily surrendered its North Carolina non-resident pharmacy license, it was inspected by FDA and the Maryland Board of Pharmacy ("Maryland Board") - Hunt Valley's home state board. The FDA and the Maryland Board did not take any disciplinary action against Hunt Valley after the inspections.

Nevertheless, on August 14, 2018, the Virginia Department of Health Professions ("Virginia DHP") issued an Order that suspended Hunt Valley's registration to conduct non-resident pharmacy dispensing in Virginia ("Virginia Order"). In support of the Virginia Order, the Virginia DHP contended that Hunt Valley voluntarily surrendered its North Carolina permit on July 30, 2018 in lieu of disciplinary action by the North Carolina Board of Pharmacy and that a suspension of its Virginia registration was required on this basis. However, prior to issuing the Virginia Order, the Virginia DHP did not communicate with Hunt Valley, or any representative of Hunt Valley regarding Hunt Valley's decision to surrender its North Carolina pharmacy permit or its reasons for doing so. Importantly, Hunt Valley surrendered its North Carolina permit solely for company business reasons, and it did not surrender its North Carolina permit in lieu of disciplinary action. As such, Hunt Valley appealed the Virginia Order soon after it was issued.

To resolve this matter, the Virginia DHP issued an order on November 30, 2018 that reinstated Hunt Valley's Virginia registration as of August 14, 2018 (the day the Virginia Order was entered) and incorporated explicit language that the Virginia Order was non-disciplinary.

As such, Hunt Valley believes that it has been in compliance with applicable state laws and regulations throughout this process.

STATE OF MARYLAND

Department of Assessments and Taxation

I, MICHAEL L. HIGGS OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES, OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT HUNT VALLEY PHARMACY, LLC (W20306338), REGISTERED FEBRUARY 20, 2020, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF MARYLAND, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS MARCH 17, 2020.



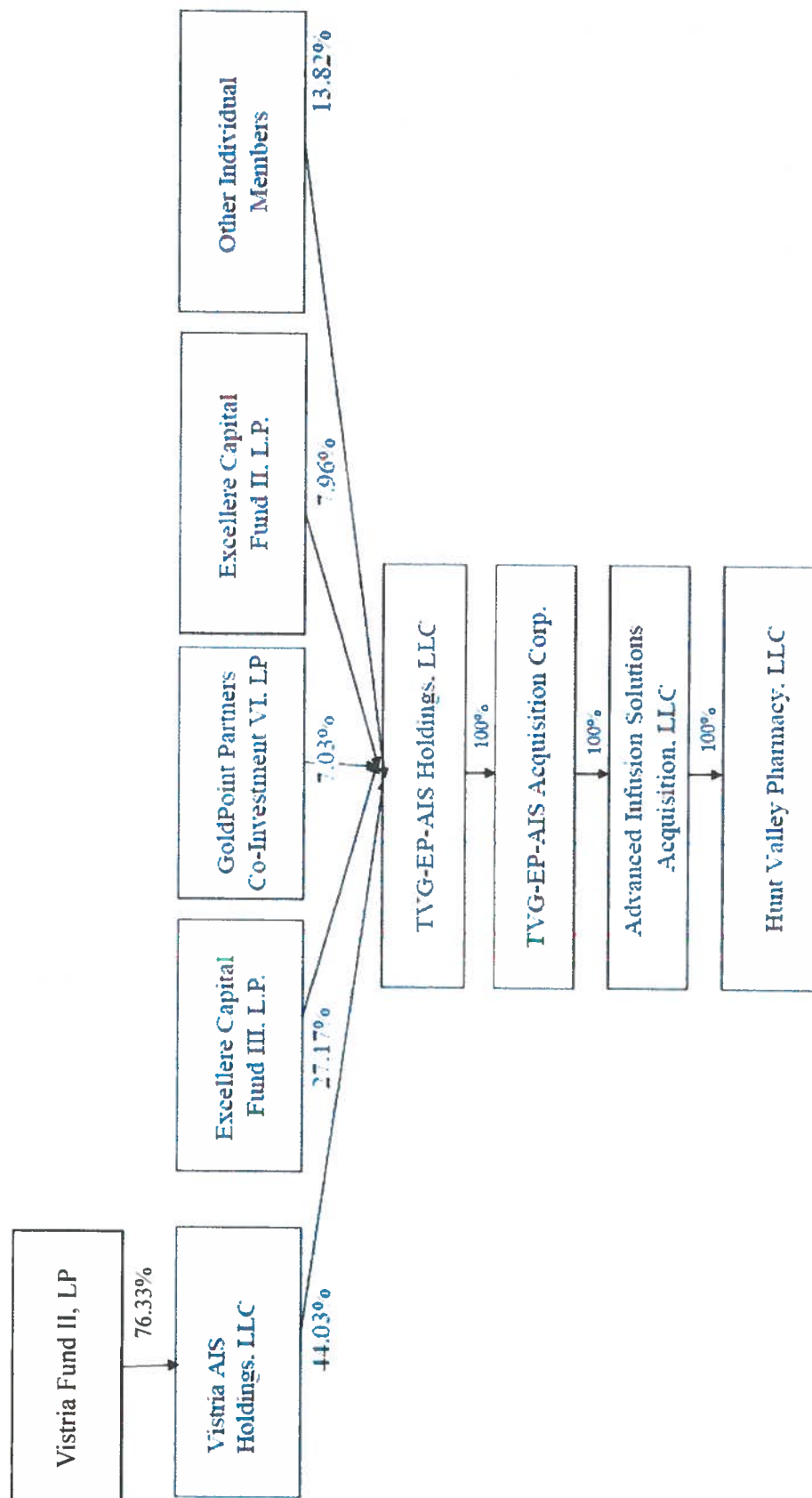
Michael L. Higgs
Director



301 West Preston Street, Baltimore, Maryland 21201
Telephone Baltimore Metro (410) 767-1340 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: 2DycnjZwxECIQyGloCJMUA
To verify the Authentication Code, visit <http://dat.maryland.gov/verify>

Organizational Structure



Hunt Valley Pharmacy, LLC DBA Hunt Valley PharmaLAB

State of Incorporation: MD

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

Officers:

Chief Executive Officer: Simon Castellanos

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

Vice President/Asst. Secretary: Christopher Ryan Glaws

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

Vice President/Asst. Secretary: Jonathan Maschmeyer

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

Chief Financial Officer: Ross Kamm

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

President,
Ophthalmology Services:

Tim Askew

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

Senior Director of Pharmacy,
Ophthalmology Services:

Brian Trentler

Business Address: 10 Warren Road, Ste. 220
Cockeysville, MD 21030

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Michael Ford

Responsible Person of Hunt Valley Pharmacy, LLC dba Hunt Valley Pharmacy
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Ford, COO

Print Name of Authorized Person

3-24-2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF MS)
Madison) ss. COUNTY)

I, Michael Ford, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the COO for Hunt Valley Pharmacy, LLC (the Hunt Valley Pharmacy AB Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Michael Ford, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Michael Ford
Name

SUBSCRIBED AND SWORN TO
 before me, a notary public this
24th day of March, 2020.

Danette Lindsey
 NOTARY PUBLIC



PHARMACY WAIVER REGISTRATION

STATE OF MARYLAND
DEPARTMENT OF HEALTH

103155

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Hunt Valley Pharmacy, Llc Dba Hunt Valley Pharmalab
10 Warren Road
Suite 220
COCKEYSVILLE MD 21030

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT

Hunt Valley Pharmacy, Llc Dba Hunt Valley Pharmalab

IS A REGISTERED Active

License Expiration Date

Pharmacy Waiver 05/31/2020

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
PW0525	05/31/2020

SIGNATURE OF BEARER

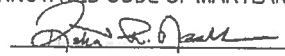
State of  Maryland

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Hunt Valley Pharmacy, Llc Dba Hunt Valley Pharmalab
IS A REGISTERED Active
License Expiration Date
Pharmacy Waiver 05/31/2020

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
PW0525	05/31/2020



SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Pharmacy Waiver Change of Information

A Pharmacy Waiver must report changes in their names, addresses, place of employment or other contact information in order to receive renewal notices, newsletters and other important information. A copy of a legal document, such as a Marriage Certificate, must accompany name changes.

To report changes, submit a completed Change of Information form. The form may be downloaded from the Board's website at <http://dhmh.maryland.gov/pharmacy/Pages/ChangeRequest.aspx>, or contact the Board to have the form sent to you.

Return the completed form by mail, fax or email to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051
Toll Free: (800)-542-4964 Fax: (410) 358-6207
Email: dhmh.mdbop@maryland.gov

SIGNATURE OF BEARER



Details

Demographic Information

Name: Hunt Valley Pharmacy, LLC dba Hunt Valley PharmaLAB

Address Information

Address: 10 Warren Road

Suite 220

City: COCKEYSVILLE

State: MD

Zip: 21030

Maryland License\Permit Information

Number: PW0525	Type: Pharmacy Waiver	Status: Mail Order/InternetActive
Original Issued: 2/26/2020	Date Renewed:	Expires: 5/31/2020

Specialty Information

No Speciality Information

Related Documents

Close Window

11D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)

Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership – Pages 1,2,6,8

☒ Non Publicly Traded Corporation – Pages 1,2,4,8

☐ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: OPS International Inc. dba Olympia Pharmacy

Physical Address: 4600 L B McLeod Rd, Orlando, FL 32811.

Mailing Address: 6700 Conroy Rd, Ste 155

City: Orlando State: FL Zip Code: 32835

Telephone: 407-673-2222 Fax: 407-673-1234

Toll Free Number: 1-833-684-0495 (Required per NAC 639.708)

E-mail: confidence@olympiapharmacy.com Website: www.OlympiaPharmacy.com

Managing Pharmacist: Britney Baker License Number: PS54155

TYPE OF PHARMACY**AND****SERVICES PROVIDED**

Yes/No

☒ ☐ Retail☐ ☒ Hospital (# beds _____)☐ ☒ Internet☐ ☒ Nuclear☐ ☒ Ambulatory Surgery Center☒ ☐ Community☐ ☐ Other: N/A

All boxes must be checked

For the application to be complete

Yes/No

☐ ☒ Off-site Cognitive Services☐ ☒ Parenteral **☐ ☒ Parenteral (outpatient)☐ ☒ Outpatient/Discharge☒ ☐ Mail Service☐ ☒ Long Term Care☒ ☐ Sterile Compounding **☒ ☐ Non Sterile Compounding☒ ☐ Mail Service Sterile Compounding **☐ ☐ Other Services: N/A

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Marco Loleit

Print Name of Authorized Person

Date

5/5/20

Page 2

Board Use Only

Date Processed: 5.12.2020

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: FLParent Company if any: N/AMailing Address: 6700 Conroy Rd, Ste 155City: Orlando State: FL Zip: 32835Telephone: 407-673-2222 Fax: 407-673-1234Contact Person: Confidence Ekeanyanwu

For any corporation non publicly traded, disclose the following:

① 100% owner
of business

1) List top 4 persons to whom the shares were issued by the corporation?

① a) Marco Lolait 647 E Jackson St., Orlando, FL 32801
Name Addressb) _____
Name Addressc) _____
Name Addressd) _____
Name Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:Monday thru Friday 9:30 am 6 pmSaturday Closed am Closed pmSunday Closed am Closed pm24 Hours N/AA Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: MARCO LOLEIT
 Business Name: OPS International Inc. dba Olympia Pharmacy
 Current Business Address: 6700 Conroy Rd, Ste 155
 City: Orlando State: FL Zip Code: 32835
 Telephone: 407-673-2222 Fax: 407-673-1234

List any physician shareholders and percentage of ownership.

Name: _____ %: _____
 Name: _____ %: _____
 Name: _____ %: _____
 Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9:30 am 6 pm

Saturday close am close pm

Sunday close am close pm

24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

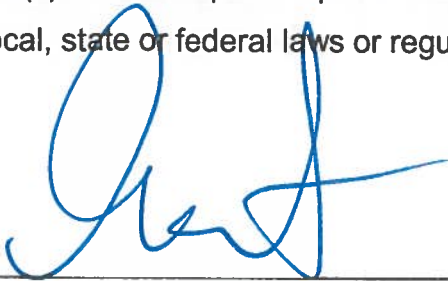
I, Marco Loleit

Responsible Person of OPS International Incorporated

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Marco Loleit

Print Name of Authorized Person

5/5/20

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF FL)
Orange) ss.
COUNTY)

I, Marco Lolait, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner for OPS International Inc. (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of- State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

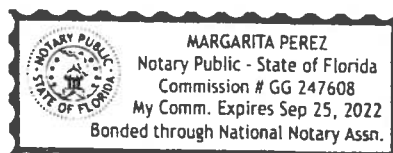
FURTHER AFFIANT SAYETH NOT.

I, Marco Lolait, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO
before me, a notary public this
5 day of May, 2020.

NOTARY PUBLIC

Margarita Perez
Name



STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
03/04/2020	PH.32627	116509

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date: FEBRUARY 28, 2021

OPS INTERNATIONAL INCORPORATED

OLYMPIA PHARMACY

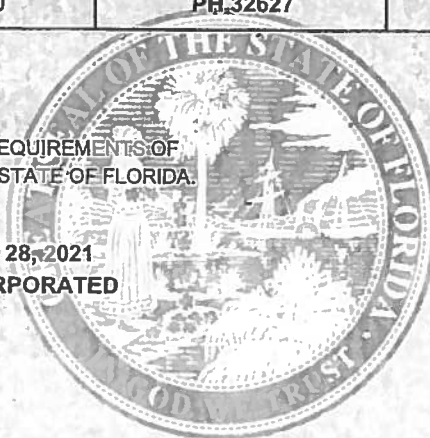
4600 LB MCLEOD ROAD

ORLANDO, FL - 32811

QUALIFICATION(S):

Schedule II & III

Community Pharmacy



Ron DeSantis
GOVERNOR

Scott A. Rivkees, MD
State Surgeon General

DISPLAY IF REQUIRED BY LAW



Department of Health

License Number: PH32627

Data As Of 4/15/2020

Profession	Pharmacy
License	PH32627
License Status	CLEAR/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2021
License Original Issue Date	03/03/2020
Address of Record	4600 LB MCLEOD ROAD ORLANDO, FL 32811
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.



Department of Health

License Number: PH32707

Data As Of 5/1/2020

Profession	Pharmacy
License	PH32707
License Status	CLEAR/
Qualifications	Schedule II & III Special Sterile Compounding
License Expiration Date	2/28/2021
License Original Issue Date	04/23/2020
Address of Record	4600 L B MCLEOD ROAD ORLANDO, FL 32811
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

State of Florida

Department of State

I certify from the records of this office that OPS INTERNATIONAL INCORPORATED is a corporation organized under the laws of the State of Florida, filed on October 3, 2013, effective October 2, 2013.

The document number of this corporation is P13000081512.

I further certify that said corporation has paid all fees due this office through December 31, 2019, that its most recent annual report/uniform business report was filed on April 6, 2019, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Twelfth day of February, 2020*



Randy Be
Secretary of State

Tracking Number: 9107518418CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>

11E



RECEIVED
3.3.2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)

Check box below for type of ownership and complete all required forms.

☒ Publicly Traded Corporation – Pages 1,2,3,7

☐ Partnership - Pages 1,2,5,7

☐ Non Publicly Traded Corporation – Pages 1,2,4,7

☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Option Care Enterprises, Inc. dba Option Care

Physical Address: 2750 Arthur St., Roseville, MN 55113

Mailing Address: 3000 Lakeside Drive, Suite 300N

City: Bannockburn State: IL Zip Code: 60015

Telephone: (651) 635-9272 Fax: (651) 305-0242

Toll Free Number: (877) 360-9272 (Required per NAC 639.708)

E-mail: oc-peandl@optioncare.com Website: optioncare.com

Managing Pharmacist: Alexandra Demello License Number: 116301

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
- ☐ ☒ Hospital (# beds _____)
- ☐ ☒ Internet
- ☐ ☒ Nuclear
- ☐ ☒ Ambulatory Surgery Center
- ☒ ☐ Community
- ☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
- ☒ ☐ Parenteral **
- ☒ ☐ Parenteral (outpatient)
- ☐ ☒ Outpatient/Discharge
- ☒ ☐ Mail Service
- ☐ ☒ Long Term Care
- ☒ ☐ Sterile Compounding **
- ☐ ☒ Non Sterile Compounding
- ☒ ☐ Mail Service Sterile Compounding **
- ☐ ☒ Other Services: _____

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.


Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the **State of Nevada** regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Clifford Berman
Print Name of Authorized Person

2/28/2020
Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Option Care Infusion Services, Inc.

Corporation Name: Option Care Enterprises, Inc.

Mailing Address: 3000 Lakeside Drive, Suite 300N

City: Bannockburn State: IL Zip: 60015

Telephone: (312) 940-2500 Fax: (847) 332-0298

Contact Person: Jessica Veltum

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

Hours of Operation for the pharmacy:

Monday thru Friday	<u>8</u> am	<u>5</u> pm	Saturday	_____am	_____pm
Sunday	_____am	_____pm	24 Hours	<u>on call</u>	

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Must be included with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Michael Shapiro -- President/CFO and Treasurer

Clifford E. Berman – Secretary

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Clifford E. Berman

Responsible Person of Option Care Enterprises, Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Clifford E. Berman

Print Name of Authorized Person

2/28/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Minnesota)
Ramsey) ss.
COUNTY)

I, Alexandra Demello, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge for Option Care (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Alexandra Demello, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Alexandra Demello
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
23 day of January, 2020.
Maria Elena Aguirre
NOTARY PUBLIC





TEXAS
Health and Human
Services

Texas Health and Human Services Commission

Cecile Erwin Young
Acting Executive Commissioner

July 30, 2018

CERTIFIED MAIL: 7016 3010 0000 9153 4345

Sent First Class Mail: 7/30/2018

ADMINISTRATOR
OPTION CARE
PO BOX 377
DEERFIELD, IL 60015

RE: OPTION CARE ENTERPRISES INC dba OPTION CARE, License No. 004685
Proposal to Assess Administrative Penalties

Dear Administrator:

Pursuant to Texas Health and Safety Code (HSC) Chapter 142 and 40 Texas Administrative Code (TAC) Chapter 97, this is notice that the Texas Health and Human Services Commission (HHSC) proposes to assess administrative penalties in the amount of \$1,500.00 for state licensing violations identified during OPTION CARE ENTERPRISES INC dba OPTION CARE's (the agency) March 9, 2018 survey.

Your agency's violation(s) of the state licensing regulations constitutes an independent basis for the following enforcement recommendation. For specific details regarding violations cited, please refer to the March 09, 2018 state form titled "Statement of Licensing Violations and Plan of Correction" which was mailed to the agency after the survey.

State Licensing Violations

Reference the Statement of Licensing Violations, item Z409 §97.285(2) Infection Control Level B

The agency failed to enforce written policies to control infections and communicable diseases that included requirements to document infections that the client acquires while receiving services from the agency as applicable for its category of licensure. **A proposed administrative penalty in the amount of \$750.00 has been assessed.**

Reference the Statement of Licensing Violations; item Z537 §97.401(b)(2)(B) Licensed Home Health Services - Level B

The agency failed to make sure that clients receiving skilled treatment under the direction of a practitioner had formal plans of care that contained all required elements. **A proposed administrative penalty in the amount of \$750.00 has been assessed.**

Enforcement Options

As a result of the proposed enforcement action, the agency may choose one of the following options within 20 calendar days of receiving this Notice of Violation (NOV) letter:

OPTION CARE
July 30, 2018
Page 2

- Option 1 Accept, in writing, the proposed enforcement action outlined within this letter by paying an administrative penalty in the amount of \$1,500.00. Payment of the administrative penalty must be made by **cashier's check or money order** and mailed to:

**Texas Health and Human Services Commission
ARTS Mail Code 1470
P.O. Box 149055
Austin, TX 78714-9030**

The cashier's check or money order must be made payable to the Texas Health and Human Services Commission **and must include the notation: "Deposit in the HCSSA Administrative Penalty Fund, ARTS Service Code # 529201108."** **Please include the attached payment coupon along with your check or money order.** Should the proposed enforcement action outlined in this letter be accepted, an Order will be entered approving the determination and ordering the agency to pay the proposed penalty; **or**

- Option 2 You may appeal this enforcement action to HHSC. HHSC will docket the appeal request with the State Office of Administrative Hearings (SOAH). The request must be in writing, in the form of a petition or letter, and must state the basis of the appeal. You must include a legible copy of the letter or notice received from HHSC that specified the proposed enforcement action. The request for a hearing is not complete and will not be docketed at SOAH for hearing without a copy of the Enforcement Action letter. Your request for a hearing must be sent to HHSC at:

**Legal Services (W-615)
Office of General Counsel
Texas Health and Human Services Commission
P.O. Box 149030
Austin, TX 78714
Fax: (512) 438-5759**

If a request for a hearing is not complete within **20 days** of receipt of this letter, unless otherwise provided by statute, you will be deemed to have consented to the HHSC action and request for a hearing will be denied, and the proposed action outlined above will be taken. Specifically, an Order will be entered approving the determination and ordering that the agency pay an administrative penalty in the amount of \$1,500.00.

All submissions will be filed at SOAH and must be redacted to meet SOAH privacy requirements at 1 TAC RULE §155.101. Redaction must include all personal identifiers that are protected by law from disclosure or that are unnecessary for resolution of the case. Any documents received containing unredacted confidential information will be returned.

OPTION CARE
July 30, 2018
Page 3

If you have questions regarding the above-described procedures, please call Lydia Maese, Enforcement Specialist, at (512) 438-2409.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Cavuto", with a small mark to the right.

Brian Cavuto, Manager
Provider Licensing Enforcement Unit
LTC Regulatory Services Division

OPTION CARE
July 30, 2018
Page 4

PAYMENT COUPON

**HCSSA ADMINISTRATIVE PENALTIES
Provider Licensing Enforcement Unit – (LM)**

“Deposit in the HCSSA Administrative Penalty Fund, ARTS Service Code # 529201108”

Agency License No.: **004685**

Claim Amount: \$1,500.00

Name: **OPTION CARE ENTERPRISES INC dba OPTION CARE**
Address: **9030 KIRBY DRIVE**
HOUSTON, TX 77054

Please make cashier's check or money order payable to the Texas Health and Human Services Commission **and return with this coupon** to:

**Texas Health and Human Services Commission
ARTS Mail Code 1470
P.O. Box 149055
Austin, TX 78714-9030**

AFFIDAVIT

STATE OF ILLINOIS

COUNTY OF LAKE

Clifford Berman, Secretary of Option Care Enterprises, Inc., personally came and appeared before me, the undersigned Notary, and makes this his statement and General Affidavit upon oath and affirmation of belief and personal knowledge that the following matters, facts and things set forth are true and correct to the best of his knowledge:

The applicant pharmacy has never been disciplined by a local, state or federal licensing, enforcement or regulatory agency and no investigation or disciplinary action is pending against the applicant pharmacy.

Applicant pharmacy is one of a chain of over 75 home infusion pharmacies under common ownership, and while the licenses of all of those pharmacies are current and in good standing, some have on occasion been the subject of disciplinary action. Information about the disciplinary actions are as follows:

1. Option Care Enterprises, Inc., owns a separate pharmacy in San Antonio, TX that was disciplined on August 6, 2003. The pharmacy was reprimanded and assessed a \$1,500 administrative penalty in connection with a dispensing/compounding error.
2. Option Care Enterprises Inc. owned a separate pharmacy in Ann Arbor, MI. On July 16 2008, the Colorado Board of Pharmacy fined the pharmacy \$5,000.00 for failure to comply with the registration and data submission requirements of Colorado's Electronic Drug Monitoring Program (PDMP). Please find the Stipulation and Agreed Board Order attached hereto.
3. Option Care Enterprises, Inc. owns a separate pharmacy in Lombard, IL. On June 30, 2010, the Colorado Board of Pharmacy imposed a fine with surcharge of \$5,500 against the pharmacy for failure to comply with the registration and data submission requirements of Colorado's Electronic Drug Monitoring Program (PDMP). Please find the Stipulation and Agreed Board Order attached hereto.
4. Option Care Enterprises, Inc. owns a separate pharmacy in Eatontown, NJ. On December 21, 2010, the pharmacy was disciplined and fined \$3,500 by the New Jersey Board of Pharmacy ("Board") for various facility deficiencies. Please see the Board notice and certification attached hereto.
5. Option Care Enterprises, Inc. owns another pharmacy in Eatontown, New Jersey. On March 3, 2013, the pharmacy was disciplined and fined \$500.00 by the New Jersey Board of Pharmacy ("Board") due to a sprinkler in the ante room was not flush with ceiling. Please see the Board notice and certification attached hereto.
6. Option Care Enterprises, Inc. owns a separate pharmacy in Lombard, IL. On February 20, 2014, the pharmacy was reprimanded and assessed a \$4,500 civil penalty by the Maine Board of Pharmacy ("Board") because the notice of a change of pharmacist-in-charge was received by the Board 14 days late. Please find the consent agreement attached hereto.

7. Option Care Enterprises, Inc. owns a separate pharmacy in Irving, TX. On August 6, 2015, the facility was assessed a \$4,250 administrative penalty by the Texas Department of Aging and Disability Services for various alleged violations.
8. We also own a pharmacy in Chantilly, VA. On September 16, 2015, the Virginia Board of Pharmacy fined our pharmacy \$1,000.00 for deficiencies concerning clean room flooring and late submission of annual documentation. All requirements have since been satisfied and the case is now closed. Please find the consent order attached hereto.
9. Option Care Enterprises, Inc. owns a separate pharmacy in Overland Park, KS. The Overland Park pharmacy was disciplined on March 31, 2016 for operating for more than 30 days after a change of pharmacist-in-charge without a complete and correct application for change of PIC on file with Pharmacy Board. Attached please find the consent order.
10. Option Care Enterprises, Inc. owns a separate pharmacy located in Southborough, MA. On July 11, 2017, the Massachusetts Board of Pharmacy imposed a probation period of one year in response to a self-reported quality related event. Effective July 13, 2018 the pharmacy successfully completed its probation period and the license was restored to full, unrestricted status. Attached please find the consent order and letter confirming successful completion of probation.
11. Option Care Enterprises, Inc. also owns a separate pharmacy in Chantilly, VA. On August 24, 2017, The Virginia Board of Pharmacy fined the Chantilly pharmacy \$5,500.00 for findings during routine pharmacy inspection. Please find the order attached hereto.
12. Option Care Enterprises, Inc. also owns a separate pharmacy in Louisville, KY. On June 26, 2018, The Kentucky Board of Pharmacy fined the Louisville pharmacy \$100.00 for allowing a technician to practice for over two weeks on a non-renewed license. Please find the agreed order attached hereto.
13. Option Care Enterprises, Inc. owns a separate pharmacy in Houston, TX. On July 30, 2018, the facility was assessed a \$1,500.00 administrative penalty by the Texas Health and Human Services Commission for various alleged violations.
14. Option Care Enterprises, Inc. owns another pharmacy in Eatontown, New Jersey. On September 18, 2018, the pharmacy was disciplined and fined \$2,550.00 by the New Jersey Board of Pharmacy ("Board") for findings during a routine inspection. Please see the Board notice and certification attached hereto.
15. We also own a pharmacy in Chantilly, VA. On May 15th, 2019, the Virginia Board of Pharmacy fined our pharmacy \$2,000.00 for findings during a pharmacy inspection October 17th, 2018. All requirements have since been satisfied. Please find the consent order attached hereto.
16. Option Care Enterprises, Inc. also owns a separate pharmacy in Louisville, KY. On November 19, 2019, The Kentucky Board of Pharmacy fined the Louisville pharmacy \$500.00 for a dispensing error in which wrong medication was dispensed. Please find the consent order attached hereto.
17. Option Care Enterprises, Inc. owns another pharmacy in Englewood, Colorado. On January 28, 2020, the pharmacy was disciplined and fined \$500.00 with a surcharge of \$75.00 by the Colorado Board of Pharmacy ("Board") due to findings during a routine pharmacy inspection conducted on November 6, 2019. Please find the consent order attached hereto.

18. Option Care Enterprises, Inc. also owns a separate pharmacy in Louisville, KY. On June 26, 2018, The Kentucky Board of Pharmacy fined the Louisville pharmacy \$100.00 for allowing a technician to practice for over two weeks on a non-renewed license. On August 19, 2019, the Illinois Department of Financial Regulation issued a "sister state" discipline. Please find the partially signed consent order attached hereto.

DATED this the 28 day of February, 2020.



Signature of Affiant

SWORN to be subscribed before me this 28 day of February, 2020.

(SEAL)



Notary Public

My commission expires: 03/20/23

Option Care Enterprises, Inc., owns a separate pharmacy in San Antonio, TX that was disciplined on August 6, 2003. The pharmacy was reprimanded and assessed a \$1,500 administrative penalty in connection with a dispensing/compounding error.

AGREED BOARD ORDER #H-03-001-B

RE: IN THE MATTER OF BEFORE THE TEXAS STATE
 OPTION CARE ENTERPRISES, INC. BOARD OF PHARMACY
 (PHARMACY LICENSE #21745)

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacy license number 21745 issued to Option Care Enterprises, Inc., 5407 Bandera Road, Suite 102, San Antonio, Texas 78238.

By letter dated March 12, 2003, the Texas State Board of Pharmacy gave preliminary notice to Option Care Enterprises, Inc. of its intent to take disciplinary action with respect to pharmacy license number 21745 issued to Option Care Enterprises, Inc.. This action was taken as a result of an investigation which produced evidence indicating that Option Care Enterprises, Inc. may have violated:

Section 551.003(16); Section 565.001(a)(1), (2), (12), and (13); Section 565.002(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Subtitle J (Vernon 2001);

Section 281.7(a)(12) and (13); Section 291.36(b)(3) and (27); Section 291.36(c)(1)(B)(i), (ix), and (xvi); Section 291.36(c)(2)(A)(iv) and (vi); Section 291.36(c)(2)(B)(ii), (iii), and (v); Section 291.36(d)(2)(B)(iii) and (iv); and Section 295.3 of the Texas Pharmacy Rules of Procedure, 22 TEX. ADMIN. CODE (2002); and

Section 431.003: Section 431.021(a), (b), and (r); and Section 431.112(a)(1) of - the Texas Food Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. (Vernon 2001), in that, allegedly:

COUNT

On or about June 24, 2002, Kenton Graham Wylie, while acting as an employee (pharmacist-in-charge) of Option Care Enterprises, Inc., 5407 Bandera Road, San Antonio, Texas 78238, incorrectly dispensed 400 meq magnesium sulfate ($MgSO_4$) in a compounded total parenteral nutrition (TPN) on a prescription drug order calling for 20 meq magnesium sulfate ($MgSO_4$). The intravenous TPN was ordered by the physician for patient C.B., a thirteen-year-old child, to be administered via "central line." The incorrect mixture contained twenty (20) times the prescribed amount of magnesium sulfate ($MgSO_4$). The prescription order was labeled as containing 20 meq magnesium sulfate.

Agreed Board Order #H-03-001-B
Option Care Enterprises, Inc.
Page 2

As a result of taking the incorrect dosage of the medication, patient C.B. was seen at the emergency room of North Central Baptist Hospital on June 26, 2002, where he was determined to have toxic levels of magnesium. He received emergency care and the TPN infusion was stopped. He was emergently transferred to Wilford Hall Medical Center for dialysis, where he went into a coma and died on June 30, 2002. The prescription was assigned prescription number 128274.

An informal conference was held in the office of the Texas State Board of Pharmacy on April 16, 2003, with Kathy Lozano, General Manager of Option Care Enterprises, Inc.; Lisa Kim Barnum, R.Ph., Pharmacist-in-Charge of Option Care Enterprises, Inc.; Kenton Graham Wylie, R.Ph.; Keith Kendall, Outside Counsel for Option Care Enterprises, Inc.; and Joseph P. Bonaccorsi, Senior Vice President/General Counsel/Secretary of Option Care Enterprises, Inc., in attendance. The Texas State Board of Pharmacy was represented by: Kerstin E. Arnold, General Counsel; Lori Tullos Barta, Assistant General Counsel; Allison Benz, R.Ph., M.S., Assistant Director of Enforcement; Joe Lewis, Chief Investigator; and W. Michael Brimberry, R.Ph., M.B.A., Board Member.

At the aforementioned conference, Joseph P. Bonaccorsi stated he was present for and on behalf of Option Care Enterprises, Inc. By their appearance at the informal conference and by their signatures on this Order, Kathy Lozano and Joseph P. Bonaccorsi agree that the Texas State Board of Pharmacy has jurisdiction in this matter and do hereby waive the right to notice of hearing, to a formal administrative hearing, and to judicial review of this Order.

After discussion of the matters previously outlined in this Order, and subsequent communications, Kathy Lozano and Joseph P. Bonaccorsi, on behalf of Option Care Enterprises, Inc., agreed to the entry of an Order disposing of the need for further disciplinary action in this matter. By their signatures on this Order, Kathy Lozano and Joseph P.

Agreed Board Order #H-03-001-B
Option Care Enterprises, Inc.
Page 3

Bonaccorsi neither admit nor deny the truth of the matters previously set out in this Order with respect to the above alleged violations.

Should this Order not be accepted by the Board, it is agreed that neither the presentation of the Order to the Board nor the Board's consideration of the Order, will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participation in proceedings related to the matters set forth in the Order.

Kathy Lozano and Joseph P. Bonaccorsi, on behalf of Option Care Enterprises, Inc., understand that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

At the conclusion of the aforementioned conference, and subsequent communications, it was agreed among the parties that Option Care Enterprises, Inc. shall comply with the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy does hereby ORDER that pharmacy license number 21745 held by Option Care Enterprises, Inc. (hereinafter referred to as "Respondent") shall be, and such license is hereby reprimanded.

It is further ORDERED that Respondent shall pay an administrative penalty of one thousand five hundred dollars (\$1,500.00) for the Count previously set out in this Order. This administrative penalty is due sixty (60) days after the entry of this Order.

It is further ORDERED that Respondent shall ensure that all pharmacists at Option Care Enterprises, Inc. complete the Institute for Safe Medication Practices (ISMP®)

Agreed Board Order #H-03-001-B

Option Care Enterprises, Inc.

Page 4

Medication Safety Self AssessmentTM. The ISMP® assessment must be completed, and Respondent must submit documentation of completion, along with an action plan implementing recommendations from the ISMP® assessment, to the Texas State Board of Pharmacy, Enforcement Division, within ninety (90) days of entry of this Order.


It is finally ORDERED that failure to comply with any of the terms and conditions in this Order constitutes a violation and shall be grounds for further disciplinary action against the Texas pharmacy license held by Respondent.

Agreed Board Order #H-03-001-B
Option Care Enterprises, Inc.
Page 5

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of August, 2003.



MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

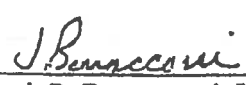


Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

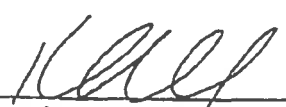
APPROVED AS TO FORM AND AGREED TO:



Kathy Lozano, General Manager of Option Care Enterprises, Inc.



Joseph P. Bonaccorsi, Legal Counsel for Option Care Enterprises, Inc.
Senior Vice President, General Counsel, Secretary
Optioncare®
485 Half Day Road, Suite 300
Buffalo Grove, Illinois 60089



Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy



To Whom It May Concern:

Option Care Enterprises Inc. owned a separate pharmacy in Ann Arbor, MI. On July 16 2008, the Colorado Board of Pharmacy fined the pharmacy \$5,000.00 for failure to comply with the registration and data submission requirements of Colorado's Electronic Drug Monitoring Program (PDMP). Please find the Stipulation and Agreed Board Order attached hereto.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case No. 2008-002665

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE
NONRESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF OPTION CARE
ENTERPRISES, INC., REGISTRATION NO. 5371,

RESPONDENT.

IT IS HEREBY STIPULATED by and between the State Board of Pharmacy ("Board") Option Care Enterprises, Inc. ("Respondent"), to resolve all matters pertaining to Colorado State Board of Pharmacy Case Number 2008-002665 as follows:

1. The Board has jurisdiction over Respondent, its registration as a Nonresident Prescription Drug Outlet, and the subject matter of this Stipulation and Final Agency Order pursuant to the provisions of title 12, article 22, C.R.S., otherwise known as the Pharmaceuticals and Pharmacists Act.
2. Respondent has been registered as a prescription drug outlet in the State of Colorado at all times relevant to this disciplinary action.
3. Respondent admits to these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.
4. Respondent's address of record with the Board and current location is 1143 Highland Drive, Ste D., Ann Arbor, Mi 48108.
5. On March 3, 2008, the Board initiated a complaint against Respondent, because Respondent failed to comply with the data submission requirements of Colorado's Electronic Prescription Drug Monitoring Program (PDMP).
6. Respondent hereby admits that the following facts are true and waives any further proof in this or any other proceeding before or initiated by the Board in this case:
 - a. On or about October 29, 2007, Board staff sent an informational letter to Respondent detailing the Board's PDMP and its expectation that all

nonresident pharmacies provide the Board with copies of their DEA registration and to begin submitting data retroactive to July 1, 2007 to the PDMP.

- b. On or about January 4, 2008, a second letter was sent to Respondent, reminding them of their obligation to comply with the PDMP requirements.
 - c. Respondent failed to timely comply with PDMP requirements, as well as submit data as required despite Board staff's repeated requests to do so.
7. Respondent admits that the conduct described above constitutes a violation of section 12-22-709, C.R.S., and that such conduct provides grounds for disciplinary action against Respondent's Nonresident Prescription Drug Outlet registration. Respondent accepts the following discipline:

DISPOSITION

\$5,000.00 Fine and Terms

8. Fine. Respondent shall remit a fine of five thousand dollars (\$5,000.00), payable to the State of Colorado. Such fine shall be due and payable at the time this Stipulation and Final Agency Order is executed by the Board's Program Director.
9. Compliance with PDMP. At all times Respondent is registered with the Colorado State Board of Pharmacy, it shall comply with the data submission requirements of the PDMP.
10. Acknowledgments. The undersigned authorized agent for Respondent has read this Stipulation and Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable.
11. Advisements and Waivers. Respondent enters into this Stipulation and Final Agency Order freely and voluntarily, whether or not it has consulted with legal counsel. The undersigned authorized agent for Respondent acknowledges Respondent's understanding that it has the following rights:
 - a. To have formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges;
 - c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
 - d. To appeal this Board order.

Respondent freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

12. Violations. Time is of the essence to this Stipulation and Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Stipulation and Final Agency Order. Respondent acknowledges and agrees that any violation of this Stipulation and Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Stipulation and Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Stipulation and Final Agency Order.
13. Integration and Severability. Upon execution by all parties, this Stipulation and Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Stipulation and Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Stipulation and Final Agency Order shall be given full force and effect.
14. Public Record. Upon execution by all parties, this Stipulation and Final Agency Order shall be a public record, maintained in the custody of the Board.
15. Effective Date. This Stipulation and Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY
Authorized Agent of Respondent


Option Care Enterprises, Inc.

Dated: 7/8/08



Subscribed and sworn to by Paul Mastrapa, in his/her
capacity as an authorized agent of Option Care Enterprises, Inc. before me in the
County of COOK, State of IL, this 7th day of
July, 2008.

Elizabeth L. Rizzio
Notary Public



My commission expires: 01/07/12

STIPULATION AND FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved,
accepted, and hereby made an order of the Board.

DONE AND EFFECTIVE THIS 11th DAY OF July, 2008.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director



To Whom It May Concern:

Option Care Enterprises, Inc. owns a separate pharmacy in Lombard, IL. On June 30, 2010, the Colorado Board of Pharmacy imposed a fine with surcharge of \$5,500 against the pharmacy for failure to comply with the registration and data submission requirements of Colorado's Electronic Drug Monitoring Program (PDMP). Please find the Stipulation and Agreed Board Order attached hereto.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.

BEFORE THE STATE BOARD OF PHARMACY**STATE OF COLORADO****Case No. 2010-002901****STIPULATION AND FINAL AGENCY ORDER**

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF OPTION CARE ENTERPRISES DBA WALGREENS SPECIALTY INFUSION PHARMACY, REGISTRATION NO. OSP 5861,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Option Care Enterprises DBA Walgreens Specialty Infusion Pharmacy ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Number 2010-002901 as follows:

1. On December 23, 2009, Respondent Pharmacy became registered by the Board as a non-resident prescription drug outlet in the State of Colorado and was issued Registration No. OSP 5861 ("Colorado Registration").
2. The Board has jurisdiction over Respondent Pharmacy, its Colorado Registration, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2009), otherwise known as the Pharmaceuticals and Pharmacists Act.
3. Respondent Pharmacy's address of record with the Board and current location is 2050 S. Finley Rd., Ste. 20, Lombard, IL 60148.
4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.
5. On January 5, 2010, Board staff sent Respondent Pharmacy correspondence detailing the requirements of Colorado's Electronic Prescription Drug Monitoring Program ("PDMP") and submission of data required under the PDMP ("Correspondence"). The Correspondence set out the date by which Respondent Pharmacy was required to register with the PDMP and begin submitting the required data. The Correspondence specifically stated that Respondent Pharmacy was required by regulation to submit a "zero" report indicating no dispensing transactions of controlled substances in the State of Colorado in the event there were no dispensing transactions in Colorado during the relevant reporting period.

6. Respondent Pharmacy failed to register with the PDMP, failed to begin submitting the required data reporting dispensing transactions of controlled substances in the State of Colorado, and did not submit any "zero" reports indicating no dispensing transactions of controlled substances in the State of Colorado by the required deadlines.
7. On February 11, 2010, the Board initiated a Complaint against Respondent Pharmacy because it failed to come into compliance with the registration and/or data submission requirements of the PDMP as directed in the Correspondence.
8. Respondent Pharmacy failed to come into compliance with the registration and/or data submission requirements of the PDMP within thirty days from the due date of the response to the Complaint, and/or failed to maintain compliance for two consecutive reporting periods thereafter.
9. Respondent Pharmacy does not contest that the conduct described above constitutes a violation of §§12-22-125(1)(c) and 12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's Colorado Registration pursuant to Board Policy 30-7.

DISPOSITION

\$5,000.00 Fine with 10% Surcharge and Terms

10. **Fine with Surcharge.** Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S. Respondent Pharmacy shall pay a fine of **Five Thousand Dollars and No Cents (\$5,000.00)**. Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of **Five Thousand, Five Hundred Dollars and No Cents (\$5,500.00)**. The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.
11. **Compliance with PDMP.** At all times Respondent Pharmacy is registered with the Colorado State Board of Pharmacy, it shall comply with the data submission requirements of the PDMP. Respondent Pharmacy understands and acknowledges that future violations of PDMP reporting requirements, including failure to submit a "zero" report in the event of no dispensing transactions in Colorado during the relevant reporting period, shall lead to additional penalties pursuant to Board Policy 30-8.
12. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having had the opportunity to consult with its own

legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

- a. To have a formal notice of hearing and charges served upon it;
- b. To respond to said formal notice of charges;
- c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
- d. To appeal this Board order.

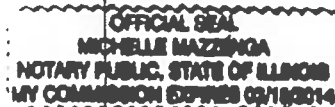
Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

13. **Acknowledgments.** The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.
14. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
17. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

WALGREENS

Fax 630-495-2830

Jun 14 2010 02:29pm P005/006



ACCEPTED AND AGREED BY

Lori Zitek
Authorized Agent of Respondent Pharmacy

Dated: 06/15/2010

Subscribed and sworn to before me in the County of Lake, State
of Illinois, this 15th day of June, 2010 by
Lori Zitek, in his/her capacity as an authorized agent of Option Care
Enterprises DBA Walgreens Specialty Infusion Pharmacy.

My commission expires: 3/18/14

Michelle Mazzingia
Notary Public

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved,
accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 15th DAY OF June, 2010.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director



To Whom It May Concern:

Option Care Enterprises, Inc. owns a separate pharmacy in Eatontown, NJ. On December 21, 2010, the pharmacy was disciplined and fined \$3,500 by the New Jersey Board of Pharmacy ("Board") for various facility deficiencies. Please see the Board notice and certification attached hereto.

If you have any questions or need additional information please contact the licensing department via email at oc-PEandL@optioncare.com.



CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark, NJ 07102



PAULA T. DOW
Attorney General

THOMAS R. CALCAGNI
Acting Director

December 21, 2010

Mailing Address:

P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

By Certified and Regular Mail

Grace M. Dressner, RPIC
Walgreens Infusion Services 4647
6 Industrial Way West, Suite C
Eatontown, NJ 07724-2268

Re: Inspection Report # 8-5219-10-1264

Dear Ms. Dressner:

This letter is to advise you that the New Jersey State Board of Pharmacy (the "Board") has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the board has preliminarily found that you are responsible for the violations noted on **Attachment A**.

The Board has determined that it will first offer you an opportunity to settle this matter and thereby avoid the initiation of formal disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the acknowledgment below and agree to the following:

1. **Cease and desist** in engaging in the conduct alleged and pay a penalty in the amount of **\$3,500.00** (to be paid upon signing of this certification).
2. Provide to the Board a **Letter of Correction**.

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. Any disposition by way of a settlement will be a public record, and will have the same effect as an order of the Board. Any failure to comply with the terms to which you agree will be deemed a violation.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you either personally or with the assistance of an attorney will have an opportunity to respond to the charges and submit evidence and present testimony as may be necessary in order for the Board to make a final determination concerning the charges of unlawful activity.

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

CERTIFICATION

I, Grace M. Dressner, hereby acknowledge that I have read and reviewed the Board's letter regarding allegations of violations of the Board's enabling act and/or regulations.

Please check one: ☐

☒ I acknowledge the conduct which has been charged and agree to:

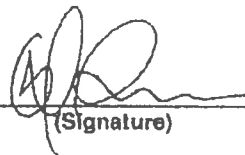
1. **Cease and desist** in engaging in the conduct alleged and pay a penalty in the amount of **\$3,500.00** (to be paid upon signing of this certification).
2. Provide to the Board a **Letter of Correction**.

I am also aware that the action taken against me by the Board here is a matter of public record, and that the Board's letter and this certification are public documents.

I hereby waive any rights I may have to a hearing in this matter in order to defend myself against any charges, but ask the Board to **consider my explanation** before rendering its final decision. I understand that the Board may order any of the terms specified in its letter and that if it does so I will be obligated to comply. I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents. Failure to comply may subject me to further disciplinary action and any failure to make a required payment will result in the filing of a certificate of debt.

I **request a formal administrative hearing** to contest the charges specified in the UPL. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.

DIVISION OF PROFESSIONAL REGULATION
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., PO BOX 130
NEWARK, NJ 07102


(Signature)

02-28-2011
(Dated)

Grace M. Dressner
(Print Name)

Dated:

Ref: Grace M. Dressner, RPIC
Walgreens Infusion Services
6 Industrial Way West, Suite C
Eatontown, NJ 07724-2268
License# 28RS00684700

Inspection Report #8-5219-10-1264
Letter of Correction
12-8-10
Complaint #74289

JB/sk

You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred in the matter.

Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact The Board of Pharmacy, at (973) 504-6450.

The enclosed certification should be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within fifteen (15) days, the Board's settlement offer will be withdrawn, and you will be deemed in default. The allegations against you will be deemed uncontested. The Board will then proceed to schedule the matter for final review and will enter an appropriate order. Once an order has been entered, your failure to pay any penalties may result in further action to suspend or revoke your license.

NEW JERSEY STATE
BOARD OF Pharmacy

By: _____

Joanne Boyer
Joanne Boyer, RPh
Executive Director

DIVISION OF
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., NEWARK, NJ 07102

cc: Michael J. Simko, Attorney, Corporate & Regulatory Law

JB/sk

Attachment A

WALGREENS INFUSION SERVICES (Option Care Enterprises, Inc.), 6 Industrial Way West, Suite C, Eatontown, NJ 07724-2268, Grace M. Dressner, RPIC. Bureau File# 8-5219-10-1264. Period 11-22-10.

REFERENCE: Transfer of Ownership

DETAILS:

Cite	Fine	Description
[13:39-4.15(b)1]	\$2,500.00	Entrances to the pharmacy department are not connected to a monitored security system that transmits an audible visual or electronic signal warning of intrusion.
[13:39-11.17(g)]	\$500.00	The sprinkler heads in the controlled environment are not flush with the ceiling.
[13:39-11.17(g)]	\$500.00	Controlled environment has window sills.
[13:39-11.10(a)7] [13:39-7.12(a)12]	Warning	Prescription labels do not have the phrase "Use By", instead the labels read "Discard After" 1. RxR15655, Cefazidime 25M/100ML 2. RxT15632, TPN
Total:	\$3,500.00	

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101



To Whom It May Concern:

Option Care Enterprises, Inc. owns another pharmacy in Eatontown, New Jersey. On March 3, 2013, the pharmacy was disciplined and fined \$500.00 by the New Jersey Board of Pharmacy ("Board") due to a sprinkler in the ante room was not flush with ceiling. Please see the Board notice and certification attached hereto.

If you have any questions or need additional information please contact the licensing department via email at oc-PEandL@optioncare.com.



CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark, NJ 07102



JEFFREY S. CHIESA
Attorney General

ERIC T. KANEFSKY
Acting Director

**CERTIFIED MAIL,
RETURN RECEIPT REQUESTED**

March 7, 2013

Grace M. Dressner, RPIC
Walgreens Infusion Services
6 Industrial Way West, Suite C
Eatontown, New Jersey 07724

Re: Inspection Report #8-5219-12-X
Date of Inspection: September 14, 2012

Dear Ms. Dressner:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on **Attachment A**.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF \$500.00 and PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making

DIVISION OF CONSUMER AFFAIRS
 BOARD OF PHARMACY
 124 HALSEY ST., 6TH FL., NEWARK, NJ 07102

CERTIFICATION

I, Grace M. Dressner, hereby acknowledge that I have read and reviewed the Board's letter dated March 7, 2013 regarding allegations of violations of the Board's enabling act and/or regulations.

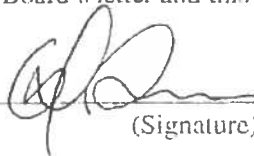
Please Check One:

☒ I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of \$500.00** (to be paid upon signing of this certification).
2. **Send a Letter of Corrective Action**, as requested by the Board, with this certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents.

- ☐ I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.
- ☐ I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.



(Signature)

Dated: 03-21-2013

Grace M. Dressner

(Print Name)

Ref: Grace M. Dressner, RPIC
Walgreens Infusion Services
6 Industrial Way West, Suite C
Eatontown, New Jersey 07724
(28RS00664700)
Inspection Report #8-5219-12-X

AR/rh
(2/2013)


BOARD OF
124 HALSEY ST., 6TH FLOOR
NEWARK, NJ 07102

its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By:


Anthony Rubinaccio, R. Ph.
Executive Director

DIVISION 1
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., ROOM 600A
NEWARK, NJ 07101

AR/rh
(2/2013)

ATTACHMENT A

15. Walgreens Infusion Services - 6 Industrial Way West, Suite C, Eatontown, New Jersey 07724

Pharmacist-In-Charge: Grace M. Dressner

Bureau File #8-5219-12-X. Period: 9/14/12

Reference: Board of Pharmacy inspection conducted pursuant to N.J.S.A.45:14-48(a)11&12 and N.J.S.A.45:1-18.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.17(g)	The Ante Room has a sprinkler head that is not flush with the ceiling.	\$500.00
TOTAL: \$500.00		

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101



To Whom It May Concern:

Option Care Enterprises, Inc. owns a separate pharmacy in Lombard, IL. On February 20, 2014, the pharmacy was reprimanded and assessed a \$4,500 civil penalty by the Maine Board of Pharmacy ("Board") because the notice of a change of pharmacist-in-charge was received by the Board 14 days late. Please find the consent agreement attached hereto.

If you have any questions or need additional information please contact the licensing department via email at oc-PEandL@optioncare.com.

STATE OF MAINE
BOARD OF PHARMACY

IN RE:)	
)	
WALGREENS SPECIALTY INFUSION)	CONSENT AGREEMENT
PHARMACY)	
)	

Complaint No. 2013 PHA 9590

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Walgreens Specialty Infusion Pharmacy in the State of Maine. The parties to this Consent Agreement are: Walgreens Specialty Infusion Pharmacy ("Walgreens"), the State of Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, Walgreens was licensed by the Board as a mail order pharmacy, license no. MO40001410, located at 2050 S. Finley Road, Suite 20, Lombard, Illinois.
2. The Board received a change in pharmacist in charge application from Walgreens on October 21, 2013, which disclosed that effective October 1, 2013, Joann Berry-Bedell was the pharmacist in charge of Walgreens.

3. Board Investigator Thomas Avery filed a complaint with the Board alleging that Walgreens failed to timely notify the Board of a change in the registered pharmacist in charge which the Board docketed as Complaint No. 2013 PHA 9590.
4. Title 32 M.R.S. § 13753 requires that change of a pharmacist in charge requires notice to the Board no later than seven (7) days after the change. Upon a change in pharmacist in charge, a mail order prescription pharmacy shall file a new application with the Board no later than seven (7) days after the change. Board Rule Chapter 11, § 3.
5. No later than October 7, 2013, Walgreens was required to file an application and notify the Board of the change in the pharmacist in charge, but it failed to do so until October 21, 2013.
6. On January 2, 2014, following a presentation of the complaint, the Board voted to offer Walgreens this Consent Agreement in order to finally resolve Complaint No. 2013 PHA 9590.
7. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Senior Consumer Assistance Specialist, 35 State House Station, Augusta, Maine 04333-0035 by February 8, 2014, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

8. Walgreens admits the facts stated above and that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. §§ 8003(5-A)(A)(4) and (5), and Board Rule Chapter 11, § 3, for its failure to notify the Board of the change in pharmacist in charge and file the required application within seven (7) days of the change.

9. Walgreens agrees to accept the following discipline:
- a. A REPRIMAND; and
 - b. A CIVIL PENALTY in the amount of four thousand five hundred dollars (\$4,500.00), payment which shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Senior Consumer Assistance Specialist, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333, within thirty (30) days of the execution of this Consent Agreement.
10. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.
11. Violation of any of the terms or conditions of this Consent Agreement by Walgreens shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.
12. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.
13. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.
14. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.
15. Walgreens acknowledges by its authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement,

that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

WALGREENS SPECIALTY INFUSION
PHARMACY

DATED: 2/6/14

BY: Michael Felish
Authorized Representative

MICHAEL FELISH
Printed Name

DATED: 2/14/14

Joseph Bruno
JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 2/26/2014

Michael Miller
MICHAEL MILLER
Assistant Attorney General



To Whom It May Concern:

Option Care Enterprises, Inc. owns a separate pharmacy in Irving, TX. On August 6, 2015, the facility was assessed a \$4,250 administrative penalty by the Texas Department of Aging and Disability Services for various alleged violations.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.



COMMISSIONER
Jon Welzenbaum

August 6, 2015

Certified Mail: 7014 1200 0000 6226 6380

Administrator
Walgreens Infusion Services
PO Box 377
Deerfield, IL 60015

Sent First Class Mail: 08/06/15

**RE: Walgreens Infusion Services, License No. 007713
Proposal to Assess Administrative Penalties**

Dear Administrator:

Pursuant to Texas Health and Safety Code (HSC) Chapter 142 and 40 Texas Administrative Code (TAC) Chapter 97, this is notice that the Texas Department of Aging and Disability Services (DADS) proposes to assess administrative penalties in the amount of \$4,250.00.

On June 15, 2015, surveyors from DADS conducted a survey at Walgreens Infusion Services and prepared a Statement of Licensing Violations. This document was mailed to Walgreens Infusion Services on June 30, 2015.

The recommendation for the enforcement action, administrative penalties, was based on state licensing violations identified during the June 15, 2015, survey. For specific details regarding these violations, please refer to the June 15, 2015 state form titled "Statement of Licensing Violations and Plan of Correction."

State Licensing Violations

Your agency's violation of any one of the following state licensing regulations, identified in the Statement of Licensing Violations dated June 15, 2015, constitutes an independent basis for the enforcement recommendation:

40 TAC §97.243(b)(1)(F) For specific details, see item **Z-125** in the Statement of Licensing Violations. The agency administrator failed to employ or contract with qualified personnel. As a result, a proposed administrative penalty in the amount of **\$1000.00** has been assessed.

40 TAC §97.256(h)(4) For specific details, see item **Z-284** in the Statement of Licensing Violations. The agency failed to provide and discuss a written list of community disaster resources for use in the event that an emergency/disaster occurred in the agency service area including the Transportation Assistance Registry available through 2-1-1. As a result, a proposed administrative penalty in the amount of **\$750.00** has been assessed.

Walgreens Infusion Services
 August 6, 2015
 Page 2

40 TAC §97.287(a)(1) For specific details, see item **Z-400** in the Statement of Licensing Violations. The agency failed to perform an annual review of the Quality Assessment and Performance Improvement Program. As a result, a proposed administrative penalty in the amount of **\$750.00** has been assessed.

40 TAC §97.401(b)(2)(B) For specific details, see item **Z-525** in the Statement of Licensing Violations. The agency failed to ensure that the client's Plan of Care contained all necessary elements for treatments, including safety measures to prevent injury. As a result, a proposed administrative penalty in the amount of **\$750.00** has been assessed.

40 TAC §97.407(10) For specific details, see item **Z-659** in the Statement of Licensing Violations. The agency failed to ensure care coordination in order to assure continuity of care. As a result, a proposed administrative penalty in the amount of **\$1000.00** has been assessed.

Enforcement Options

As a result of the proposed enforcement action, Walgreens Infusion Services may choose one of the following options within 20 calendar days of receiving this Notice of Violation (NOV) letter:

- Option 1 Accept, in writing, the proposed enforcement action outlined within this letter by paying an administrative penalty in the amount of \$4,250.00. Payment of the administrative penalty must be made by **cashier's check or money order** and mailed to:

**Texas Department of Aging and Disability Services
 Accounts Receivable (E-411)
 P.O. Box 149030
 Austin, TX 78714-9030**

The cashier's check or money order must be made payable to the Department of Aging and Disability Services and must include the notation: **"Deposit in the HCSSA Administrative Penalty Fund, ARTS Service Code # 539200007."** Please include the attached payment coupon along with your check or money order. Should the proposed enforcement action outlined in this letter be accepted, an Order will be entered approving the determination and ordering Walgreens Infusion Services to pay the proposed penalty; or

- Option 2 You may appeal this enforcement action to DADS. DADS will docket the appeal request with the State Office of Administrative Hearings (SOAH). The request must be in writing, in the form of a petition or letter, and must state the basis of the appeal. You must include a legible copy of the letter or notice received from

Walgreens Infusion Services
August 6, 2015
Page 3

DADS that specified the proposed enforcement action. The request for a hearing is not complete and will not be docketed at SOAH for hearing without a copy of the Enforcement Action letter. Your request for a hearing must be sent to DADS at:

**Legal Services (W-615)
Office of General Counsel
Texas Department of Aging and Disability Services
P.O. Box 149030
Austin, TX 78714**

Fax: (512) 438-5759

If a request for a hearing is not complete within *20 days* of receipt of this letter, unless otherwise provided by statute, you will be deemed to have consented to the DADS action and request for a hearing will be denied, and the proposed action outlined above will be taken. Specifically, an Order will be entered approving the determination and ordering that Walgreens Infusion Services pay an administrative penalty in the amount of \$4,250.00.

All submissions will be filed at SOAH and must be redacted to meet SOAH privacy requirements at 1 TAC RULE §155.101. Redaction must include all personal identifiers that are protected by law from disclosure or that are unnecessary for resolution of the case. Any documents received containing unredacted confidential information will be returned.

If you have questions regarding the above-described procedures please call Robert Taylor, Enforcement Program Specialist, at (512) 438-4804.

Sincerely,



Susan Diamond, Manager
Provider Licensing Enforcement
Regulatory Services Division
Department of Aging and Disability Services

Walgreens Infusion Services
August 6, 2015
Page 4

(E-351) HCSSA ADMINISTRATIVE PENALTIES PAYMENT COUPON (E-351)
(E-351) Provider Licensing Enforcement Unit (E-351)- (rt)
"Deposit in the HCSSA Administrative Penalty Fund, ARTS Service Code # 539200007"

Agency License No.: 007713

Claim Amount: \$4,250.00

Name: Walgreens Infusion Services
Address: 6611 Beltline Road, Ste 100
Irving, TX 75063

Please make cashier's check or money order payable to the Department of Aging and Disability Services and return with this coupon to:

Texas Department of Aging and Disability Services
Accounts Receivable (E-411)
P.O. Box 149030
Austin, TX 78714-9030



To Whom It May Concern:

We also own a pharmacy in Chantilly, VA. On September 16, 2015, the Virginia Board of Pharmacy fined our pharmacy \$1,000.00 for deficiencies concerning clean room flooring and late submission of annual documentation. All requirements have since been satisfied and the case is now closed. Please find the consent order attached hereto.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.



0201003388

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

Board of Pharmacy

804/367-4456

804-527-4472 (fax)

September 17, 2015

Option Care
Formally Known as Walgreen Infusion Services
Loretta D. Lombardo, Pharmacist-in-Charge
4170 Lafayette Center Drive, Suite 300
Chantilly, VA 20151

RE: Case # 158963

Dear Ms. Lombardo:

Enclosed please find a certified true copy of the Inspection Deficiency Notice and Consent Order that was entered by the Board on September 16, 2015. Further, this confirms receipt of the monetary penalty and the documentation indicating the corrective action taken. As all requirements have been satisfied, the case is now closed.

Sincerely,

Rose E. DeMatteo
Compliance Case Manager

Enclosure

Board of Audiology & Speech-Language Pathology – Board of Counseling – Board of Dentistry – Board of Funeral Directors & Embalmers
Board of Long-Term Care Administrators – Board of Medicine – Board of Nursing – Board of Optometry – Board of Pharmacy
Board of Physical Therapy – Board of Psychology – Board of Social Work – Board of Veterinary Medicine
Board of Health Professions

Virginia Board of Pharmacy

9960 Mayland Drive, Suite 300

Henrico, VA 23233

804-367-4456

804-527-4472 (Fax)

pharmbd@dhp.virginia.gov

August 6, 2015

Walgreens Infusion Services

Permit Number: 0201003388

Amended Notice

After an inspection conducted on August 27, 2014 at Walgreens Infusion Services, the deficiencies identified in the inspection summary that was provided to the facility were found. Those deficiencies constitute violations of the statutes and regulations cited below:

1. (\$500) Major 26: Documentation annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations exceeds 12 months; §54.1-3410.2
2. (\$500) Major 32: Have clean room, but not all physical standards in compliance, e.g. flooring; §54.1-3410.2

If you wish to contest the violations cited above and in the inspection summary that was provided to the facility, you may submit documentation for the Board's consideration within 14 days of the date of this notice. In the alternative, you may request, in writing, an informal conference to further discuss this matter before a committee of the Board within 30 days of the date of this notice. Documents for consideration or a request for an informal conference should be mailed to:

Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233

If you do not want to contest the cited violations, in lieu of proceeding to an informal conference, you may sign the Consent Order below, submit a total penalty of \$1,000 by check or money order, made payable to the Treasurer of Virginia, and provide documentation of corrective action taken to remedy all of the cited violations. The Consent Order, the penalty, and documentation of corrective action should be sent in one mailing to the address provided above within 30 days of the date of this Notice.

Failure to respond to this document within thirty (30) days of the date of this Notice will result in an informal conference being scheduled to determine whether violations of the statutes and regulations of the Board of Pharmacy have occurred. A notice of the informal conference will be mailed to the attention of the facility's Pharmacist-in-Charge [or the Owner if no PIC] with the scheduled date and time. If it is determined at the conclusion of the informal conference that the pharmacy is in violation of the laws and regulations of the Board of Pharmacy, the permit holder

DEFICIENCY NOTICE AND CONSENT ORDER
Permit Number: 0201003388

may be subject to disciplinary sanctions by the Board in addition to the penalty listed above. If you have any questions, please contact the Board office.

Amended Consent Order

The Virginia Board of Pharmacy ("Board") and Walgreens Infusion Services ("Pharmacy") enter into the following Consent Order as evidenced by the signature of the Pharmacist-in-Charge [or the Owner if no PIC] hereto. The deficiencies cited in the Notice above and the inspection summary that was provided to the facility constitute violations of the statutes and regulations as cited above in the Notice. These violations were identified during an inspection conducted on August 27, 2014.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

Pharmacy, by affixing the signature of the Pharmacist-in-Charge (or Owner if no PIC) hereon, agrees to the following:

1. The Pharmacist-in-Charge (or Owner if no PIC) has the right to seek advice of counsel prior to signing this document;
2. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that without his consent, no legal action can be taken against the Pharmacy except pursuant to the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia;
3. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that he has the following rights, among others: the right to an informal fact finding conference before the Board, the right to reasonable notice of said hearing, the right to representation by counsel, and the right to cross-examine witnesses;
4. The Pharmacist-in-Charge (or Owner if no PIC) waives all such right to an informal conference;
5. The Pharmacist-in-Charge (or Owner if no PIC) admits to the violations cited herein and waives his right to contest such violations in any subsequent proceeding before the Board;
6. The Pharmacist-in-Charge (or Owner if no PIC) consents to the entry of the following Order affecting the permit of the Pharmacy in Virginia.

WHEREFORE, on the basis of the foregoing, the Board, effective upon entry of this Order, and in lieu of further proceedings, hereby ORDERS as follows:

1. Pharmacy shall pay a monetary penalty of \$1,000 to the Board within 30 days of the date of the Notice.
2. Pharmacy shall submit documentation of immediate action taken to correct all violations.
3. Any violation of the terms and conditions of this Order or of any law or regulation affecting the conduct of Pharmacy in the Commonwealth of Virginia shall constitute grounds for the

DEFICIENCY NOTICE AND CONSENT ORDER

Permit Number: 0201003388

suspension or revocation of the permit of Pharmacy, and an administrative proceeding shall be convened to determine whether such permit shall be suspended or revoked.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Notice and Consent Order shall remain in the custody of the Department of Health Professions as public record and shall be made available for public inspection or copying upon request.

Loetta D. Lombardo RPh

Signature of PIC or Owner

9/1/15

Date

Loetta D. Lombardo, RPh

Printed Name of Person Signing

PIC

Position/Title

FOR THE BOARD:*Caroline D. Juran*

Caroline D. Juran, Executive Director

9/1/15

Entered

Option Care Enterprises, Inc., owns a separate pharmacy in Overland Park, KS that was disciplined on March 31, 2016 for operating for more than 30 days after a change of pharmacist-in-charge without a complete and correct application for change of PIC on file with Pharmacy Board.

Summary Orders attached.

Filed

MAR 31 2016

K.
BOARD OF PHARMACY

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)

Case No. 15-252

Option Care)

Registration No. 2-13170)SUMMARY ORDER

NOW on this 31 day of March, 2016, comes before the Kansas Board of Pharmacy (the "Board"), through its Investigation Member, the matter of Option Care ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Investigation Member enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 2-13170 which entitles Respondent to function as a pharmacy in the State of Kansas ("Respondent's Registration").
2. On or about September 15, 2015, the Board office received a notification of a pharmacist in charge ("PIC") change from Respondent indicating Imad Numair, R. Ph. would be assuming the role of pharmacist in charge ("PIC"), effective September 15, 2015.
3. On or about October 15, 2015, the Board received Respondent's written application for a Non-Resident Pharmacy Registration for Change of PIC.

Matter of Option Care, No. 15-252 (Kan. Bd. of Pharmacy)

SUMMARY ORDER

Page 1 of 5

4. Because Respondent is a resident pharmacy in the State of Kansas, on October 15, 2015 the Board electronically requested Respondent and the new PIC complete a Resident Pharmacy Registration for Change of PIC.

5. On October 16, 2015, Respondent emailed the completed application form to the Board. The application indicated that Mr. Numair had not previously been a PIC.

6. On October 16, 2015, the Board sent a PIC examination to Respondent and Mr. Numair, indicating that Mr. Numair had 30 days from the date of the previous PIC's resignation to complete the examination and return it to the Board.

7. On December 2, 2015, the Board received an email from Mr. Numair indicating he was a PIC from 2004-2005 and from 2006-2007.

8. On December 2, 2015, the Board processed the PIC change and issued the license.

CONCLUSIONS OF LAW

9. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed \$5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

10. Pursuant to K.A.R. 68-1-2a(b), each registrant required to have a PIC that operates for more than 30 days without a designated PIC shall be deemed to be in violation of K.S.A. 65-1627(e).

11. Pursuant to K.A.R. 68-1-2(a) and (c), each prospective PIC shall take a pharmacy law examination administered by the Board. However, a PIC who has already passed the examination shall not be required to retake it upon assuming the duties of a PIC.

12. Respondent notified the Board of the PIC change on September 15th and submitted a Change in PIC application on October 15th. However, Respondent failed to submit the correct application for a resident pharmacy and then provided inaccurate information regarding Mr. Numair's PIC experience.

13. Since Respondent indicated that the Change of PIC was effective on September 15th, Respondent had 30 days to have a designated PIC, or until October 15, 2015.

14. Respondent failed to submit the complete Change of PIC application to the Board until December 2nd, which was 46 days beyond the 30-day window for designating a new PIC.

15. Respondent violated K.A.R. 68-1-2a(b) when it failed to provide a completed application for a designated PIC to the Board within 30 days.

16. Though Respondent need not have completed the requested PIC examination, the failure to respond until 46 days after the expiration of the allotted time constitutes a violation.

ORDER

Based upon the foregoing findings of fact and conclusions of law, Respondent is ordered to pay a fine to the Board. A violation of K.A.R. 68-1-2a(b) warrants a base fine of \$1,000.00. Every day that Respondent is in violation of the regulation, the fine accrues \$20.00. Because Respondent was 46 days late, the fine accrued \$920.00. Respondent has 30 days from the date of this order to pay the full \$1,920.00, or until Wednesday, May 4th, 2016.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy,

Matter of Option Care, No. 15-252 (Kan. Bd. of Pharmacy)

SUMMARY ORDER

Page 3 of 5

800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order revoking the Respondent's Registration, as a pharmacy technician shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

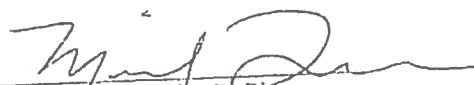
3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

3/30/16
Date


Michael Lonergan, R.Ph.
Investigation Member
Kansas Board of Pharmacy

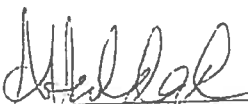
CERTIFICATE OF SERVICE

I hereby certify that I did, on the 31 day of March, 2016, deposit in the United States Mail, postage prepaid, a copy of the foregoing Summary Order, properly addressed to the following:

Option Care
8940 Nieman Rd.
Overland Park, KS 66214

and the original hand delivered to:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Ste. 1414
Topeka, KS 66612



Kansas Board of Pharmacy Staff



To Whom It May Concern:

Option Care Enterprises, Inc. owns a separate pharmacy located in Southborough, MA. On July 11, 2017, the Massachusetts Board of Pharmacy imposed a probation period of one year in response to a self-reported quality related event. Effective July 13, 2018 the pharmacy successfully completed its probation period and the license was restored to full, unrestricted status. Attached please find the consent order and letter confirming successful completion of probation.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 Bureau of Health Professions Licensure
 239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
 Governor

KARYN E. POLITO
 Lieutenant Governor

Tel: 617-973-0800
 TTY : 617-973-0988
www.mass.gov/dph/boards

MARYLOU SUDDERS
 Secretary

MONICA BHAREL, MD, MPH
 Commissioner

July 16, 2018

Option Care
 Manager of Record
 257 Turnpike Rd
 Southborough, MA 01772

RE: In the Matter of Option Care, Board of Registration in Pharmacy,
 PHA-2016-0026; License No. DS3584

NOTICE OF RESTORATION OF UNRESTRICTED LICENSURE
(SUCCESSFUL COMPLETION OF PROBATION)

Dear Manager of Record:

As you know, the pharmacy entered into a Consent Agreement for Probation, ("Agreement"), effective July 11, 2017 with the Board of Registration in Pharmacy ("Board"). A copy of the Agreement is enclosed with this letter for your records.

Please be advised that after review and as authorized by Division Policy 15-01, the Board's Executive Director and I determined that the pharmacy has now complied in full with all requirements of the Agreement and that the minimum monitoring period has been satisfied. Accordingly, I am restoring the drug store's license to full, unrestricted status, effective July 13, 2018. Please allow for up to five (5) business days from the date of this letter until the updated license status appears on the "Check a License" website.

Sincerely,

Karen L. Fishman

Karen Fishman
 Probation Department Coordinator

Enclosure
 KF/rf

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
 Option Care)
 DS3584)
 Expires: December 31, 2017)

PHA-2016-0026

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and the Option Care Pharmacy ("Pharmacy" or "Licensee"), DS3584, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacy's record maintained by the Board:

1. The Pharmacy acknowledges that the Board opened a Complaint against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2016-0026.¹
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about February 12, 2016 and February 16, 2016, Option Care improperly compounded and dispensed prescriptions written for blinatumomab 65 mcg in 280 ml 0.9 % NaCl. Specifically, the final volume of the infusion bags, as dispensed, was approximately 180 ml.
 - b. The root cause analysis indicated the repeater pump used to prepare the compounded sterile preparations was incorrectly programed or not properly calibrated, resulting in the errors.
3. The Pharmacy acknowledges that the foregoing facts warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A and 61 and under 247 CMR 10.03(1)(v).

¹ The term "license" applies to both a current license and the right to renew an expired license.

4. The Pharmacy agrees that its license shall be placed on PROBATION for one (1) year ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
5. During the Probationary Period, the Pharmacy further agrees that it shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.
6. During the Probationary Period, and within 90 days of the Effective Date, the Pharmacy agrees to submit documentation demonstrating all staff received training from an ICU Medical PharmaAssist representative on the proper use of the ICU Medical PharmaAssist Pump.
7. The Board agrees that in return for the Pharmacy's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.
8. If the Pharmacy has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate one (1) year after the Effective Date upon written notice to the Pharmacy from the Board².
9. If the Pharmacy does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ during the Probationary Period, the Pharmacy agrees to the following:
 - a. The Board may upon written notice to the Pharmacy, as warranted to protect the public health, safety, or welfare:
 - i. EXTEND the Probationary Period; and/or
 - ii. MODIFY the Probation Agreement requirements; and/or
 - iii. IMMEDIATELY SUSPEND the Pharmacy's license.

² In all instances where this Agreement specifies written notice to the Pharmacy from the Board, such notice shall be sent to the Pharmacy's address of record.

³ The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the Effective Date, which (1) alleges that the Pharmacy engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Pharmacy shall have an opportunity to respond.

- b. If the Board suspends the Pharmacy's license pursuant to Paragraph 9(a)(iii), the suspension shall remain in effect until:
- i. the Board provides the Pharmacy written notice that the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and the Pharmacy sign a subsequent agreement; or
 - iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance with this Agreement, and/ or (2) contained in the Subsequent Complaint.
10. The Pharmacy agrees that if the Board suspends its license in accordance with Paragraph 9, it will immediately return its current Massachusetts license to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, it will no longer be authorized to operate as a pharmacy in the Commonwealth of Massachusetts and shall not in any way represent itself as a pharmacy until such time as the Board reinstates its license or right to renew such license.
11. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication it would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq. The Pharmacy further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaints.
12. The Pharmacy acknowledges that it has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.

13. The Pharmacy acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.
14. The Pharmacy certifies that it has read this Agreement. The Pharmacy understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.

Megan K. Daglund 6/30/17 [Signature] 6/30/17
 Witness (sign and date) Signature and Date
MICHAEL SHAPIRO
 Print Name

[Signature]
 David Sencabaugh, R. Ph.
 Executive Director
 Board of Registration in Pharmacy

7-11-17
 Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 7/12/17 by
 Certified
 Mail No. 7015 3010 0001 7080 3134



To Whom It May Concern:

Option Care Enterprises, Inc. also owns a separate pharmacy in Chantilly, VA. On August 24, 2017, The Virginia Board of Pharmacy fined the Chantilly pharmacy \$5,500.00 for findings during routine pharmacy inspection. Please find the order attached hereto.

If you have questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.



COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Board of Pharmacy

804/367-4456
804-527-4472 (fax)

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

July 21, 2017

Loretta D. Lombardy, Pharmacist-in-Charge
Option Care
4170 LaFayette Center Drive
Suite 300
Chantilly, VA 201511254

RE: Case Number 178482

Dear Ms. Lombardy:

Enclosed is a certified true copy of the Order entered by the Virginia Board of Pharmacy ("Board") following the informal conference for Option Care.

If you object to this Order and desire a formal hearing before the Board, a written request must be received by the Board within 33 days from the date of service of the Order. If no written request is received by that time, this Order will be final.

Should you have any questions or concerns regarding this matter, please contact our office at (804) 367-4456.

Sincerely,

J. Samuel Johnson
Deputy Executive Director

Enclosure

cc: Mykl Egan, Adjudication Specialist, Administrative Proceedings Division
Edward D. Rickert, Esquire, Attorney
Nikia L. Gray, Esquire, Attorney

Board of Audiology & Speech-Language Pathology – Board of Counseling – Board of Dentistry – Board of Funeral Directors & Embalmers
Board of Long-Term Care Administrators – Board of Medicine – Board of Nursing – Board of Optometry – Board of Pharmacy
Board of Physical Therapy – Board of Psychology – Board of Social Work – Board of Veterinary Medicine
Board of Health Professions

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: OPTION CARE
Permit Number: 0201-003388
Case Number: 178482

ORDER**JURISDICTION AND PROCEDURAL HISTORY**

Pursuant to Virginia Code §§ 2.2-4019 and 54.1-2400(10), a Special Conference Committee of the Virginia Board of Pharmacy ("Board") held an informal conference on June 28, 2017, in Henrico County, Virginia, to inquire into evidence that Option Care may have violated certain laws and regulations governing the conduct of a pharmacy in the Commonwealth of Virginia.

Loretta D. Lombardy, Pharmacist-in-Charge of Option Care, appeared as a representative of Option Care at this proceeding. The pharmacy was represented by Edward D. Rickert, Esquire and Nikia L. Gray, Esquire.

NOTICE

By letter dated May 26, 2017, the Board sent a Notice of Informal Conference ("Notice") to Option Care notifying it that an informal conference would be held on June 28, 2017. The Notice was sent by certified and first class mail to the legal address of record on file with the Board.

Upon consideration of the evidence, the Committee adopts the following Findings of Fact and Conclusions of Law and issues the Order contained herein.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Option Care, Chantilly, Virginia, was issued Permit Number 0201-003388 to conduct a pharmacy on April 10, 1997, which is scheduled to expire on April 30, 2018. At all times relevant to the findings contained herein, said permit was current and active.
2. An unannounced inspection of Option Care on January 25, 2017, revealed the following deficiencies:

ORDER – Option Care
Page 2 of 3

a. Option Care violated Virginia Code §§ 54.1-3316(7) and 54.1-3410.2(D), (E) and (I)(1) and 18 VAC 110-20-321 and 18 VAC 110-20-355(A) of the Regulations Governing the Practice of Pharmacy (“Regulations”) in that a review of sterile compounding records for January 2017 revealed that one of the compounding records did not have a pharmacist’s verification signature indicating that the preparation of the product was supervised by a pharmacist.

b. Option Care violated Virginia Code §§ 54.1-3316(7) and 54.1-3410.2(E) and (I)(4) and 18 VAC 110-20-321 of the Regulations in that one of the two employees assigned to perform low and medium-risk compounding had not completed his gloved fingertip testing as required by the United States Pharmacopeia–National Formulary (“USP-NF”) within the required time period.

c. Option Care violated Virginia Code § 54.1-3316(7) and 18 VAC 110-20-240(A)(1) of the Regulations in that the inventory taken on April 4, 2016 and April 7, 2015 did not separate the C-III through C-V medications.

d. Option Care violated Virginia Code § 54.1-3316(7) and 18 VAC 110-20-418(B)(2)(e)(4) of the Regulations in that zero error reports were not being maintained or reported to the necessary safety organization.

3. Ms. Lombardy stated to the Committee that the errors have been corrected.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:


1. Option Care is assessed a MONETARY PENALTY of \$5,500.00. This penalty shall be paid to the Board by certified check or money order made payable to the Treasurer of Virginia within 30 days from the date of entry of this Order. Failure to pay the full monetary penalty by the due date may cause the matter to be sent for collection and constitutes grounds for an administrative proceeding and further discipline.

2. Option Care shall comply with all laws and regulations governing the conduct of a pharmacy in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the conduct of a pharmacy shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD



Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

ENTERED AND MAILED: 7/21/17

NOTICE OF RIGHT TO APPEAL

Pursuant to Virginia Code § 54.1-2400(10), Option Care may, not later than 5:00 p.m., on August 24, 2017, notify Caroline D. Juran, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, in writing that it desires a formal administrative hearing before the Board. Upon the filing with the Executive Director of a request for the hearing, this Order shall be vacated. This Order shall become final on August 24, 2017, unless a request for a formal administrative hearing is received as described above.





To Whom It May Concern:

Option Care Enterprises, Inc. also owns a separate pharmacy in Louisville, KY. On June 26, 2018, The Kentucky Board of Pharmacy fined the Louisville pharmacy \$100.00 for allowing a technician to practice for over two weeks on a non-renewed license. Please find the agreed order attached hereto.

If you have questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.

**COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 18-0280A**

IN RE: PHARMACY PERMIT NO. P07485 HELD BY OPTION CARE ENTERPRISES INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and Option Care Enterprises Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

- (1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned permit no. P07485.
- (2)
 - (a) An investigation of Respondent's pharmacy revealed that Rakita Moore worked on various dates between March 31 – April 18, 2018, without being appropriately registered with the Board. Consequently, the Respondent was in violation of KRS 315.121(1)(g).
 - (b) The above facts subject Respondent to discipline pursuant to KRS 315.121(1)(h).
- (3) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the Board filing a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

- (A) Respondent shall be fined \$100.00 payable by June 27, 2018. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg. Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.
- (B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Cathy Hanna, President
Kentucky Board of Pharmacy

Date

 Corp. Secretary
Option Care Enterprises Inc., Respondent

June 26, 2018
Date



To Whom It May Concern:

Option Care Enterprises, Inc. owns a separate pharmacy in Houston, TX. On July 30, 2018, the facility was assessed a \$1,500.00 administrative penalty by the Texas Health and Human Services Commission for various alleged violations.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.



To Whom It May Concern:

Option Care Enterprises, Inc. owns another pharmacy in Eatontown, New Jersey. On September 18, 2018, the pharmacy was disciplined and fined \$2,550.00 by the New Jersey Board of Pharmacy ("Board") for findings during a routine inspection. Please see the Board notice and certification attached hereto.

If you have any questions or need additional information please contact the licensing department via email at oc-PEandL@optioncare.com.



PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102



GURBIR S. GREWAL
Attorney General

PAUL R. RODRIGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL RETURN RECEIPT REQUESTED

February 25, 2019

Grace Dressner, RPh.
c/o Edward D. Rickert, Esq.
Quarles & Brady LLP
300 N. LaSalle Street
Suite 4000
Chicago, IL 60654-3406

Re: Option Care, Eatontown, NJ
Inspection #8-5219-18-X
Date of Inspection: 3/1/18

Dear Ms. Dressner:

The New Jersey State Board of Pharmacy, at the January 28, 2019 meeting, reviewed correspondence submitted requesting mitigation relating to the above-referenced inspection.

The Board moved to deny this mitigation.

Please complete the attached **Certification** form, submit **\$2,550.00** for fines incurred and a **Letter of Corrective Action** to the Board within fifteen (15) days receipt of this letter.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____

Anthony Rubinaccio, RPh
Executive Director

AR/rh
(4/18)

CERTIFICATION

I, Grace M. Dressner, hereby acknowledge that I have read and reviewed the Board's letter dated February 25, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check:

☒ I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of \$2,550.00** (to be paid upon signing of this Certification).
2. **Send a Letter of Corrective Action**, as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.



(Signature)

Dated: 03-12-19

Grace M. Dressner
(Print Name)

Ref: Grace Dressner, RPIC
Option Care, Suite C
(28RS00664700)
6 Industrial Way West, Ste. C
Eatontown, NJ 07724
Inspection #8-5219-18-X

AR/rh
(4/18)

ATTACHMENT A

Option Care – 6 Industrial Way West, Suite C, Eatontown, New Jersey 07724

Pharmacist-In-Charge: Grace Dressner

Bureau File #8-5219-18-X, Period: 3/1/18

Reference: Board of Pharmacy inspection activity conducted pursuant to N.J.S.A.45:1-18 and N.J.S.A.45:14-48(a)11&12.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-3.1(c)	Per diem pharmacist, Deedar Singh, was unable to produce his wallet-sized license when asked to do so. Mr. Singh admitted to not having it on his person.	\$50.00
N.J.S.A.45:1-45(h)	The pharmacy failed to submit information regarding dispensed controlled dangerous substance (CDS) prescriptions to the NIPMP on a daily basis, including submission of zero-dispensed reports. It appears that the pharmacy did not submit zero-dispensed reports for the period beginning December 16, 2017 to January 19, 2018.	Warning
N.J.A.C.13:39-11.13(a)	Pharmacists were not observed to be providing immediate, personal supervision to technicians engaged in compounding sterile preparations in the cleanroom. The pharmacists are seated at desks next to the cleanroom window. They are seated there in order to provide supervision to technicians without having to be present in the cleanroom. During the inspection activity, there was a time when no pharmacists were seated at their desks while technicians were in the cleanroom compounding. No supervision was being provided as there was also no pharmacist present in the cleanroom.	\$2,500.00
TOTAL: \$2,550.00		

4/16/18



To Whom It May Concern:

We also own a pharmacy in Chantilly, VA. On May 15th, 2019, the Virginia Board of Pharmacy fined our pharmacy \$2,000.00 for findings during a pharmacy inspection October 17th, 2018. All requirements have since been satisfied. Please find the consent order attached hereto.

If you have any questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.

Virginia Board of Pharmacy

9960 Mayland Drive, Suite 300

Henrico, VA 23233

804-367-4456

804-527-4472 (Fax)

pharmbd@dhp.virginia.gov

October 17, 2018

Option Care

Permit Number: 0201003388

Notice

After an inspection conducted on October 17, 2018 at Option Care, the deficiencies identified in the inspection summary that was provided to the facility were found. Those deficiencies constitute violations of the statutes and regulations cited below:

1. (\$2,000) Deficiency 32: Have clean room, but not all physical standards in compliance; § 54.1-3410.2

If you wish to contest the violations cited above and in the inspection summary that was provided to the facility, you may submit documentation for the Board's consideration within 14 days of the date of this notice. In the alternative, you may request, in writing, an informal conference to further discuss this matter before a committee of the Board within 30 days of the date of this notice. Documents for consideration or a request for an informal conference should be mailed to:

Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233

If you do not want to contest the cited violations, in lieu of proceeding to an informal conference, you may sign the Consent Order below, submit a total penalty of \$2,000 by check or money order, made payable to the Treasurer of Virginia, and provide documentation of corrective action taken to remedy all of the cited violations. The Consent Order, the penalty, and documentation of corrective action should be sent in one mailing to the address provided above within 30 days of the date of this Notice.

Failure to respond to this document within thirty (30) days of the date of this Notice will result in an informal conference being scheduled to determine whether violations of the statutes and regulations of the Board of Pharmacy have occurred. A notice of the informal conference will be mailed to the attention of the facility's Pharmacist-in-Charge [or the Owner if no PIC] with the scheduled date and time. If it is determined at the conclusion of the informal conference that the pharmacy is in violation of the laws and regulations of the Board of Pharmacy, the permit holder may be subject to disciplinary sanctions by the Board in addition to the penalty listed above. If you have any questions, please contact the Board office.

DEFICIENCY NOTICE AND CONSENT ORDER
Permit Number: 0201003388

Consent Order

The Virginia Board of Pharmacy ("Board") and Option Care ("Pharmacy") enter into the following Consent Order as evidenced by the signature of the Pharmacist-in-Charge [or the Owner if no PIC] hereto. The deficiencies cited in the Notice above and the inspection summary that was provided to the facility constitute violations of the statutes and regulations as cited above in the Notice. These violations were identified during an inspection conducted on October 17, 2018.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

Pharmacy, by affixing the signature of the Pharmacist-in-Charge (or Owner if no PIC) hereon, agrees to the following:

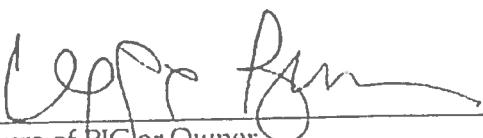
1. The Pharmacist-in-Charge (or Owner if no PIC) has the right to seek advice of counsel prior to signing this document;
2. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that without his consent, no legal action can be taken against the Pharmacy except pursuant to the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia;
3. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that he has the following rights, among others: the right to an informal fact finding conference before the Board, the right to reasonable notice of said hearing, the right to representation by counsel, and the right to cross-examine witnesses;
4. The Pharmacist-in-Charge (or Owner if no PIC) waives all such right to an informal conference;
5. The Pharmacist-in-Charge (or Owner if no PIC) admits to the violations cited herein and waives his right to contest such violations in any subsequent proceeding before the Board;
6. The Pharmacist-in-Charge (or Owner if no PIC) consents to the entry of the following Order affecting the permit of the Pharmacy in Virginia.

WHEREFORE, on the basis of the foregoing, the Board, effective upon entry of this Order, and in lieu of further proceedings, hereby ORDERS as follows:

1. Pharmacy shall pay a monetary penalty of \$2,000 to the Board within 30 days of the date of the Notice.
2. Pharmacy shall submit documentation of immediate action taken to correct all violations.
3. Any violation of the terms and conditions of this Order or of any law or regulation affecting the conduct of Pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of the permit of Pharmacy, and an administrative proceeding shall be convened to determine whether such permit shall be suspended or revoked.

DEFICIENCY NOTICE AND CONSENT ORDER
Permit Number: 0201003388

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Notice and Consent Order shall remain in the custody of the Department of Health Professions as public record and shall be made available for public inspection or copying upon request.

	May 15, 2019
Signature of PIC or Owner	Date
Clifford Berman	Corporate Secretary
Printed Name of Person Signing	Position/Title

FOR THE BOARD:

Caroline D. Juran, Executive Director

Entered



To Whom It May Concern:

Option Care Enterprises, Inc. also owns a separate pharmacy in Louisville, KY. On November 19, 2019, The Kentucky Board of Pharmacy fined the Louisville pharmacy \$500.00 for a dispensing error in which wrong medication was dispensed.

If you have questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.

COMMONWEALTH OF KENTUCKY
Kentucky Board of Pharmacy
Case No. 19-0272A

IN RE: Option Care Enterprises Inc
d/b/a Option Care
11403 Bluegrass Parkway
Suite 400
Louisville, Kentucky 40299
Permit: P07485

AGREED ORDER

The Kentucky Board of Pharmacy ("Board") and Option Care Enterprises Inc ("Respondent"), based upon the information presented and being sufficiently advised, hereby agree to the entry of this Agreed Order to obviate a formal hearing.

STIPULATIONS OF FACT

The parties stipulate to the following factual statements that serve as the factual basis for this Agreed Order:

- (a) Respondent at all time's material hereto is a pharmacy in the Commonwealth of Kentucky, having been assigned Permit No. PO7485.
- (b) Respondent allegedly sold a misbranded drug due to a medication error. Patient was allegedly dispensed a prescription for heparin syringes that contained sodium chloride syringes.
- (c) Respondent is subject to discipline pursuant to KRS 217.065(1)
- (d) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

STIPULATED CONCLUSIONS OF LAW


The parties stipulate to the following Conclusions of Law, which serve as the legal bases for this Agreed Order:

1. Respondent's permit to practice as a pharmacist in the Commonwealth is subject to regulation and discipline by the Kentucky Board of Pharmacy.
2. There is probable cause to believe that Respondent has violated KRSE 217.065(1).

ORDER


- (a) The Respondent is fined \$500.00 payable on or before November 14, 2019. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601.
 - (b) On or before November 19, 2019, Respondent shall submit a written Corrective Action Plan (CAP) detailing the measures that Respondent shall take to prevent medication errors.
 - (c) By entering into this Agreed Order, Respondent expressly acknowledges that the Respondent understands or was fully and completely informed of Respondent's right to due process by an attorney of Respondent's choosing, that the Respondent fully understands those rights, and that the Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order. By entering this Agreed Order respondent expressly agrees to assent to the jurisdiction of the Kentucky Board of Pharmacy.
3. The above information shall be reported to the National Association of Boards of Pharmacy ("NABP") and is subject to disclosure under the Kentucky Open Records Act.

 CRAIG MARTIN
 President
 Kentucky Board of Pharmacy



 OPITION CARE ENTERPRISES INC
 Respondent Clifford Berman
 Corporate Secretary

 DATE



 DATE



Matthew G. Bevin
Governor

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

Board Members
Peter P. Cohron, R.Ph.
Jody Forgy, Consumer
John Fuller, Pharm.D.
Craig Martin, Pharm D.
Ron Poole, R.Ph.
Jill Rhodes, Pharm.D.

Executive Director
Larry A. Hadley, R.Ph.

October 19, 2019

Option Care Enterprises, Inc.
d/b/a Option Care
11403 Bluegrass Parkway, Suite 400
Louisville, Kentucky 40299
License: P07485

RE: Case No. 19-0272A

Dear Permit Holder:

This letter follows the recent investigation by Amanda Harding, R.Ph., Pharmacy and Drug Inspector. The investigative report was reviewed by the Case Review Committee. The Committee adopted a recommendation as follows:

Attempt by Board Staff to resolve through Agreed Order.

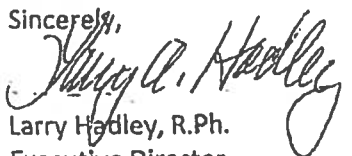
The Committee recommendation was placed before the Board of Pharmacy. The Board accepted the recommendation. Acceptance occurred without benefit of the disclosure of the subject of the complaint or evidentiary review to prevent bias and preserve the integrity of the Board in the event a full Board hearing becomes necessary.

The purpose of this letter is to offer you an opportunity to informally resolve this matter through an Agreed Order prior to the filing of a formal Complaint. Find enclosed a proposed Agreed Order setting forth terms the Board will accept. Review the proposed Agreed Order carefully. Feel free to consult with legal counsel. If acceptable, sign and return the Agreed Order to the Board office by November 20, 2019. We will send you a copy of the Agreed Order after it is signed by the Board President.

Option Care Enterprises, Inc.
19-0272A
October 19, 2019
Page 2

Should you fail to respond by returning the proposed Agreed Order or contacting me by November 20, 2019, your case will be referred to the Office of the Attorney General to conduct an Administrative Hearing.

Sincerely,


Larry Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Enclosure



To Whom It May Concern:

Option Care Enterprises, Inc. owns another pharmacy in Englewood, Colorado. On January 28, 2020, the pharmacy was disciplined and fined \$500.00 with a surcharge of \$75.00 by the Colorado Board of Pharmacy ("Board") due to findings during a routine pharmacy inspection conducted on November 6, 2019. Please find the consent order attached hereto.

If you have any questions or need additional information please contact the licensing department via email at oc-PEandL@optioncare.com.

BEFORE THE STATE BOARD OF PHARMACY**STATE OF COLORADO****Case No. 2019-8031**

STIPULATION AND FINAL AGENCY ORDER

**IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE PRESCRIPTION
DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF OPTION CARE,
REGISTRATION NO. PDO 178,**

Respondent Pharmacy.

**IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board
of Pharmacy ("Board") and Option Care, ("Respondent Pharmacy") to resolve all
matters pertaining to Board Case Number 2019-8031, as follows:**

FINDINGS AND CONCLUSIONS

- 1. The Board has jurisdiction over Respondent Pharmacy, its registration as an in-state prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to provisions of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 280, C.R.S. (2019).**
- 2. Respondent Pharmacy was originally registered in the State of Colorado on or about September 30, 2003, being issued registration #PDO 178, and has been so registered at all times relevant to this disciplinary action.**
- 3. Respondent Pharmacy's address of record with the Board and current location is 345 Inverness Dr S, Bldg A, Ste 140, Englewood, CO 80112.**
- 4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.**
- 5. In an inspection of Respondent Pharmacy conducted on November 6, 2019, a Board inspector found one repeated deficiency, over three (3) inspections on November 6, 2019, December 6, 2018, and August 8, 2017. Specifically, the failure to label compound prescriptions with the required statement.**
- 6. Respondent Pharmacy admits that its conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Rules and provides grounds for disciplinary action against Respondent Pharmacy's Colorado registration as a prescription drug outlet:**

Colorado Revised Statutes

12-280-126. Unprofessional conduct - grounds for discipline.

(1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this article 280, including commission of an act declared unlawful in section 12-280-129, or an applicable provision of article 20 or 30 of this title 12;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

(k) Has failed to meet generally accepted standards of pharmacy or pharmacy technician practice.

Pharmacy Board Rules and Regulations

21.21.70 Labeling of CSPs.

a. Labeling of CSPs dispensed pursuant to a prescription order or LTCF chart order shall include at least the following:

(6) A clear statement that this product was compounded by the pharmacy, except for radiopharmaceuticals prepared from FDA-approved, commercially available kits and/or drug products.

7. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

DISPOSITION

8. Fine with Surcharge. Pursuant to section 12-280-127(5)(a), C.R.S., Respondent Pharmacy shall pay a fine of five hundred dollars (\$500.00). Respondent Pharmacy understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Pharmacy shall therefore pay

a total amount of five hundred and seventy five dollars (\$575.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

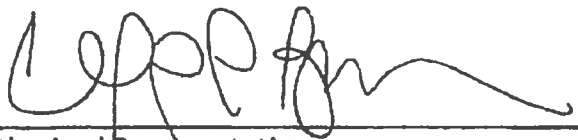
9. **Other Requirements.** Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent Pharmacy shall:
 - a. promptly pay all its own fees and costs associated with this Final Agency Order;
 - b. comply fully with this Final Agency Order; and
 - c. comply fully with the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceuticals and pharmacists in the State of Colorado.
10. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under section 12-280-127(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:
 - a. To have a formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges;
 - c. to have a formal disciplinary hearing pursuant to sections 12-20-403, 12-280-126, and 12-280-127, C.R.S.; and
 - d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.
13. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
14. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
15. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Pharmacy at Respondent Pharmacy's address of record with the Board, or (b) service by electronic means on Respondent Pharmacy at Respondent Pharmacy's electronic address of record. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Pharmacy



Authorized Representative

Clifford Berman, Corporate Secretary

Name/ Title

Dated: 1/21/2020

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 28 day of January, 2020.

State Board of Pharmacy

BY: 

Dmitry Kunin

Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 28th day of JANUARY 2020, addressed as follows:



Agent of the Board

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE)	
ILLINOIS DEPARTMENT OF FINANCIAL)	
AND PROFESSIONAL REGULATION,)	
v.)	Case No. 2018-07504
OPTION CARE ENTERPRISES, INC.,)	
License No. 054.020423,)	
Complainant,)	
Respondent.)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by attorney Paula McGee, and Respondent Option Care Enterprises, Inc., ("Respondent"), by attorney Alex Cooper of Quarles & Brady, LLP, agree to the following:

STIPULATIONS

Respondent holds Illinois pharmacy license no. 054.020423 pursuant to the Pharmacy Practice Act, 225 ILCS 85/et seq. ("Act"), which is presently in active status. On or about June 26, 2018, the Kentucky Board of Pharmacy issued a public Consent Agreement whereby Respondent agreed to pay a fine in the amount of one hundred dollars (\$100.00) due to Respondent allowing an unlicensed pharmacy technician to work from approximately March 31, 2018 to approximately April 19, 2018. For the purposes of this Consent Order, Respondent admits that an adverse action was taken against Respondent in the State of Kentucky. Respondent's actions and/or omissions constitute grounds for discipline under the Act, 225 ILCS 85/30(a)(8).

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Respondent has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, the right to contest any charges brought and present mitigating evidence, and the right to administrative review of any order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Board of Pharmacy ("Board") or Director. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the

2/12/2020
Date


Respondent Option Care Enterprises, Inc.

Date

Alex Cooper, Quarles & Brady, LLP
Attorney for Respondent

Date

Department Attorney Paula McGee

Date

Board of Pharmacy Member

The foregoing Consent Order is approved in full.

Dated this ____ day of _____, 2020.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY DEBORAH HAGAN

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No. 2018-07504
License No. 054.020423



To Whom It May Concern:

Option Care Enterprises, Inc. also owns a separate pharmacy in Louisville, KY. On June 26, 2018, The Kentucky Board of Pharmacy fined the Louisville pharmacy \$100.00 for allowing a technician to practice for over two weeks on a non-renewed license. On August 19, 2019, the Illinois Department of Financial Regulation issued a "sister state" discipline. Please find the partially signed consent order attached hereto.

If you have questions or need additional information please feel free to contact the licensing department via email at oc-PEandL@optioncare.com.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE)	
ILLINOIS DEPARTMENT OF FINANCIAL)	
AND PROFESSIONAL REGULATION,)	
v.)	Case No. 2018-07504
OPTION CARE ENTERPRISES, INC.,)	
License No. 054.020423,)	
Respondent.)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by attorney Paula McGee, and Respondent Option Care Enterprises, Inc., ("Respondent"), by attorney Alex Cooper of Quarles & Brady, LLP, agree to the following:

STIPULATIONS

Respondent holds Illinois pharmacy license no. 054.020423 pursuant to the Pharmacy Practice Act, 225 ILCS 85/et seq. ("Act"), which is presently in active status. On or about June 26, 2018, the Kentucky Board of Pharmacy issued a public Consent Agreement whereby Respondent agreed to pay a fine in the amount of one hundred dollars (\$100.00) due to Respondent allowing an unlicensed pharmacy technician to work from approximately March 31, 2018 to approximately April 19, 2018. For the purposes of this Consent Order, Respondent admits that an adverse action was taken against Respondent in the State of Kentucky. Respondent's actions and/or omissions constitute grounds for discipline under the Act, 225 ILCS 85/30(a)(8).

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Respondent has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, the right to contest any charges brought and present mitigating evidence, and the right to administrative review of any order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Board of Pharmacy ("Board") or Director. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the

Department or any person and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent has been informed that this Consent Order will be presented to the Director. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Respondent and the Department agree, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of disciplinary measures which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by attorney Paula McGee, and Respondent, by attorney Alex Cooper of Quarles & Brady, LLP, agree:

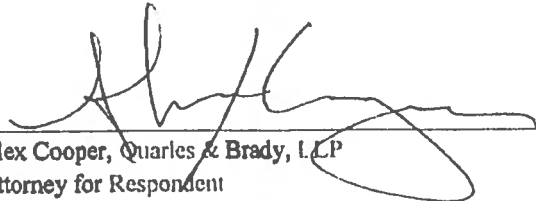
- A. Respondent's Illinois pharmacy license no. 054.020423 shall be reprimanded.
- B. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes, including the National Association of Boards of Pharmacy. This Consent Order will be available to the general public.
- C. This Consent Order shall become effective upon the Director's signature, as dated below.

Signatures on the following page.

2/12/2020
Date


Respondent Option Care Enterprises, Inc.

2/12/2020
Date


Alex Cooper, Quarles & Brady, LLP
Attorney for Respondent

Date

Department Attorney Paula McGee

Date

Board of Pharmacy Member

The foregoing Consent Order is approved in full.

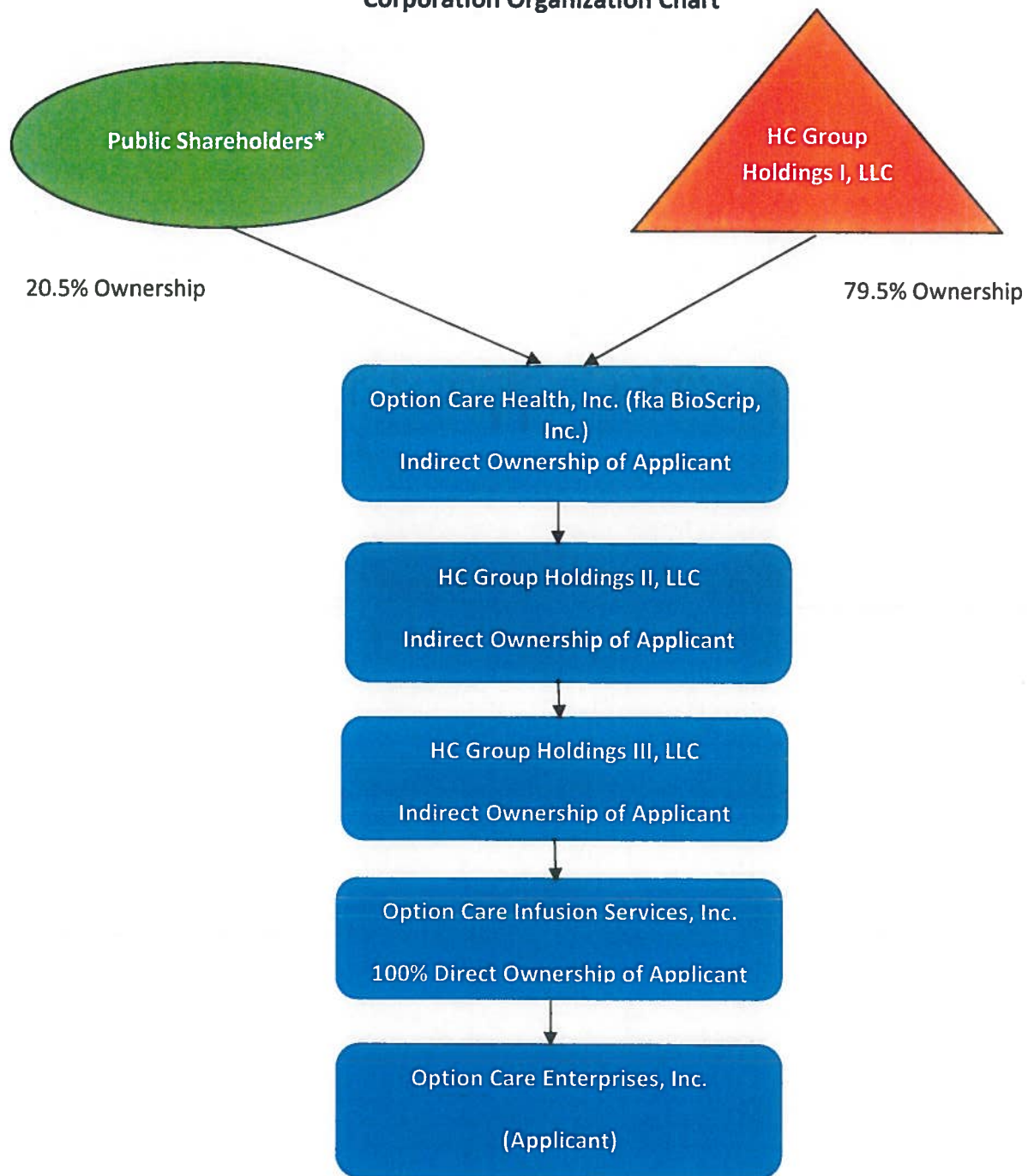
Dated this ____ day of _____, 2020.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY DEBORAH HAGAN

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No. 2018-07504
License No. 054.020423

Corporation Organization Chart



**** Each legal entity owns 100% of the legal entity direct below itself on the org chart.**

*Option Care Health, Inc. (fka BioScrip, Inc.) is a publicly held company with stock traded on the NASDAQ. Public shareholders change from time to time and no shareholder owns a 10% or more interest in Option Care Health, Inc.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): February 3, 2020

Option Care Health, Inc.
(Exact name of registrant specified in its charter)

Delaware
(State or Other Jurisdiction
Of Incorporation)

001-11993
(Commission
File Number)

05-0489664
(I.R.S. Employer
Identification No.)

3000 Lakeside Dr. Suite 300N, Bannockburn, IL 60015
(Address of principal executive offices, including zip code)

(312) 940-2443
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value per share	OPCH	Nasdaq Global Select Market

Item 3.03 Material Modification to Rights of Security Holders.

To the extent required by Item 3.03 of Form 8-K, the information regarding the reverse stock split contained in Item 5.03 and Item 8.01 of this Current Report on Form 8-K is incorporated by reference herein.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On January 30, 2020, as approved as described below under Item 8.01, Option Care Health, Inc. (the "Company") filed a certificate of amendment to its certificate of incorporation (the "Certificate of Amendment") with the Secretary of State of the State of Delaware to effect a reverse stock split of the Company's common stock at a ratio of 1-for-4, effective on February 3, 2020.

The Certificate of Amendment is filed as Exhibit 3.1 to this Current Report on Form 8-K.

Item 8.01 Other Events.

The Company's board of directors has determined to set the reverse stock split ratio at 1-for-4. The effective date of the reverse stock split is February 3, 2020. The shares began trading on a split-adjusted basis at market open on February 3, 2020.

Upon the effectiveness of the reverse stock split on February 3, 2020, every four shares of the issued and outstanding shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"), were automatically combined and reclassified into one issued and outstanding share of the Company's Common Stock. The reverse stock split does not affect any stockholder's ownership percentage of the Company's Common Stock, alter the par value of the Company's Common Stock or modify any voting rights or other terms of the Company's Common Stock.

In connection with the reverse stock split, at the market open on February 3, 2020, the Company's Common Stock began trading on the Nasdaq Global Select Market under the symbol "OPCH". The Common Stock was assigned a new CUSIP number (68404L 201) and began trading on a split-adjusted basis.

On February 3, 2020, the Company issued a press release announcing the foregoing. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.* The following exhibits are filed as part of this Current Report on Form 8-K:

Exhibit Number	Description
<u>Exhibit 3.1</u>	<u>Certificate of Amendment of the Certificate of Incorporation, filed January 30, 2020.</u>
<u>Exhibit 99.1</u>	<u>Press Release issued by Option Care Health, Inc., dated February 3, 2020.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 3, 2020

OPTION CARE HEALTH, INC.

By: /s/ Michael Shapiro

Name: Michael Shapiro

Title: Chief Financial Officer

CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
OPTION CARE HEALTH, INC.

* * * * *

Option Care Health, Inc., a corporation duly organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify as follows:

FIRST. That the present name of the Corporation is Option Care Health, Inc. and that the Corporation was originally formed as MIM Corporation, a Delaware corporation, and filed its original Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Secretary of State") on March 22, 1996. A Third Amended and Restated Certificate of Incorporation was filed with the Secretary of State on August 6, 2019 (the "Certificate of Incorporation").

SECOND. That the Certificate of Incorporation of the Corporation be, and hereby is, amended to effect a change in Article Four, Section 1 thereof, relating to the total number of shares of common stock the Corporation has authority to issue. Specifically, Article 4, Section 1 of the Certificate of Incorporation shall be deleted in its entirety and replaced with a new Article 4, Section 1 to read as follows:

ARTICLE FOUR

Section 1. Authorized Shares. The total number of shares of all classes of capital stock which the Corporation shall have the authority to issue is 262,500,000 shares, consisting of two classes as follows:

1. 12,500,000 shares of Preferred Stock, par value \$0.0001 per share (the "Preferred Stock"); and
2. 250,000,000 shares of Common Stock, par value \$0.0001 per share (the "Common Stock").

The Preferred Stock and Common Stock shall have the designations, rights, powers and preferences and the qualifications, restrictions and limitations thereof, if any, set forth below.

THIRD. That the Certificate of Incorporation of the Corporation be, and hereby is, amended to add a new Section 4 to Article Four which shall read in its entirety as follows:

Section 4. Reverse Stock Split. Upon the filing of the Certificate of Amendment to the Certificate of Incorporation of the Corporation first inserting this sentence with the Secretary of State of Delaware (the "Effective Time"), each four (4) authorized shares of Common Stock, at the Effective Time, shall, without further action by the Corporation or any holder thereof, be changed into, reclassified and converted into one (1) authorized share of Common Stock. Fractional shares of Common Stock shall not be issued as a result of the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional share interests of Common Stock in connection with the Reverse Stock Split shall, with respect to such fractional interest, be entitled to receive cash, without interest, in lieu of fractional shares of Common Stock. Each certificate that prior to such combination represented shares of Common Stock ("Old Certificates") shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined. For the avoidance of doubt, the foregoing Reverse Stock Split shall apply to all shares of Common Stock underlying any warrants, stock options, or any other rights to purchase Common Stock, in each case outstanding immediately prior to the Effective Time.

FOURTH. That the Board of Directors of the Corporation approved this Certificate of Amendment pursuant to the provisions of Section 242 of the General Corporation Law of the State of Delaware.

FIFTH. That this Certificate of Amendment shall become effective on February 3, 2020.

IN WITNESS WHEREOF, the undersigned officer of the Corporation has executed this Certificate of Amendment to the Certificate of Incorporation of the Corporation.

OPTION CARE HEALTH, INC.
a Delaware corporation

By: /s/ Clifford E. Berman

Name: Clifford E. Berman

Its: Secretary



OPTION CARE HEALTH COMPLETES REVERSE STOCK SPLIT AND TICKER SYMBOL CHANGE

BANNOCKBURN, IL., February 3, 2020 – Option Care Health, Inc. (the “Company” or “Option Care Health”) (NASDAQ: OPCH), the nation’s largest independent provider of home and alternate site infusion services, announced today that it has completed the reverse 1-for-4 stock split of its shares of common stock, as previously disclosed in the Company’s filings with the Securities and Exchange Commission. As of market open on February 3, 2020, the Company’s common stock, which was previously listed on the Nasdaq Capital Market under the symbol “BIOS”, will begin trading on a split-adjusted basis on the Nasdaq Global Select Market under the ticker symbol “OPCH” and will be assigned a new CUSIP number (68404L 201).

No other action is required by current stockholders relative to either the ticker symbol change or the reverse stock split.

About Option Care Health

Option Care Health is the nation’s largest independent provider of home and alternate site infusion services. With over 6,000 teammates, including 2,900 clinicians, we work compassionately to elevate standards of care for patients with acute and chronic conditions in all 50 states. Through our clinical leadership, expertise and national scale, Option Care Health is reimagining the infusion care experience for patients, customers and employees. To learn more, please visit our website at OptionCareHealth.com.

For Investor Inquiries:

Bob East, Asher Dewhurst, Jordan Kohnstam
Westwicke
443-213-0500
optioncarehealth@westwicke.com

State of Minnesota

BOARD OF PHARMACY
2829 UNIVERSITY AVE SE #530
MINNEAPOLIS, MN 55414-3251

HAS ISSUED

PHARMACY LICENSE NUMBER: 262204
(ACTIVE)

Sterile Product Compounding, Home Health Care

To:

OPTION CARE
2750 ARTHUR STREET
ROSEVILLE MN 55113

EFFECTIVE DATE

05/21/2019

EXPIRATION DATE

06/30/2020

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OPTION CARE ENTERPRISES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF FEBRUARY, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "OPTION CARE ENTERPRISES, INC." WAS INCORPORATED ON THE NINETEENTH DAY OF JULY, A.D. 1994.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

2419872 8300

SR# 20201439137

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202464147

Date: 02-26-20



Minnesota Health Licensing Boards

Minnesota Board of Pharmacy

License/Registration Verification as of February 25, 2020

Name	Option Care
Address	2750 Arthur Street Roseville, MN 55113

License/Registration Information

Type	Pharmacy License
Category	Sterile Product Compounding, Home Health Care
Number	262204
Status	Active
Original Issue Date	07/25/2002
Date	05/21/2019
Expiration Date	06/30/2020
Disciplinary Action	No

This data is authorized to be used as primary source verification of a Minnesota License.

Disclaimer: While we believe this information to be reliable, human or mechanical error remains a possibility, as does delay in the posting or updating of information. Therefore there is no guarantee as to the accuracy, completeness, timeliness, or currency of the data listed in the individual section. The Board is not responsible for the use, or result obtained from the use, of this information.

11F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,8

☐ Partnership - Pages 1,2,6,8

☐ Non Publicly Traded Corporation – Pages 1,2,4,8

☒ Sole Owner – Pages 1,2,7,8

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Pope Shenouda LLC

Physical Address: 2228 US Hwy 19, Holiday, FL 34691

Mailing Address: 2228 US Hwy 19, Holiday, FL 34691

City: Holiday State: FL Zip Code: 34691

Telephone: 727-934-1300 Fax: 727-934-1313

Toll Free Number: 844-565-5155 (Required per NAC 639.708)

E-mail: firstchoicepharmacy@yahoo.com Website: www.1stchoicepharmacy.net

Managing Pharmacist: George Hanna License Number: PS40421

TYPE OF PHARMACY

AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☒ ☐ Long Term Care
☒ ☐ Sterile Compounding **
☒ ☐ Non Sterile Compounding
☒ ☐ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

George Hanna

Print Name of Authorized Person

4/14/2020
Date

Page 2

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: George Hanna

Business Name: Pope Shenouda LLC

Current Business Address: 2228 US Hwy 19

City: Holiday State: FL Zip Code: 34691

Telephone: 727-934-1300 Fax: 727-934-1313

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday	<u>9</u> am	<u>6</u> pm	Saturday	<u>10</u> am	<u>1</u> pm
Sunday	_____am	_____pm	24 Hours	_____	

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA


I, George Hanna

Responsible Person of Pope Shenouda LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

George Hanna

Print Name of Authorized Person

4/14/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Florida)
Pasco) ss.
COUNTY)

I, George Hanna, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner for 1st Choice Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of- State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, George Hanna, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

George Hanna
Name



SUBSCRIBED AND SWORN TO
before me, a notary public this
10th day of April, 2020.

Laura Able *Laura Able*
NOTARY PUBLIC



Posted April 1, 2020

State of Florida

Department of State

I certify from the records of this office that POPE SHENOUDA LLC is a limited liability company organized under the laws of the State of Florida, filed on December 10, 2007, effective December 7, 2007.

The document number of this limited liability company is L07000122168.

I further certify that said limited liability company has paid all fees due this office through December 31, 2019, that its most recent annual report was filed on February 28, 2019, and that its status is active.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Sixth day of January, 2020*



Randy R.
Secretary of State

Tracking Number: 4958032172CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>

AC#8618849

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/03/2018	PH 23208	103571

THE PHARMACY

named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

COPE SHENOUDA, LLC


1st Choice Pharmacy

228 US HWY 19

WALDSTADT, FL 34691

QUALIFICATION(S):
COMMUNITY PHARMACY
SCHEDULE II & III
3:1 PHARMACY TECHNICIAN RATIO APPROVED




Rick Scott
GOVERNOR


Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

11G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership – Pages 1,2,5,7
☒ Non Publicly Traded Corporation – Pages 1,2,4,7 ☐ Sole Owner – Pages 1,2,6,7

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Procure Pharmaceutical Services

Physical Address: 264 Smith Township State Road, Suite 5

Mailing Address: 264 Smith Township State Road, Suite 5

City: Burgettstown State: PA Zip Code: 15021

Telephone: 724-414-1425 Fax: 855-445-4203

Toll Free Number: 855-315-1403 (Required per NAC 639.708)

E-mail: Michelle.mikus@deltacarerx.com Website: www.procurepharmacy.com

Managing Pharmacist: Michelle Mikus License Number: RP448182

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☐ ☒ Community
☒ ☐ Other: Hospice

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral **
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☒ ☐ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding **
☒ ☐ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding **
☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required. Attached

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Michelle J. Mikus
Original Signature of Person Authorized to Submit Application, no copies or stamps

Michelle J. Mikus
Print Name of Authorized Person

4-1-2020
Date

Page 2

Board Use Only

Date Processed: 4/20/2020

Amount: \$500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Ohio
 Parent Company if any: Easy Rx Pad LLC
 Mailing Address: 4249 Sunset Blvd
 City: Steubenville State: OH Zip: 43952
 Telephone: 724-414-1425 Fax: 855-445-4203
 Contact Person: Andy Mihalyo or Michelle Mikus

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) <u>Andrew J. Mihalyo 51%</u>	<u>N. Federal Hwy, #</u> , <u>Ft. Lauderdale FL 33304</u>
Name	Address
b) <u>Mary G. Mihalyo 25%</u>	<u>Whitchall Pl, Wintersville OH 43953</u>
Name	Address
c) <u>Andrew M. Mihalyo 24%</u>	<u>Whitchall Pl, Wintersville OH 43953</u>
Name	Address
d) <u>—</u>	<u>—</u>
Name	Address

2) Provide the number of shares issued by the corporation. N/A - see above %

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? 9-25-2008

5) Provide a copy of the corporation's stock register evidencing the above information N/A.

Articles of Organization attached.

List any physician shareholders and percentage of ownership.

Name: N/A %: —

Name: — %: —

Hours of Operation for the pharmacy:

Monday thru Friday	<u>—</u> am <u>—</u> pm	Saturday	<u>—</u> am <u>—</u> pm
Sunday	<u>—</u> am <u>—</u> pm	24 Hours	<u>✓</u>

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: —

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Michelle Mikus

Responsible Person of Prower Pharmaceutical Services

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Michelle J. Mikus

Original Signature of Person Authorized to Submit Application, no copies or stamps

Michelle J. Mikus

Print Name of Authorized Person

4-1-2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF _____)
) ss.
 _____ COUNTY)

I, Michelle J. Mikus, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager for Procure Pharmaceutical Services (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

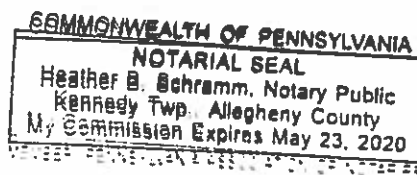
FURTHER AFFIANT SAYETH NOT.

I, Michelle J. Mikus, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

Michelle J. Mikus

SUBSCRIBED AND SWORN TO
 before me, a notary public this
14 day of April, 2020.
[Signature]
 NOTARY PUBLIC



UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show EASY RX PAD, LLC, an Ohio For Profit Limited Liability Company, Registration Number 1808622, was organized within the State of Ohio on September 25, 2008, is currently in FULL FORCE AND EFFECT upon the records of this office.



*Witness my hand and the seal of the
Secretary of State at Columbus, Ohio
this 1st day of April, A.D. 2020.*

A handwritten signature in cursive script, appearing to read "Frank LaRose".

Ohio Secretary of State

Validation Number: 202009201848

PALS Payment Receipt - MICHELLE JACQUELINE MIKUS

1 message

RA-STPALSNOTIFY@pa.gov <RA-STPALSNOTIFY@pa.gov>
To: michelle.mikus@deltacarerx.com

Wed, Apr 1, 2020 at 2:31 PM

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

Dear MICHELLE JACQUELINE MIKUS :

This letter acknowledges receipt of your request. You can access www.pals.pa.gov website and check the status of your request using the UserID and Password you have created when you submit your request.

Payment Receipt

RECEIPT NUMBER: PAID0001626304
RECEIVED DATE: Apr 1 2020 2:26PM
RECEIVED FROM: MICHELLE JACQUELINE MIKUS
RECEIVED AMOUNT: \$ 15.00
PAYMENT TYPE: Credit Card
APPLICANT NAME: MICHELLE JACQUELINE MIKUS

Application No / Transaction No	Fee Type	Fee Amount	Full Name
TN0013096135 (Pharmacy-PP482456)	Verification/Certification of License	15.00	MICHELLE JACQUELINE MIKUS

*License verification from PA
to NV requested 4-1-2020!*

633

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs

Pharmacy

License Number
PP482456

Expiration Date
08/31/2021

Active

PROCURE PHARMACEUTICAL SERVICES
MICHELLE J MIKUS
264 SMITH TWP STATE RD STE 5
BURGETTSTOWN, PA 15021

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE

- 1 SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED
- 2 DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION

Pennsylvania Licensing System (PALS)

Visit our website at: www.pals.pa.gov to
renew your license, change your personal or
license address, or order duplicate licenses.

PROCURE PHARMACEUTICAL SERVICES
MICHELLE J MIKUS
264 SMITH TWP STATE RD STE 5
BURGETTSTOWN, PA 15021

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

19 0827045

License Type
Pharmacy

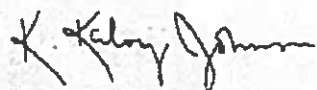
PROCURE PHARMACEUTICAL SERVICES
MICHELLE J MIKUS
264 SMITH TWP STATE RD STE 5
BURGETTSTOWN, PA 15021

License Status
Active

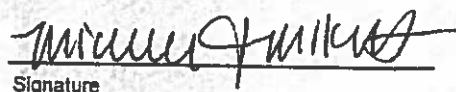
Initial License Date
05/28/2014

Expiration Date
08/31/2021

License Number
PP482456



Acting Commissioner of Professional and Occupational Affairs


Signature

Easy Rx Pad, LLC, d/b/a Procure Pharmaceutical Services has had no disciplinary actions on its license to practice pharmacy in any other state. However, it has recently agreed to probation for a term of one year on its controlled substance registration in the State of Missouri. Please see attached a copy of the Missouri pharmacy license and controlled substance registration. The probationary term resulted from a lapse in the pharmacy's controlled substance registration that was overlooked when the Pharmacy did not receive a renewal notice and the expiration date of the Missouri controlled substance registration was not included separately from that of the Missouri pharmacy license in their internal tracking system. Upon identification of the oversight, the pharmacy immediately renewed the registration and implemented numerous interventions to prevent the possibility of this oversight occurring in the future. Because the relevant Missouri dispensary is located in a hospice facility, the Pharmacy rapidly resolved this matter with the State of Missouri to protect hospice patients from any gap in their care.



Michelle Mikus, PharmD

3-30-2020

PR Home (<https://pr.mo.gov/>) » Pharmacy Home (<https://pr.mo.gov/pharmacists.asp>) » Pharmacy Licensee Search (<https://pr.mo.gov/pharmacy-licensee-search.asp>)

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Easy Rx Pad LLC
Profession Name:	Pharmacy
Licensee Number:	2014037464
Expiration Date:	10/31/2021
Original Issue Date:	10/21/2014
Address:	Michelle Mikus, PIC
Address Con't:	264 Smith Township State Rd Ste 5
City, State Zip:	Burgettstown, PA 15021
County:	Unknown/Out of State
Practitioner DBA Name:	Procure Pharmaceutical Services
Classification:	Class C

Current Discipline Status:	None
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Board of Pharmacy (<https://pr.mo.gov/pharmacists>)

3605 Missouri Boulevard

P.O. Box 625

Jefferson City, MO 65102-0625

573.751.0091 Telephone

573.526.3464 Fax

800.735.2966 TTY

800.735.2466 Voice Relay

MissouriBOP@pr.mo.gov (<mailto:MissouriBOP@pr.mo.gov>)

<https://pr.mo.gov/pharmacists> (<https://pr.mo.gov/pharmacists>)


Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569



Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	EASY RX PAD LLC (PROCURE PHARMACEUTICAL SERVICES)
BNDD Number:	2500041072
Description:	LTCF AUTOMATED DISP SYSTEM (LTCF ADS)
Street Address:	1000 N MASON RD
City/State/Zip:	CREVE COEUR, MO 63141.6310
Phone Number:	877-227-8718
Registration Effective:	11/25/2019
Registration Expires:	11/30/2020
BNDD Discipline:	YES
Drug Schedule Type:	2 3 4 5
Enrollment Date:	11/25/2019

Validation Date of the Registration is: 11/25/2019

Direct Inquiries to:

BNDD

PO BOX 570

Jefferson City, Missouri 65102 0570

Easy Rx Pad LLC
4249 Sunset Blvd
Steubenville OH 43952

dba Procure Pharmaceutical Services
264 Smith Township State Road Suite 5
Burgettstown PA 15021

Corporate Officers:

Andrew J Mihalyo, President

Mary G. Mihalyo, CEO

Andrew M. Mihalyo, CFO

Michelle Mikus, VP Pharmacy Services

200827000542

DATE 09/26/2008	DOCUMENT ID 200827000542	DESCRIPTION ARTICLES OF ORGNZTN/DOM. PROFIT LIM.LIAB. CO. (LCP)	FILING 125.00	EXPED .00	PENALTY .00	CERT .00	COPY .00
--------------------	-----------------------------	---	------------------	--------------	----------------	-------------	-------------

Receipt

This is not a bill. Please do not remit payment.

WILLIAM F BLAKE JR
4110 SUNSET BLVD
STEUBENVILLE, OH 43952

STATE OF OHIO CERTIFICATE

Ohio Secretary of State, Jennifer Brunner**1808622**

It is hereby certified that the Secretary of State of Ohio has custody of the business records for

EASY RX PAD, LLC

and, that said business records show the filing and recording of:

Document(s):

ARTICLES OF ORGNZTN/DOM. PROFIT LIM.LIAB. CO.

Document No(s):

200827000542

United States of America
State of Ohio
Office of the Secretary of State

Witness my hand and the seal of the
Secretary of State at Columbus, Ohio
this 25th day of September, A.D.
2008.

A handwritten signature in cursive script, appearing to read "Jennifer Brunner".

Ohio Secretary of State

12

12A

RECEIVED
7/14/2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA Medical Device, Equipment & Gases (MDEG)

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New MDEG ☒ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: MP or MW MP01163)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☒ Partnership - Pages 1,2,3,6
☐ Non Publicly Traded Corporation – Pages 1,2,3,5a,5b ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION to be completed by all types of ownership

MDEG Name: ActivStyle, Inc.

Physical Address: 3500 Lakeside Ct Ste 200 Reno, NV 89509-4829

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 220 W Germantown Pike Suite 250

City: Plymouth Meeting State: PA Zip Code: 19462

Telephone: 612-928-6826 Fax: 866-301-2167

E-mail: licensing@adapthealth.com Website: www.activstyle.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8:00 to 4:30 Tue: 8:00 to 4:30 Wed: 8:00 to 4:30 Thu: 8:00 to 4:30

Fri: 8:00 to 4:30 Sat: Closed Sun: Closed Holidays: Closed

MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: Justin Garcia

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases** ☒ Assistive Equipment ☐ Oral Nutrition Only
☐ Respiratory Equipment** ☒ Parenteral and Enteral Equipment**
☐ Life-sustaining equipment** ☐ Orthotics and Prosthesis
☐ Diabetic Supplies Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name: Justin Garcia Telephone: 612-928-6826

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

1265720003-Medicare 1407173497-NV Medicaid

_____	_____	_____
_____	_____	_____
_____	_____	_____

- 1) Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒
- 2) Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐
- 3) Are any of the owners health professionals? If yes, please check the box and list name.

<input type="checkbox"/> Practitioner	Name: <u>N/A</u>
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: _____
<input type="checkbox"/> Physician's Assistant	Name: _____
<input type="checkbox"/> Physical Therapist	Name: _____
<input type="checkbox"/> Occupational Therapist	Name: _____
<input type="checkbox"/> Registered Nurse	Name: _____
<input type="checkbox"/> Respiratory Therapist	Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

- 1) Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Diane Siegel

Print Name of Authorized Person

Date

7/10/20

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR NEVADA MDEG LICENSE**OWNERSHIP IS A PARTNERSHIP**

List names of 4 largest partners and percentage of ownership:

Name: AdaptHealth LLC %: 100%

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Partnership Name: ActivStyle, Inc.Mailing Address: 220 W Germantown Pike Ste 250City Plymouth Meeting State: PA Zip Code: 19462Telephone Number: 410-409-8741 Fax Number: 484-244-5488Contact Person: Diane Siegel dsiegel@adapthealth.com**PARTNERSHIP****Include with the application for a partnership**

Complete personal history record for each partner. Must be original signature(s), no copies or stamps. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 07/01/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for In State MDEG License

ActivStyle Inc. 3500 Lakeside Ct Ste 200 Reno NV 89509-4829

Name and Address of Establishment for Which License Is Requested

ActivStyle Inc.

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Parnes

Yehoshua

Last Name	First Name	Middle Name
N/A		

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Sean Court, Lakewood, N.

Present Residence Address-Street or RFD	City	State/Zip
Germantown Pike, Suit	Dates 8/16/17 to present	Plymouth Meeting PA 19462

Present Business Address	City	State/Zip
President	Dates 8/16/17 to present	

Occupation	Phone Residence	Business
		775-329-0799

Date of Birth	Place of Birth (City, County, State)	Sex
41	New York, Kings County, New York	Male

Age	Social Security Number	Sex
Green	Brown	Caucasian

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
			180	Healthy	6'3"

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Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

Page 1

MARITAL INFORMATION-Continued

A. Current Marriage _____

Spouse's full name (Maiden) _____ Date _____ City, County and State _____
 _____ Shaidy Carlbach Parnes _____ S.S. N _____

Date of Birth _____ Place of Birth _____

Resident address _____ Sean Court, Lakewood, N _____
 _____ Street _____ City _____ State _____ Zip _____

Telephone: Residence _____ Business _____

Spouse's employer _____ Chemed Health _____ Occupation _____ APN _____

Address of employer _____ 1771 Madison Ave, Lakewood NJ 08701 _____
 _____ Street _____ City _____ State _____ Zip _____

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					

3. FAMILY INFORMATION:**A. Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Abraham Parn	Jerusalem, Israel,	Sean Court, Lakewood NJ 08701	
Ahuba Parn	Lakewood NJ	Sean Court Lakewood, NJ 08701	
Eli Parnes	Lakewood NJ,	Sean Court, Lakewood NJ 08701	
Jack Parnes	Lakewood NJ, 1	Sean Court, Lakewood NJ 08701	
Shashona Parnes	Lakewood NJ,	Sean Court, Lakewood NJ 08701	
Miriam Parnes	Lakewood NJ	Sean Court Lakewood NJ 08701	

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

4P

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father			
David Parnes		11th Street, Brooklyn, NY	- Professor
Mother			
Janet Parnes		11th Street Brooklyn NY	- Lab Manager
Father-in-Law			
Jonah Carlebach		Liberty Drive, Lakewood NJ	-Sales
Mother-in-Law			
Rachel Carelbach		Liberty Drive, Lakewood, N.	Teacher

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Aaron Parnes		Brooklyn, NY	self-employed
Spouse			
Nechama Weiss	unknown		N/A
Eli Parnes		Baltimore MD	Teacher
Spouse			
Bracha Leah Cohen	unknown		Teacher
Shiffrah Garfunkle (Parnes)		Lakewood NJ	Speech Therapist
Spouse			
Yitzchock Garfunkle	unknown		Student
Avigauil Fischler		Baltimore, MD	Physical Therapist
Spouse			
Shmuel Fischler	unknown		Social Worker

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Mirrers Yeshiva Elementary	1791 Ocean Parkway Brooklyn NY 11223	1982-1991	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	Mirrers Yeshiva High School	1791 Ocean Parkway Brooklyn NY 11223	1991-1995	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College	Touro College	6th Avenue and West 23rd St, New York, NY 10010	1998-2000	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
University	Talmudic Law School -BMG	Lakewood NJ 08701	1999-2003	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Other				Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any _____

College or university where obtained _____

Applicant's initial

5 MILITARY INFORMATION:

- A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch Date of entry-active service

Date of separation Type of discharge

Rating at separation Serial number

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

- B. Have you registered for the draft? Yes ☐ No ☒

County State Date registered

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

- A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

- B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.
- C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒
- D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒
- E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒
- F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? city, county and state
- G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? city, county and state
- H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☐ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
2003-2006	51 Lopsley Lane, Lakewood NJ		
2006-Present	Sean Court, Lakewood NJ		

Applicant's initial

up

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year 11/2004	Name/Mailing Address of Employer/Business Caring Distribution 5722 18th Ave Brooklyn New York	Reason for Leaving Better Opportunity
Title Sales Manager	Description of Duties Manage sales activities	Name of Supervisor John Carlebach
Month and Year 1/2005 - Present	Name/Mailing Address of Employer/Business Ocean Home Health Supply LLC 1000 Airport Rd Lakewood NJ 08901	Reason for Leaving
Title VP Operations/MFMT	Description of Duties Operations for Durable Medical Equipment Company	Name of Supervisor Luke McGee
Month and Year April 2017-Present	Name/Mailing Address of Employer/Business AdaptHealth LLC (previously QMES LLC) 220 W Germantown Pike Suite 250 Plymouth Meeting PA 19462	Reason for Leaving
Title President	Description of Duties Providing vision, strategic leadership for company	Name of Supervisor Luke McGee
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Eli Friedman	Home	Chelsea Ct, Lakewood NJ			732	10
Employer Plains Capital LLC	Business	428 Clifton Ave #100 Lakewood NJ 08701			732-886-6202	
Name Danny Kagan	Home	Sean Court, Lakewood NJ				5
Employer	Business					
Name Shmuel Peper	Home	Newbury Ct Lakewood NJ 08701				5
Employer	Business					
Name Moshe Shapira	Home	Spruce St Lakewood NJ 08701				10
Employer	Business					
Name Luke McGee	Home	1 Spruce Street, Philadelphia, PA 19102				
Employer Quadrant Capital Management	Business	Passaic Avenue Suite 301 Fairfield, NJ 07004				

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☒ No ☐
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
Safe Deposit Box, Lakewood New Jersey - TD Bank			Michael Parnes

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☒

If yes, state type, where and years held

12. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Ocean Home Health Supply LLC New Jersey - 1000 Airport Rd, Suite 101 Lakewood NJ 08701

Medical Equipment Business, NJ Division of Taxation, see attached list

Applicant's initial



13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer) Yes ☐ No ☒

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒



Date of photograph 1-13-20

Applicant's initial up

STATE OF

New Jersey

SS.

COUNTY OF

OceanI, Yehoshua Parnes

, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Y Parnes

Original Signature of Applicant

Subscribed and Sworn to before me this

13

day of

July 2020Nh

Notary Public

(seal)



Applicant's Initial

Y P

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CERTIFICATE OF LIABILITY INSURANCE

5/17/2021

DATE (MM/DD/YYYY)

6/30/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies 1185 Avenue of the Americas, Suite 2010 New York NY 10036 646-572-7300	CONTACT NAME: _____ PHONE (A/C, No, Ext): _____ FAX (A/C, No): _____ E-MAIL ADDRESS: _____ <table style="width: 100%;"> <tr> <th style="text-align: left;">INSURER(S) AFFORDING COVERAGE</th> <th style="text-align: left;">NAIC #</th> </tr> <tr> <td>INSURER A: Benchmark Insurance Company</td> <td>41394</td> </tr> <tr> <td>INSURER B: Hartford Fire Insurance Company</td> <td>19682</td> </tr> <tr> <td>INSURER C: _____</td> <td>_____</td> </tr> <tr> <td>INSURER D: _____</td> <td>_____</td> </tr> <tr> <td>INSURER E: _____</td> <td>_____</td> </tr> <tr> <td>INSURER F: _____</td> <td>_____</td> </tr> </table>	INSURER(S) AFFORDING COVERAGE	NAIC #	INSURER A: Benchmark Insurance Company	41394	INSURER B: Hartford Fire Insurance Company	19682	INSURER C: _____	_____	INSURER D: _____	_____	INSURER E: _____	_____	INSURER F: _____	_____
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INSURER C: _____	_____														
INSURER D: _____	_____														
INSURER E: _____	_____														
INSURER F: _____	_____														
INSURED 1422153 ActivStyle, Inc. 3500 Lakeside Ct, Ste 200 Reno NV 8959-4829															

COVERAGES **CERTIFICATE NUMBER:** 16832304 **REVISION NUMBER:** XXXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL SUBR INSD WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PROJECT <input type="checkbox"/> LOC OTHER: _____	N N	D1019 G6279-1	5/17/2020	5/17/2021	EACH OCCURRENCE \$1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$1,000,000 MED EXP (Any one person) \$10,000 PERSONAL & ADV INJURY \$1,000,000 GENERAL AGGREGATE \$3,000,000 PRODUCTS - COMP/OP AGG \$1,000,000 \$ _____
	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> HIRED AUTOS ONLY <input type="checkbox"/> NON-OWNED AUTOS ONLY <input type="checkbox"/> AUTOS ONLY		NOT APPLICABLE			COMBINED SINGLE LIMIT (Ea accident) \$XXXXXXX BODILY INJURY (Per person) \$XXXXXXX BODILY INJURY (Per accident) \$XXXXXXX PROPERTY DAMAGE (Per accident) \$XXXXXXX \$XXXXXXX
A	<input checked="" type="checkbox"/> UMBRELLA LIAB <input checked="" type="checkbox"/> OCCUR <input type="checkbox"/> EXCESS LIAB <input type="checkbox"/> CLAIMS MADE <input type="checkbox"/> DED <input type="checkbox"/> RETENTIONS	N N	UM1019 6280-1	5/17/2020	5/17/2021	EACH OCCURRENCE \$10,000,000 AGGREGATE \$10,000,000 \$XXXXXXX
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N N/A	NOT APPLICABLE			PER STATUTE OTH-ER E.L. EACH ACCIDENT \$XXXXXXX E.L. DISEASE - EA EMPLOYEE \$XXXXXXX E.L. DISEASE - POLICY LIMIT \$XXXXXXX
A	Prof Liab	N N	D1019 G6279-1	5/17/2020	5/17/2021	\$1MM per occ \$3MM agg
B	Blanket BPP		39 UUN DF2446	5/17/2020	5/17/2021	Limit \$58,939,860

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

16832304
 National Supplier Clearinghouse
 AG-495 Palmetto GBA
 P.O. Box 100142
 Columbia SC 29202-3142

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Michael A. Calabrese

AdaptHealth LLC Entities						
Legal Name	President	Address				
AdaptHealth LLC	Yehoshua Parnes	220 W Germantown Pike Suite 250	Plymouth Meeting	PA	19462	
ActivStyle, Inc	Yehoshua Parnes	1701 Broadway Street NE	Minneapolis	MN	55413	
AdaptHealth - Missouri LLC	Yehoshua Parnes	5436 Bleaux Ave, Ste A	Springdale	AR	72762-0750	
AdaptHealth Patient Care Solutions Inc.	Yehoshua Parnes	600 Lindbergh Drive	Moon Township	PA	15108-2777	
Advocate Medical Services, Inc. dba ActivStyle	Yehoshua Parnes	5912 Breckenridge Parkway Suite G	Tampa	FL	33610	
Aircare Home Respiratory LLC	Yehoshua Parnes	13311 Garden Grove Blvd, Ste D	Garden Grove	CA	92843-2202	
All American Home Aid, Inc. dba ActivStyle	Yehoshua Parnes	169 W Springfield St Unit B	Boston	MA	02118-1403	
American Ancillaries Inc	Yehoshua Parnes	4135 N Rancho Drive, Suite 110	Las Vegas	NV	89130-3494	
Americoast Maryland LLC	Yehoshua Parnes	9321 Philadelphia Road, Suite K-L	Rosedale	MD	21237-4100	
Associated Healthcare Systems, Inc.	Yehoshua Parnes	34 Riley Ave, Suite 3	Plattsburgh	NY	12901-1644	
Bennett Medical Services	Yehoshua Parnes	2600 Mill Street, Suite 600	Reno	NV	89502-0105	
Braden Partners, L.P.	Yehoshua Parnes	4882 McGrath St, Ste 220	Ventura	CA	93003-7721	
Champlain Valley Brace & Limb LLC dba ActivStyle	Yehoshua Parnes	762 State Rte 3 Ste 15	Plattsburgh	NY	12901-7472	
Choice Medical Healthcare LLC	Yehoshua Parnes	56 E Broadway, Ste 600	Salt Lake City	UT	84111-2211	
Clearview Medical Incorporated	Yehoshua Parnes	2503 Gravel Drive	Fort Worth	TX	76118-6904	
First Choice Home Medical Equipment, LLC	Yehoshua Parnes	259 Quigley Blvd, Suite 1	New Castle	DE	19720-4186	
Florida Home Medical Supply Inc dba Colonial Medical Supplies	Yehoshua Parnes	614 E ALTAMONTE DR	ALTAMONTE SPRINGS	FL	32701-4803	
Gould's Discount Medical LLC	Yehoshua Parnes	3901 Dutchman's Lane, Suite 100	Louisville	KY	40207-4726	
Halprin, Inc.	Yehoshua Parnes	2375 State Rd 332, Suite 1000	Canandaigua	NY	14424-7509	
Healthline Medical Equipment, LLC	Yehoshua Parnes	4709 Lydia Dr	Wichita Falls	TX	76308-4537	
Home Medical Express Inc.	Yehoshua Parnes	621 IL Route 83, Ste 101	Bensenville	IL	60106-1325	
Home MediService LLC	Yehoshua Parnes	540 S Union Ave	Havre de Grace	MD	21078-3410	

Home Wellness, Inc. dba ActivStyle Hometown Home Health LLC	Yehoshua Parnes	700 Route 130 N Suite 208 65 Salem Church Road	Cinnaminson Jasper	NJ GA	08077-3366 30143-5804
MARY Medical Inc. dba ActivStyle Med Way Medical, Inc	Yehoshua Parnes	4656 E Dakota Avenue Ste 104 1837 South 4130 West, Units A&B	Fresno Salt Lake City	CA UT	93726-4727 84104-4826
Med-Equip, Inc	Yehoshua Parnes	701B Ashland Avenue, Ashland Center Two, Bay 6	Folcroft	PA	19032-2026
Medstar Surgical & Breathing Equipment, Inc.	Yehoshua Parnes	99 Powerhouse Rd, Suite 205	Roslyn Heights	NY	11577-2039
Ocean Home Health of PA Inc	Yehoshua Parnes	122 Mill Road, Suite A160	Phoenixville	PA	19460-1412
Ocean Home Health Supply LLC	Yehoshua Parnes	1000 Airport Road, Suite 101	Lakewood	NJ	08701-5960
Ogles Oxygen LLC	Yehoshua Parnes	1890 W Oak Pkwy, Ste A	Marietta	GA	30062-2278
Olean General Health Care Systems, LLC	Yehoshua Parnes	234 Homer Street	Olean	NY	14760-1132
Palmetto Oxygen LLC	Yehoshua Parnes	104 Corporate Blvd, Ste 402	West Columbia	SC	29169-4600
Roberts Home Medical LLC	Yehoshua Parnes	20465 Seneca Meadows Parkway	German town	MD	20876-7005
Royal HomeStar, LLC	Yehoshua Parnes	2710 Emrick Boulevard	Bethlehem	PA	18020-8012
Royal Medical Supply, Inc.	Yehoshua Parnes	1951 Old Cuthbert Road, Suite 413	Cherry Hill	NJ	08034-1411
Sleep Therapy LLC	Yehoshua Parnes	2157 Troop Drive, Suite 100	Sartell	MN	56377-4563
Sleepeasy Therapeutics, Inc.	Yehoshua Parnes	3003 32nd Ave S, Ste 7C	Fargo	ND	58103-6163
Sound Oxygen Service Inc	Yehoshua Parnes	8322 S 259th Street	Kent	WA	98030-7428
Total Respiratory LLC	Yehoshua Parnes	4211 Medical Parkway, Ste B	Austin	TX	78756-3309
TriCounty Medical Equipment and Supply, LLC	Yehoshua Parnes	122 Mill Road Suite A130	Phoenixville	PA	19460-1412
Verus Healthcare LLC	Yehoshua Parnes	1569 Mallory Lane, Building 100	Brentwood	TN	37027-2872

CERTIFICATE *of* ACCREDITATION

ACCREDITATION COMMISSION FOR HEALTH CARE CERTIFIES THAT:

ActivStyle, Inc.
RENO, NEVADA

HAS DEMONSTRATED A COMMITMENT TO PROVIDING QUALITY CARE AND SERVICES TO CONSUMERS
THROUGH COMPLIANCE WITH ACHC'S NATIONALLY RECOGNIZED STANDARDS FOR
ACCREDITATION AND IS THEREFORE GRANTED ACCREDITATION FOR THE FOLLOWING:

DMEPOS

Medical Supply Provider Services

FROM *July 1, 2020* THROUGH *February 6, 2023*



PRESIDENT & CHIEF EXECUTIVE OFFICER



CHAIRMAN OF THE BOARD OF COMMISSIONERS





July 10, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

RE: Change of Ownership
ActivStyle Inc.
NV Medical Device, Equipment & Gases Permit No. MP01163

To Whom It May Concern,

Please find enclosed NV Medical Device, Equipment & Gases application for a change of ownership for ActivStyle Inc. License Number MP01163.

There is no change to the entity name, ActivStyle Inc., tax identification number, or day to day operations. ActivStyle Inc. will continue to operate from its current location with current MDEG Administrator, Justin Garcia.

We are working to have the Personal History Record completed and submitted, however, due to the notification requirement by the NV BOP for a change of ownership we are submitting the application, payment and additional supporting documents now to meet the notification requirement.

I may be reached at 410-409-8741 or via e-mail at dsiegel@adapthealth.com with any questions or if additional information is needed.

Sincerely,



Diane Siegel
Licensing Manager

Enclosures



July 16, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

RE: Change of Ownership
ActivStyle Inc.
NV Medical Device, Equipment & Gases Permit No. MP01163

To Whom It May Concern,

The NV Medical Device, Equipment & Gases application for a change of ownership for ActivStyle Inc. License Number MP01163 was overnighted on 7/13/20 and confirmed delivered on 7/14/20.

Please find enclosed additional document, Personal History Record, for Yehoshua Parnes, President, ActivStyle Inc. for processing with the application.

I may be reached at 410-409-8741 or via e-mail at dsiegel@adapthealth.com with any questions or if additional information is needed.

Sincerely,

A handwritten signature in blue ink, appearing to read "Diane Siegel", written over a circular blue ink stamp.

Diane Siegel
Licensing Manager

Enclosures

12B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR NEVADA Medical Device, Equipment & Gases (MDEG)

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
(non-refundable and not transferable money order or cashier's check only)
 Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input type="checkbox"/> New MDEG	<input checked="" type="checkbox"/> Ownership Change	<input type="checkbox"/> Name Change	<input type="checkbox"/> Location Change
(Please provide current license number if making changes: MP or MW <u>MP000147</u>)			

<input checked="" type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership – Pages 1,2,3,6
<input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5a,5b	<input type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

GENERAL INFORMATION to be completed by all types of ownership

MDEG Name: DENHAM ORTHOTICS & FITNESS / DBA EVOLVE PROSTHETICS & ORTHOTICS

Physical Address: 601 WHITNEY RANCH C-17 HENDERSON, NV 89014
(This must be a business address we can not issue a license to a home address)

Mailing Address: S/A

City: HENDERSON State: NV Zip Code: 89014

Telephone: 702 898 6000 Fax: 702 898-6080

E-mail: prosyes@gmail.com Website: evolveprosthetics.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5

Fri: 8 to 5 Sat: 8 to 5 Sun: to Holidays: to

MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: DAVID KOVACH

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|--|
| <input type="checkbox"/> Medical Gases**
<input type="checkbox"/> Respiratory Equipment**
<input type="checkbox"/> Life-sustaining equipment**
<input type="checkbox"/> Diabetic Supplies | <input type="checkbox"/> Assistive Equipment
<input type="checkbox"/> Parenteral and Enteral Equipment**
<input checked="" type="checkbox"/> Orthotics and Prosthetics
Other: <u> </u> |
|--|--|

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name: Telephone:

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

MEDICAID 1891751723 _____

MEDICARE 4385780001 _____

- 1) Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒
- 2) Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒
- 3) Are any of the owners health professionals? If yes, please check the box and list name.

<input checked="" type="checkbox"/> Practitioner <input type="checkbox"/> Advanced Practitioner of Nursing <input type="checkbox"/> Physician's Assistant <input type="checkbox"/> Physical Therapist <input type="checkbox"/> Occupational Therapist <input type="checkbox"/> Registered Nurse <input type="checkbox"/> Respiratory Therapist	Name: <u>DAVID KOVACH CP RDCO</u> Name: _____ Name: _____ Name: _____ Name: _____ Name: _____ Name: _____
--	---

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

- 1) Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

DAVID KOVACH
Print Name of Authorized Person

6/29/20
Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR NEVADA MDEG LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATIONState of Incorporation: NVParent Company if any: DENHAM ORTHOTICS & FITNESSCorporation Name: EVOLVE PROSTHETICS & ORTHOTICSMailing Address: 601 Whitney Ranch C-17City: Henderson State: NV Zip: Telephone: Fax: Contact Person: DAVID KOVACH702 898-6000 Fax: 702 898-6080

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) DAVID KOVACH ROTHBURY AVE W, NV 89141
Name Addressb) _____
Name Addressc) _____
Name Addressd) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

2) Provide the number of shares issued by the corporation. 100 % / 25003) What was the price paid per share? Undetermined4) What date did the corporation actually receive the cash assets? Dec 10th 1999

5) Provide a copy of the corporation's stock register evidencing the above information

APPLICATION FOR NEVADA MDEG LICENSE**NON PUBLICLY TRADED CORPORATION****Include with the application for a non-publicly traded corporation**

Complete personal history record for each stockholder. Must be original signature(s), no copies or stamps. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

DAVID KOVACH - PRES.

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 6/29/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for MDEG LICENSE

Nature of License

DEHAM ORTHOTICS & PROSTHETICS / REVOLV PROSTHETICS & ORTHOTICS

Name and Address of Establishment for Which License is Requested

REVOLV PROSTHETICS AND ORTHOTICS

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

KOVACH
Last Name

DAVID
First Name

ANTHONY
Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

2048 BETHUR AVE W, NV 89141
Present Residence Address-Street or RFD

City

State/Zip

601 Whiting Ranch Dr C-17
Present Business Address

Dates 2012-present

Hudson, NV 89014

City

State/Zip

Owner / Prosthetist
Occupation

Dates 2004-present

Phone
Resident

Business

702 888-6000

Date of Birth

Caldwell, MI
Place of Birth (City, County, State)

Age

Social Security Number or ITIN

Sex

Blue
Color of Eyes

Brown
Color of Hair

TAN
Complexion

230
Weight

STUD LIKE
Build

5'11"
Height

Scars, tattoos or distinguishing marks and/or characteristics

Are you a citizen of the United States? ☒ Yes ☐ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

DK

MARITAL INFORMATION-Continued

A. **Current Marriage** Aug 29th 1997 LV, NV CLARK
Date City, County and State
 Spouse's full name (Maiden) Kim PERFINSKI SS# or
 Date of Birth _____ Place of Birth LV, NV
 Resident address 5863 ZOTHBURY AVE LV, NV 89141
Street City State Zip
 Telephone: Residence _____ Business 702 898-6000
 Spouse's employer LAS CORP Occupation PITREBOIDMIST
 Address of employer FLO AT LV NV 8
Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
ANTHONY KOVACH	' '	LV, NV	Austin, TX
ETAN KOVACH	' '	LV, NV	LV, NV
ANDREW KOVACH	' '	LV, NV	LV, NV

B. Child Support Information:

Please mark the appropriate response:

☐ I am not subject to a court order for the support of child.

☒ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial DK

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Father

Deceased

Mother

JACKIE KOVACH

E. MONROE LV, NV 8910 R/A

Father-in-Law

Deceased

Mother-in-Law

PAT MOSS

Hurricane, Ut.

N/A

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

CHRIS KOVACH

1-1-81

LV, NV

Librarian

Spouse

Spouse

Spouse

Spouse

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	MT VIEW ELEM	LV, NV	83-85	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	ELDERADO H.S.	LV, NV	89-93	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	UNLV	LV, NV	93-98	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other				Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any B.S. ATCCollege or university where obtained UNLV

Applicant's initial

DK

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces?

Yes ☐No ☒

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☒No ☐

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition Date	Arresting Agency
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				

Applicant's initial _____ Page 4

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☒ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
	Rothbury Ave W, NV 89141	CLARK	2010-present
	Congare St W, NV 89141	CLARK	2002-present
	9820 Virginia Ave	Las Vegas, NV	2000-02

Applicant's initial _____ Page 5

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

4-2004	DENNAM ORTHOTICS & FITTERS	STILL HERE
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Prosthetist	Custom Fab & delivery of O&P	SELF/DENNAM
Title	Description of Duties	Name of Supervisor
02-04	Micklyn Ortho Services	AZIZ KASSER/WAVE
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Prosthetist/Resident	FAB & delivery of O&P	
Title	Description of Duties	Name of Supervisor
91-00	STAR / NOVARE	SCHOOL
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
P.T. TECH/ATC	Laundry/Maintenance	DENNAM/DAVE
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial _____ Page 6

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>DAN HAUSTEIN</u>	Home		<u>NV</u>			<u>10</u>
Employer	Business					
Name <u>JESSE BERG</u>	Home		<u>NV</u>			<u>25</u>
Employer	Business					
Name <u>GEOFF ZOGANSON</u>	Home		<u>NV</u>			<u>5</u>
Employer	Business					
Name <u>RICH FRANKS</u>	Home		<u>NV</u>			<u>20</u>
Employer	Business					
Name <u>TROY BACHILL</u>	Home		<u>NV</u>			<u>15</u>
Employer	Business					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☒ No ☐
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐
If yes, state type, where and years held

12. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Applicant's initial _____ Page 7

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer) Yes ☐ No ☒

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒



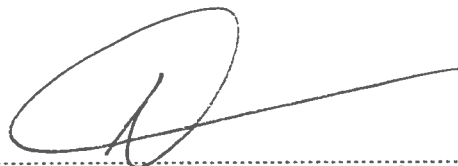
Date of photograph _____

Applicant's initial DK

STATE OF NV SS.COUNTY OF CLARK

I, DAVID KERRACH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

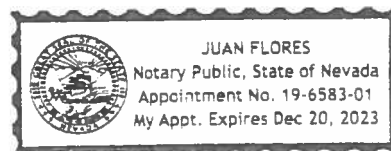
I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.



Original Signature of Applicant

Subscribed and Sworn to before me this 30th day ofJune, 2020


Notary Public



(seal)

Applicant's initial _____ Page 9

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date

6/29/20

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for ORTHOTICS & PROSTHETICS

Nature of MDEG

DENTHAM ORTHOTICS & FITNESS DBA EVOLVE PROSTHETICS & ORTHOTICS

Name and Address of Business for Which MDEG Administrator Is Requested

EVOLVE PROSTHETICS & ORTHOTICS

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

KOVACH DAVID A
 Last Name First Name Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

ROTHBURG AVE 10, NV 89441
 Present Residence Address-Street or RFD City State/Zip

617 2012 →
601 Century Ranch present Henderson, NV 89014
 Present Business Address City State/Zip

602 Century Ranch Owner 2014 → present
 Present Position with the MDEG

Phone: 702 898 6000 Fax: 702 898 6080

Email address: prosynes@gmail.com

44 Calumet, MI
 Date of Birth Place of Birth (City, County, State)

44 3 --- --- --- M
 Age Social Security Number or ITIN Sex

Blue Brown 230 6'5" 11"
 Color of Eyes Color of Hair Weight Height

Scars, tattoos or distinguishing marks and/or characteristics

Are you a citizen of the United States? ☒ Yes ☐ No

If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

<u>April 04 - Present</u>	<u>Denham Orthotics</u>	<u>32,240</u>
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
<u>Prosthetist</u>	<u>SEEING Patients, Evaluating O&P needs</u>	<u>SELF/ DAVE DENHAM</u>
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

Title	Description of Duties	Name of Supervisor
-------	-----------------------	--------------------

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

Title	Description of Duties	Name of Supervisor
-------	-----------------------	--------------------

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

Title	Description of Duties	Name of Supervisor
-------	-----------------------	--------------------

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

Title	Description of Duties	Name of Supervisor
-------	-----------------------	--------------------

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

Title	Description of Duties	Name of Supervisor
-------	-----------------------	--------------------

I have ☐ I have ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ☐ I have ☒ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ☐ I have ☒ been the subject of an administrative action whether completed or pending.
3. I have ☐ I have ☒ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

- a) Board Administrative Action:
b)

State: _____

Date: _____

Case Number: _____

- c) Criminal Action:

State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG?

☒ Yes ☐ No

5 .Will you be employed fulltime with the MDEG?

☒ Yes ☐ No

6 .Will you be present at the site of the MDEG during its normal operating hours?

☒ Yes ☐ No

If you answer No to questions 4, 5 or 6 please provide a written letter of explanation.

.....
.....
.....
.....
.....

ATTACH PHOTOGRAPH

TAKEN WITHIN LAST

30 DAYS HERE

Date of photograph _____

3. I have ☐ I have not ☒ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information and provide a written explanation and/or documents.

a) Board Administrative Action:

State: _____

b)

Date: _____

Case Number: _____

c) Criminal Action:

State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4. Will you be actively involved in and aware of the daily operation of the MDEG?

Yes ☒ No ☐

5. Will you be employed fulltime with the MDEG?

Yes ☒ No ☐

6. Will you be present at the site of the MDEG during its normal operating hours?

Yes ☒ No ☐

If you answer No to questions 4, 5 or 6 please provide

.....

.....

.....

.....

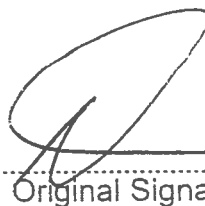
.....



Date of photograph _____

I, David Kovach, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.



Original Signature of Applicant

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE
WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **DENHAM ORTHOTICS AND FITNESS**, as a DOMESTIC CORPORATION (78) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 12 10 1999, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06 29 2020.

A handwritten signature in cursive script that reads "Barbara K. Cegavske".

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200629891259

You may verify this certificate
online at <http://www.nvsos.gov>

12C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA Medical Device, Equipment & Gases (MDEG)

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: MP or MW N/A)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☒ Non Publicly Traded Corporation – Pages 1,2,3,5a,5b ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION to be completed by all types of ownership

MDEG Name: First Care Medical Supply LLC
Physical Address: 3655 S Durango dr unit 10 Las Vegas NV 89147
(This must be a business address, we can not issue a license to a home address)
Mailing Address: 3655 S. Durango dr unit 10
City: Las Vegas State: NV Zip Code: 89147
Telephone: (702) 684 2415 Fax: _____
E-mail: Supply@Firstcaremedical.org Website: _____

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9:00 AM to 5:00 PM Tue: 9:00 AM to 5:00 PM Wed: 9:00 AM to 5:00 PM Thu: 9:00 AM to 5:00 PM
Fri: 9:00 AM to 5:00 PM Sat: closed Sun: closed Holidays: closed

MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: Knarik Avagyan

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases** ☐ Assistive Equipment
☐ Respiratory Equipment** ☐ Parenteral and Enteral Equipment**
☐ Life-sustaining equipment** ☒ Orthotics and Prosthesis
☒ Diabetic Supplies Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name: Knarik Avagyan Telephone: (702) 684 2415

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

<u>Medicaid</u>	_____	_____
<u>Medicare</u>	_____	_____
_____	_____	_____

- 1) Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

- 2) Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒

- 3) Are any of the owners health professionals? If yes, please check the box and list name.

<input type="checkbox"/> Practitioner	Name: <u>N/A</u>
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: _____
<input type="checkbox"/> Physician's Assistant	Name: _____
<input type="checkbox"/> Physical Therapist	Name: _____
<input type="checkbox"/> Occupational Therapist	Name: _____
<input type="checkbox"/> Registered Nurse	Name: _____
<input type="checkbox"/> Respiratory Therapist	Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

N/A

APPLICATION FOR NEVADA MDEG LICENSE**OWNERSHIP IS A PUBLICLY TRADED CORPORATION**State of Incorporation: N/A

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

License Contact Person: _____

Ownership Information – Complete Section 1 or 2**Do not use N/A in this section – Section 1 or 2 must be completed.**Section 1: List the corporations four largest shareholders:
(Name and percentage of ownership)

1. _____	%: _____
2. _____	%: _____
3. _____	%: _____
4. _____	%: _____

Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

Include with the application for a publicly traded corporationList of officers and directors.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

APPLICATION FOR NEVADA MDEG LICENSE

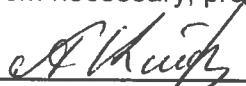
This page must be submitted for all types of ownership.

- 1) Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Knarik Aragyan
Print Name of Authorized Person

5-17-2020
Date

Board Use Only

Received: _____

Amount: _____

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: N/A

Corporation Name: First Care Medical Supply LLC

Mailing Address: 3655 S Durango dr unit 10⁵

City: Las Vegas State: NV Zip: 89101 Telephone: (702) 684-2415

Fax: _____ Contact Person: Knarik Avagyan

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) Knarik Aragyan Rain Lily Ct Las Vegas NV 89111
Name Address

b) _____
Name Address

[illegible]

d) _____

Name	Address
------	---------

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the “New Applications” tab. The forms are available under the *documents for all types of businesses*.

- 2) Provide the number of shares issued by the corporation. _____
- 3) What was the price paid per share? _____
- 4) What date did the corporation actually receive the cash assets? _____
- 5) Provide a copy of the corporation's stock register evidencing the above information

APPLICATION FOR NEVADA MDEG LICENSE

NON PUBLICLY TRADED CORPORATION

Include with the application for a non-publicly traded corporation

Complete personal history record for each stockholder. Must be original signature(s), no copies or stamps. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Knarik Aragyan

SECRETARY OF STATE

**CERTIFICATE OF EXISTENCE
WITH STATUS IN GOOD STANDING**

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **First Care Medical Supply LLC**, as a **DOMESTIC LIMITED-LIABILITY COMPANY (86)** duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 12/17/2019, and is in good standing in this state.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/17/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200417733620

You may verify this certificate
online at <http://www.nvsos.gov>

(PROFIT) INITIAL/ANNUAL LIST OF OFFICERS, DIRECTORS AND STATE BUSINESS
LICENSE APPLICATION OF:

1648

ENTITY NUMBER

FIRST CARE MEDICAL SUPPLY LLC

E3592762019-7

NAME OF CORPORATION

FOR THE FILING PERIOD OF DEC, 2019 TO DEC, 2020



100103

USE BLACK INK ONLY - DO NOT HIGHLIGHT

** YOU MAY FILE THIS FORM ONLINE AT www.nvsilverflume.gov **

☐ Return one file stamped copy. (If filing not accompanied by order instructions, file stamped copy will be sent to registered agent.)

IMPORTANT: Read instructions before completing and returning this form.

1. Print or type names and addresses, either residence or business, for all officers and directors. A President, Secretary, Treasurer, or equivalent of and all Directors must be named. There must be at least one director. An Officer must sign the form. **FORM WILL BE RETURNED IF UNSIGNED.**

2. If there are additional officers, attach a list of them to this form.

3. Return the completed form with the filing fee. Annual list fee is based upon the current total authorized stock as explained in the Annual List Fee Schedule For Profit Corporations. A \$75.00 penalty must be added for failure to file this form by the deadline. An annual list received more than 90 days before its due date shall be deemed an amended list for the previous year.

ABOVE SPACE IS FOR OFFICE USE ONLY

4. State business license fee is \$500.00/\$200.00 for Professional Corporations filed pursuant to NRS Chapter 89. Effective 2/1/2010, \$100.00 must be added for failure to file form by deadline.

5. Make your check payable to the Secretary of State.

6. **Ordering Copies:** If requested above, one file stamped copy will be returned at no additional charge. To receive a certified copy, enclose an additional \$30.00 per certification. A copy fee of \$2.00 per page is required for each additional copy generated when ordering 2 or more file stamped or certified copies. Appropriate instructions must accompany your order.

7. Return the completed form to: Secretary of State, 202 North Carson Street, Carson City, Nevada 89701-4201, (775) 684-5708

8. Form must be in the possession of the Secretary of State on or before the last day of the month in which it is due. (Postmark date is not accepted as receipt date.) Forms received after due date will be returned for additional fees and penalties. Failure to include annual list and business license fees will result in rejection of filing.

CHECK ONLY IF APPLICABLE AND ENTER EXEMPTION CODE IN BOX BELOW

☐ Pursuant to NRS Chapter 76, this entity is exempt from the business license fee. Exemption code:

NRS 76.020 Exemption Codes

NOTE: If claiming an exemption, a notarized Declaration of Eligibility form must be attached. Failure to attach the Declaration of Eligibility form will result in rejection, which could result in late fees.

001 - Governmental Entity

006 - NRS 680B.020 Insurance Co.

☐ This corporation is a publicly traded corporation. The Central Index Key number is:

☐ This publicly traded corporation is not required to have a Central Index Key number.

NAME KNARIK AVAGYAN	TITLE(S) PRESIDENT (OR EQUIVALENT OF)
ADDRESS RAIN LILY CT	CITY LAS VEGAS
	STATE NV
	ZIP CODE 89117
NAME KNARIK AVAGYAN	TITLE(S) SECRETARY (OR EQUIVALENT OF)
ADDRESS RAIN LILY CT	CITY LAS VEGAS
	STATE NV
	ZIP CODE 89117
NAME KNARIK AVAGYAN	TITLE(S) TREASURER (OR EQUIVALENT OF)
ADDRESS RAIN LILY CT	CITY LAS VEGAS
	STATE NV
	ZIP CODE 89117
NAME KNARIK AVAGYAN	TITLE(S) DIRECTOR
ADDRESS RAIN LILY CT	CITY LAS VEGAS
	STATE NV
	ZIP CODE 89117

None of the officers or directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X
Signature of Officer or
Other Authorized Signature

Title

MEMBER

Date

05/19/2020

Reset

Nevada Secretary of State List Profit
Form: 100103 Revised: 7-1-17

HEADQUARTERS:
PO Box 3867
Bellevue, WA 98009
P: 800.562.8095
F: 425.453.8696

WWW.GO GUS.COM



In CA, DBA: Griffin Insurance Services, CA License #0G66558

April 30, 2020

The McPherson Group
5515 Camino Al Norte Ste 106
North Las Vegas, NV 89031

Attn: Morris McPherson

Re: First Care Medical Supply LLC
Effective Date: 4/28/2020

We are pleased to confirm coverage for you with the following confirmation of binding. This confirmation is offered in accordance with your instructions and in reliance upon the statements made in your application. Please review carefully. Thank you for your business, the policy should follow within 30 days.

Best Regards,

Matthew Griffin
Commercial Underwriting Assistant
Griffin Underwriting Services
matthew@gogus.com

Reference #: 20235001B
Agent Fax #: (702) 649-4977

HEADQUARTERS:
PO Box 3867
Bellevue, WA 98009
P: 800.562.8095
F: 425.453.8696

WWW.GO GUS.COM

GRIFFIN UNDERWRITING SERVICES

In CA, DBA: Griffin Insurance Services, CA License #0G66558

Acct. Exec wdear

INVOICE

Invoice Number: 676004

Invoice Date: 04/30/20

Page 1

Bill To: ASI41293

The McPherson Group
5515 Camino Al Norte Ste 106
North Las Vegas, NV 89031

Insured: First Care Medical Supply LLC

Submission Number: 20235001

Policy Number: MP0046003012548

Effective Dates: 04/28/20 to 4/28/21

Insurance Company: Mesa Underwriters Specialty Insurance C

Agent Code: ASI41293

Type of Transaction	Line of Business	Company ID	Amount	Comm(\$)	Net Due
Premium - New Business	PACKAGE POLICY	RM0532	\$1,250.00	\$75.00	\$1,175.00
Policy Fee	PACKAGE POLICY	01	\$185.00	\$0.00	\$185.00
Surplus Lines Tax	PACKAGE POLICY	T0011	\$50.23	\$0.00	\$50.23
Stamping Office Fee	PACKAGE POLICY	T0021	\$5.74	\$0.00	\$5.74

TOTALS:	Amount Invoiced:	Comm %	Commission	Invoice Amount Due
	\$ 1,490.97	6.00	\$ 75.00	\$ 1,415.97

Note:

Invoice Payment Due On: 5/30/20

CONFIRMATION OF BINDING

THE TERMS AND CONDITIONS OF THIS CONFIRMATION OF INSURANCE MAY NOT COMPLY WITH THE SPECIFICATIONS SUBMITTED FOR CONSIDERATION. PLEASE READ THIS CONFIRMATION CAREFULLY AND COMPARE IT WITH ANY QUOTE AND SUBMISSION DOCUMENTS AND REVIEW THE POLICY FORMS FOR THE ACTUAL COVERAGES PROVIDED. THIS CONFIRMATION IS A TEMPORARY INSURANCE CONTRACT, SUBJECT TO THE TERMS, CONDITIONS AND LIMITATIONS OF THE POLICY(IES) OR CERTIFICATE(S) IN CURRENT USE BY THE INSURER.

In accordance with your instructions, and in reliance upon the statements made by the retail producer in the insured's application/submission, we have bound insurance at your request as follows:

Date Issued: Apr 30, 2020

Is this a Renewal? N

Submission #: 20235001B

Producer: ASI41293

The McPherson Group

5515 Camino Al Norte Ste 106

North Las Vegas, NV 89031

Insured:

First Care Medical Supply LLC

3655 S Durango Dr Ste 10

Las Vegas, NV 89147

Location of Risk: 3655 S Durango Dr Ste 10, Las Vegas, NV 89147

Insurer: Mesa Underwriters Specialty Insurance Co.

**Assigned Policy or
Certificate Number:** **MP0046003012548**

"This insurance contract is issued pursuant to the Nevada insurance laws by an insurer neither licensed by nor under the supervision of the Division of Insurance of the Department of Business and Industry of the State of Nevada. If the insurer is found insolvent, a claim under this contract is not covered by the Nevada Insurance Guaranty Association Act." Cochrane Griffin & Co Inc, License #609660

Effective Period: 4/28/2020 to 4/28/2021

Term: 365 days

12:01 A.M. STANDARD TIME AT THE LOCATION ADDRESS OF THE NAMED INSURED. THIS CONFIRMATION WILL BE TERMINATED AND SUPERSEDED UPON DELIVERY OF THE FORMAL POLICY(IES) ISSUED TO REPLACE IT.

Coverage: PACKAGE POLICY

Limits: \$2,000,000	General Aggregate
\$2,000,000	Products/Comp Ops Aggregate
\$1,000,000	Personal & Advertising Injury
\$1,000,000	Each Occurrence
\$100,000	Damage to Premises Rented to You (Any One Premises)
\$5,000	Medical Exp. (Any One Person)
N/A	Additional Insured perform CG2011 (x1)

Property Cause of Loss: Special Form Excluding Theft
\$40,000 Business Personal Property-90% Coinsurance, RC

Deductible: \$500 General Liability
\$1,000 Property

Exposures: \$52,000 Sales (15314) Medical, Hospital and Surgical Supply Stores
Each-1 (11111) Additional Insured perform CG2011

Terms/Conditions: (a) 25% minimum earned premium at inception.

(b) Endorsements / Notable Exclusions:

Common

IL 00 17 11 98 COMMON POLICY CONDITIONS
 ILN 001 09 03 FRAUD STATEMENT
 MUS 01 01 10001 0817 POLICY JACKET
 MUS 01 01 10002 1116 COMMON POLICY DECLARATION
 MUS 01 01 10003 1013 SCHEDULE OF FORMS & ENDORSEMENTS
 MUS 01 01 10007 1013 MINIMUM EARNED PREMIUM ENDORSEMENT
 MUS 01 01 10015 1013 NV NV SERVICE OF SUIT
 MUS 01 01 10043 1013 PRIVACY NOTICE
 MUS 01 01 TRIA 0115 TRIA COVERAGE ACCEPT-REJECT FORM

General Liability

CG 00 01 04 13 COMMERCIAL GENERAL LIABILITY COVG FORM
 CG 20 11 04 13 AI - MANAGERS OR LESSORS OF PREMISES

CG 21 16 04 13 EXCL. - DESIGNATED PROFESSIONAL SERVICES (Any and All Professional Exposures)

CG 21 32 05 09 EXCL - COMMUNICABLE DISEASE

CG 21 47 12 07 EMPLOYMENT-RELATED PRACTICES EXCLUSION

CG 21 55 09 99 EXCL. - TOTAL POLLUTION EXCLUSION WITH A HOSTILE FIRE EXCEPTION

CG 21 67 12 04 EXCL - FUNGI OR BACTERIA

CG 21 73 01 15 EXCL. OF CERTIFIED ACTS OF TERRORISM

CG 21 96 03 05 EXCL - SILICA OR SILICA-RELATED DUST

CG 24 26 04 13 AMENDMENT OF INSURED CONTRACT DEFINITION

IL 00 21 09 08 NUCLEAR ENERGY LIABILITY EXCL ENDT

MUS 01 01 20001 0417 GENERAL LIABILITY COVERAGE PART DECLARATIONS

MUS 01 01 20004 0916 LIABILITY DEDUCTIBLE

MUS 01 01 20023 1013 SPECIAL CONDITIONS - SUBCONTRACTORS

MUS 01 01 20058 0816 EXCL - LEAD CONTAMINATION

MUS 01 01 20063 0919 EXCL - PUNITIVE DAMAGES

MUS 01 01 20080 0816 EXCL - EARTH MOVEMENT

MUS 01 01 20082 0816 EXCL - ASBESTOS

MUS 01 01 20084 0816 NON-STACKING OF LIMITS ENDORSEMENT

MUS 01 01 20094 0718 AMENDMENT OF CONDITIONS - PREMIUM AUDIT

MUS 01 01 20112 1013 EXCL - OCCUPATIONAL DISEASE

MUS 01 01 20139 0617 EXCL - INFRINGEMENT OF INTELLECTUAL PROPERTY

Property

CP 00 10 10 12 BUILDING & PERSONAL PROPERTY COVG FORM

CP 00 90 07 88 COMMERCIAL PROPERTY CONDITIONS

CP 01 40 07 06 EXCLUSION OF LOSS DUE TO VIRUS OR BACTERIA

CP 10 30 10 12 CAUSES OF LOSS - SPECIAL FORM

CP 10 33 10 12 EXCL - THEFT

IL 01 10 09 07 NV CHANGES - CONCEALMENT, MISREPRESENT OR FRAUD

IL 09 53 01 15 EXCL - CERTIFIED ACTS OF TERRORISM

MUS 01 01 30001 0417 PROPERTY COVERAGE PART DECLARATIONS

MUS 01 01 30016 1013 EXCL - ABSOLUTE ASBESTOS

MUS 01 01 30021 1013 LEAD EXCLUSION

MUS 01 01 30022 1013 POLLUTION EXCLUSION

MUS 01 01 30023 1013 SINKHOLE EXCLUSION

MUS 01 01 30024 1013 ACTUAL CASH VALUE

(c) Binding Requirements / Subject To:

25% MINIMUM EARNED PREMIUM APPLIES IN THE EVENT OF CANCELLATION

SEE CHECKLIST FOR BINDING

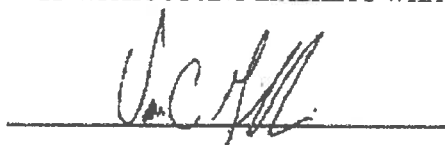
(d) All other terms and conditions apply per policy forms.

Premium:	\$1,250.00	- Minimum Premium & Deposit Only -
Fees: Policy Fee	\$185.00	
Taxes:	\$55.97	Total Due: \$1,490.97

TRIA: Terrorism Coverage: plus in taxes: **REJECTED**

Cancellation: This Confirmation is subject to the cancellation provisions as found in the policy(ies) or certificate(s) currently in use by the insurer. The Insurance effected under this confirmation can be cancelled by the insurer by mailing, to the first named insured at the address stated on the confirmation, written notice stating when such cancellation shall become effective. The Insurance effected under this confirmation may be cancelled by the named insured by giving written notice to Griffin Underwriting Services, stating when thereafter the cancellation shall become effective. Cancellation can not be effected prior to the post mark date of the written notice. In the event of cancellation by the insured, the earned premium would be subject to the minimum premium if applicable. **THE INSURANCE UNDER THIS CONFIRMATION CAN NOT BE CANCELLED FLAT;** earned premium and any applicable fees and taxes must be paid for the time that insurance has been in force.

THIS CONFIRMATION OF INSURANCE IS ISSUED BASED UPON THE INSURER'S AGREEMENT TO BIND AND IS ISSUED BY THE UNDERSIGNED WITHOUT ANY LIABILITY WHATSOEVER AS AN INSURER.



AUTHORIZED REPRESENTATIVE, GRIFFIN UNDERWRITING SERVICES

INSURED: First Care Medical Supply LLC

DATE ISSUED: Apr 30, 2020 **SUBMISSION #:** 20235001

Date 5-17-2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for MDEG
First Care Medical Supply LLC 3655 S Durango dr. unit 10 Las Vegas NV 89117
 Name and Address of Establishment for Which License Is Requested
 If applicable, Name Under Which It is Now Operated

1. PERSONAL INFORMATION:

Avagyan Knarik none
 Last Name First Name Middle Name

N/A.
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Rain Lily Ct Las Vegas NV 89117
 Present Residence Address-Street or RFD City State/Zip

3655 S Durango dr unit 10 Las Vegas NV 89117
 Present Business Address City State/Zip

Armenia, Yerevan
 Occupation Dates Phone: Resident Business (702) 684 2415

47 Armenia, Yerevan
 Date of Birth Place of Birth (City, County, State)

47 F
 Age Social Security Sex

brown brown 160 5'7"
 Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics none

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☒ Married ☐ Separated ☐ Divorced ☒ Widowed ☐ Engaged ☐

Applicant's initial A.K.

A. Current Marriage N/A

Date _____ City, County and State _____

Spouse's full name (Maiden) _____ SS# or ITIN _____

Date of Birth _____ Place of Birth _____

Resident address _____

Street _____ City _____ State _____ Zip _____

Telephone: Residence _____ Business _____

Spouse's employer _____ Occupation _____

Address of employer _____

Street _____ City _____ State _____ Zip _____

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
Arthur Gapanian	04-29-02	divorced	Las Vegas, Clark, NV	

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
Arthur Gapanian	Moorecroft St	Las Vegas	NV	89147	

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Erik Khachatryan		Armenia	21 Rain Lily Ct Las Vegas NV 89111
Gabriel Gapanian		Los Angeles	21 Rain Lily Ct Las Vegas NV 89117

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial A.K.

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father Samvel Aragyan	deceased	Armenia	
Mother Marta Aragyan	deceased	Armenia	
Father-in-Law Gabriel Gaplanian	deceased	Los Angeles	
Mother-in-Law Lusik Nalbandian	deceased	Las Vegas	

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Agasi Aragyan		Armenia	
Spouse Anahit Zohrabyan		Armenia	
Spouse			
Spouse			
Spouse			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	# 172	Armenia	1980-1985	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	# 172	Armenia	1985-1990	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	Yerevan State University			Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other				Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Masters degree organic chemistry

College or university where obtained _____

Applicant's initial A.K.

A. Have you ever served in any armed forces?

Yes ☐ No ☒Branch N/A Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☐ No ☒County N/A State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

N/A

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
------	--------------	--------	----------	------

N/AApplicant's initial A.K.

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☐ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
--	------------	-----------------------	------------------------	------------------

N/A

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
----------------	----------------	---

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
--------------------------	-------------------	------	-----------------

2012 - Present	Rain Lily Ct	Las Vegas	NV 89117
2009 - 2012	3125 W Reno Ave apt 2106	Las Vegas	NV 89118
2008 - 2009	9516 Trafforia st	Las Vegas	NV 89178
2007 - 2008	9947 Antelope Canyon	Las Vegas	NV 89147
2002 - 2007	4417 Cinderella Cn	Las Vegas	NV 89102
2001 - 2002	7 E E Twain Ave apt D	Las Vegas	NV 89109
1999 - 2001	Armenia, Yerevan		

Applicant's initial A. K.

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1-1-20-Present	First Care Medical Supply LLC 3655 Durango dr. unit 10	
Title member	Description of Duties administrator	Name of Supervisor KNAIK
6-6-19	AAA Healthcare Products Inc 18529 Rosco Blvd, Northridge	
Title clerk	Description of Duties Responsible for patients orders	Name of Supervisor Anahit
2014-2018	Flamingo Apparel 3950 Las Vegas Blvd.	
Title salesperson	Description of Duties selling products	Name of Supervisor Yori
4-1-2014	Sunset Center Pharmacy and Supply 5137 1/2 Sunset Blvd	
Title clerk	Description of Duties Responsible for patients orders	Name of Supervisor Vardan
2015-2016	E D G Express LLC 3824 S Jones Blvd. suit K	
Title manager	Description of Duties setting time tables and cargo	Name of Supervisor KNAIK
2006-2012	Charisma 3000 Paradise Rd Las Vegas 89109	
Title salesperson	Description of Duties selling apparel	Name of Supervisor MARINO
2005-2006	Regis Signature 3000 Paradise Rd.	
Title Receptionist	Description of Duties answering and directing calls	Name of Supervisor Yamara
2003-2005	Regis Signature 3770 S Las Vegas Blvd.	
Title Receptionist	Description of Duties answering and directing calls	Name of Supervisor Amy

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial A.K.

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Stella</u>	Home	<u>Masked Duck</u>	<u>Las Vegas</u>	<u>NV 89117</u>		<u>19 years</u>
Employer <u>Pharmacist</u>	Business	<u>Albertsons</u>				
Name <u>Karine</u>	Home	<u>Harbor Heights</u>	<u>Las Vegas</u>	<u>NV 89117</u>		<u>18 years</u>
Employer <u>owner</u>	Business	<u>Bridal Elegance and Tuxedos</u>				
Name <u>Sousanna</u>	Home	<u>Las Vegas</u>	<u>NV</u>	<u>89117</u>		<u>10 years</u>
Employer <u>manager</u>	Business	<u>MGM Resorts Int.</u>				
Name <u>Naira</u>	Home	<u>Glendale</u>	<u>CA</u>			<u>40 years</u>
Employer <u>manager</u>	Business	<u>IV Hospice INC</u>				
Name <u>Amy</u>	Home	<u>Las Vegas</u>	<u>NV</u>	<u>89147</u>		<u>10 years</u>
Employer <u>Lead Esthetician</u>	Business	<u>Delano Hotel</u>				

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☒
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☒

If yes, state type, where and years held

12. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Applicant's initial A.K.
Page 7

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer) Yes ☐ No ☒

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒



Date of photograph 5-21-2020

Applicant's initial A.K.

SS.

COUNTY OF

ClarkI, Knarik Avagyan,

being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

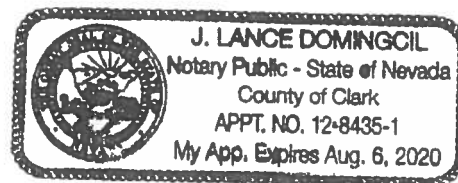
[Signature]
Original Signature of Applicant

Subscribed and Sworn to before me this 21st day of

May, 2020 by Knarik Avagyan ***

[Signature]
Notary Public

(seal)



Applicant's initial

A.K.

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 5-17-2020

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical **products provider or medical products wholesaler or b) An associate's** degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Medical Equipment and Supply
Nature of MDEG
First Care Medical Supply LLC 3655 S Durango unit 10
Name and Address of Business for Which MDEG Administrator Is Requested
Las Vegas NV 89147

 If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Avagyan Knarik _____
 Last Name First Name Middle Name

N/A
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Rain Lily Ct Las Vegas NV 89117
 Present Residence Address-Street or RFD City State/Zip

3655 S Durango dr. unit 10 Las Vegas NV 89117
 Present Business Address City State/Zip

N/A _____
 Present Position with the MDEG Dates

Pho _____ Fax: _____

Email address: supply@Firstcaremedical

Armenia
 Date of Birth Place of Birth (City, County, State)

47 _____
 Age Social Security Number or ITIN Sex F

Brown Brown 160 5'7"
 Color of Eyes Color of Hair Weight Height

Scars, tattoos or distinguishing marks and/or characteristics none

Are you a citizen of the United States? Yes ☒ No ☐

If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

1-1-2020	First Care Medical Supply LLC 3655 S. Durango	
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
member		Kneirik
Title	Description of Duties	Name of Supervisor
6-6-19	AAA Healthcare Products Inc. 18529 Roseo Blvd. Northridge	
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
clerk	Responsible for patients orders	Anahit 520
Title	Description of Duties	Name of Supervisor
4-1-2014	Sunset Center Pharmacy and Supply 5137 1/2 Sunset Blvd	
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
clerk	Responsible for patients orders	Vardan 1040
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

I have ☐ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ☐ I have not ☒ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ☐ I have not ☒ been the subject of an administrative action whether completed or pending.
3. I have ☐ I have not ☒ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information and provide a written explanation and/or documents.

- a) Board Administrative Action:
b)

State: _____

Date: _____

Case Number: _____

- c) Criminal Action:

State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4. Will you be actively involved in and aware of the daily operation of the MDEG?

Yes ☒ No ☐

5. Will you be employed fulltime with the MDEG?

Yes ☒ No ☐

6. Will you be present at the site of the MDEG during its normal operating hours?

Yes ☒ No ☐

If you answer No to questions 4, 5 or 6 please provide a writ

.....
.....
.....
.....
.....



Date of photograph 5-21-2020

I, Knarik Aragyan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, **registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.**

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.


.....
Original Signature of Applicant

12D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA Medical Device, Equipment & Gases (MDEG)

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

<input checked="" type="checkbox"/> New MDEG	<input type="checkbox"/> Ownership Change	<input type="checkbox"/> Name Change	<input type="checkbox"/> Location Change
(Please provide current license number if making changes: MP or MW _____)			

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,6
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5a,5b	<input checked="" type="checkbox"/> Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.	

GENERAL INFORMATION to be completed by all types of ownership

MDEG Name: Nevada Limb & Brace, LLC

Physical Address: 1505 Wigwam Pkwy, Suite 141 Henderson, NV 89074
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 1505 Wigwam Pkwy Suite 141

City: Henderson State: Nevada Zip Code: 89074

Telephone: (702) 899-1700 Fax: (702) 899-1813

E-mail: vanisg@NVLAB1.com Website: N/A

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8:00 to 5:00 Tue: 8:00 to 5:00 Wed: 8:00 to 5:00 Thu: 8:00 to 5:00

Fri: 8:00 to 5:00 Sat: N/A to Sun: N/A to Holidays: N/A to

MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: Vanis Ingrid Gardea

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- | | |
|--|--|
| <input type="checkbox"/> Medical Gases** | <input type="checkbox"/> Assistive Equipment |
| <input type="checkbox"/> Respiratory Equipment** | <input type="checkbox"/> Parenteral and Enteral Equipment** |
| <input type="checkbox"/> Life-sustaining equipment** | <input checked="" type="checkbox"/> Orthotics and Prosthesis |
| <input type="checkbox"/> Diabetic Supplies | Other: _____ |

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name: Roger Beihl Telephone: (702) 672-7971

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

<u>N - A</u>	_____	_____
_____	_____	_____
_____	_____	_____

- 1) Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒
- 2) Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒
- 3) Are any of the owners health professionals? If yes, please check the box and list name.

<input type="checkbox"/> Practitioner	Name: <u>N - A</u>
<input type="checkbox"/> Advanced Practitioner of Nursing	Name: _____
<input type="checkbox"/> Physician's Assistant	Name: _____
<input type="checkbox"/> Physical Therapist	Name: _____
<input type="checkbox"/> Occupational Therapist	Name: _____
<input type="checkbox"/> Registered Nurse	Name: _____
<input type="checkbox"/> Respiratory Therapist	Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

- 1) Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Vanis Ingrid Gardea

Original Signature of Person Authorized to Submit Application, no copies or stamps

Vanis Ingrid Gardea

Print Name of Authorized Person

05-13-2020

Date

Board Use Only

Received: _____

Amount: 500.00

APPLICATION FOR NEVADA MDEG LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Vanis Ingrid Gardea
Business Name: Nevada Limb & Brace, LLC
Current Business Address: 1505 Wiggam Pkwy Suite 141
City: Henderson State: NV Zip: 89074
Telephone: (702) 899-1700 Fax: (702) 899-1813

SOLE OWNER**Include with the application for a sole owner**

Complete personal history record. Must be original signature(s), no copies or stamps. Download the form from the website. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 05-13-2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Medical Device Equipment and Gases (MDEG)
Nevada Limb & Brace, LLC 1505 Wigwam Pkwy Suite 141
Henderson, NV 89074
 If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Gardea Vanis Ingrid
 Last Name First Name Middle Name
Guzman
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Coastal Fog Ave. Las Vegas NV 89183
 Present Residence Address-Street or RFD City State/Zip

1505 Wigwam Pkwy Henderson NV 89074
 Present Business Address City State/Zip

Accountant-Owner 2006 to Current
 Occupation Dates

Phone:
 Residence
 Business (702) 899-1700

San Salvador, El Salvador
 Date of Birth Place of Birth (City, County, State)

44 Female
 Age Sex

Brown Brown Medium 135 lbs. 5'2
 Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics N-A

Are you a citizen of the United States? ☒ Yes ☐ No If alien, registration No N-A

If naturalized, certificate No. _____ Date 6

Place Los Angeles, California, U.S.A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial V. I. G

MARITAL INFORMATION-Continued

A. **Current Marriage** April 2nd, 2005 San Pedro, Los Angeles, CA
Date City, County and State
 Spouse's full name (Maiden) Ruben Anthony Gardea SS# or ITIN
 Date of Birth _____ Place of Birth Torrance, California, U.S.A
 Resident address: Coastal Fog Ave. Las Vegas, NV 89101
Street City State Zip
 Telephone: Residence _____ Business (702) 899-1700
 Spouse's employer Trinity Orthopedic, LLC Occupation Paramedic Technician - Owner
 Address of employer 61 N. Pecos Rd Suite 105 Las Vegas, NV 89101
Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
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N-A

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
------	--------	------	-------	-----	-----------

N-A

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
<u>Gabriel Ruben Gardea</u>			
<u>Jacy Anthony Gardea</u>			
<u>Coastal Fog Ave. Las Vegas, NV</u>			

B. Child Support Information:

Please mark the appropriate response:

- ☐ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial V.I.G.

Page 2

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N-A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father <u>Retired</u>			
<u>Raul Mendoza</u>		<u>Flintlock Dr. Louisville, KY</u>	
Mother <u>Hospital Maintenance</u>			
<u>Edith Guzman</u>		<u>Flintlock Dr. Louisville, KY</u>	
Father-in-Law <u>Retired</u>			
<u>Jeannie Martin</u>		<u>El Cerro Dr. Buena Park, CA</u>	
Mother-in-Law <u>Deceased</u>			
<u>Lucio Gardea</u>		<u>2nd St. Long Beach, CA</u>	

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
<u>Clardia Rodriguez</u>		<u>Via Della Cavallara</u>	<u>Monteviale VI, Italy - Homemaker</u>
Spouse			
<u>Juan Rodriguez</u>		<u>Via Della Cavallara</u>	<u>Monteviale, VI Italy - U.S. Army</u>
Spouse			
<u>Heidy Gastelum</u>		<u>Windemere Dr. Louisville, KY</u>	<u>Homemaker</u>
Spouse			
<u>Concepcion Gastelum</u>		<u>Windemere Dr. Louisville, KY</u>	<u>Manager</u>
Spouse			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	<u>Limerick Ave. Elementary</u>	<u>Canoga Park, CA</u>	<u>1983-1988</u>	<u>Yes</u> <input checked="" type="radio"/> No <input type="radio"/>
High School	<u>John Freeman High</u>	<u>Los Angeles, CA</u>	<u>1991-1995</u>	<u>Yes</u> <input checked="" type="radio"/> No <input type="radio"/>
College	<u>Cal State University</u>	<u>Dominguez Hills</u>	<u>2003-2006</u>	<u>Yes</u> <input checked="" type="radio"/> No <input type="radio"/>
University	<u>Carson, CA</u>			<u>Yes</u> <input checked="" type="radio"/> No <input type="radio"/>
Other				<u>Yes</u> <input checked="" type="radio"/> No <input type="radio"/>

Type of degree obtained, if any Bachelor's Degree in AccountingCollege or university where obtained California State University, Dominguez HillsApplicant's initial N. I. G.

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces?

Yes ☐ No ☒Branch N-A Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☐ No ☒County N-A State _____ Date registered _____**6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)**

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

N-A

- B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.
- C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒
- D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒
- E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒
- F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? _____ city, county and state _____
- G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? _____ city, county and state _____
- H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10. Possible

Name	Relationship	Charge	Location	Date
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Please refer to page 10.Applicant's initial V.I.G.

Page 4

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☐ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
--	------------	-----------------------	------------------------	------------------

N - A

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
----------------	----------------	---

N - A

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
--------------------------	-------------------	------	-----------------

Aug 2019 - Current	Coastal Fog Ave.	Las Vegas, NV	89183
Dec 2013 - Aug 2019	10220 Crepe Myrtle CT	Las Vegas, NV	89183
Aug 2003 - Aug 2013	2239 Gale Ave.	Long Beach, CA	90810
Dec 1995 - Aug 2003	8601 State St apt #19	South Gate, CA	90280

Applicant's initial V.L.G.

Page 5

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
July 2019-Current	Nevada Limb & Brace, LLC 1505 Wigwam Pkwy Suite 141 Henderson, NV 89074, Administrator-Controller - Self	
June 2019-April 2020	Reno Oil of America - 5435 S. Valley View Blvd. Las Vegas, NV 89118, Accounting Manager - Sophia Del Pozo	Started my Company
May 2019-June 2019	Red Moon, LLC 101 Convention Center Dr. 7th Floor. Las Vegas, NV 89109 Assistant Controller - Melissa Lambson	Better opportunity
Sept. 2017-May 2019	M&K Enterprises, LLC 1950 East Maule Las Vegas, NV 89119, Accounting Manager - Jennifer Turner	Entity Closed
April 2017-Sept. 2017	Blue Diamond Machinery 2880 N. Nellis Blvd. Las Vegas, NV 89115 - Bookkeeper - Scott Paulo	Better opportunity
April 2016-April 2017	Cannon Nevada, LLC 6671 S. Las Vegas Blvd. Suite 210, Las Vegas, NV 89119 - Bookkeeper - Scott Paulo	Relocated
Sept. 2013-April 2016	Ampro Orthotics & Prosthetics 6877 S. Eastern Ave. Las Vegas, NV 89119, Accountant - Karen Jarvis	Entity Closed
Sept 2012-July 2015	Lobel Financial 1150 N. Magnolia Ave. Anaheim, CA 92801 Assistant Controller - Luz Hooper	Moved to Nevada

If additional space is needed, continue on page 10 or provide attachment. Continued on pg. 10.

Applicant's initial V. I. G.

Page 6

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone (714)	Years Known
Name Maria Ponce	Home	Cod Gide	Huntington Beach, CA		270-3135	18 years
Employer EB&M	Business	18002 Cowan	Irvine, CA	92614		
Name Monica Rojas	Home	Park Ave	Pasadena, CA	91030		
Employer Don Lee Farms	Business	200 E. Beach Ave.	Inglewood, CA	90302		30 years
Name Addy Trivino	Home	W.	Los Angeles, CA	90006		
Employer L.A. County	Business	14340 Sylvan St.	Los Angeles, CA	91401		25 years
Name Blanca Schreiner	Home	Cambridge Ave.	Castaic, CA	91384		
Employer Homemakers	Business	24 years				
Name Roxanna Andino	Home	S. Alta Vista Ave.	Menrovia, CA	91061		
Employer Kaiser	Business	3280 E. Foothill Blvd.	Pasadena, CA	91107		30 years

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☒ No ☐
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N-A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

N-A

12. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N-A

Applicant's initial V.I.G.

Page 7

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

N-A

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

N-A

If yes to the above, state where, when and for what reason:

N-A

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

N-A

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

N-A

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

N-A

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer)? Yes ☐ No ☒

N-A

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

N-A



Date of photograph 05-12-2020

Applicant's initial V.L.G.

STATE OF Nevada

SS.

COUNTY OF Clark

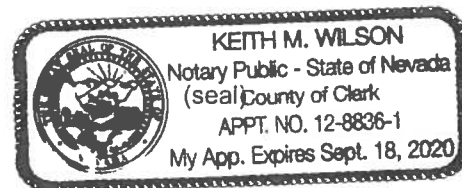
I, Vanis Ingrid Gardea, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Vanis Ingrid Gardea
Original Signature of Applicant

Subscribed and Sworn to before me this 12th day of May, 2020
by Vanis Ingrid Gardea.

K-MW
Notary Public



Applicant's initial V.I.G.

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From pg. 6

ADDITIONAL INFORMATION - Entity Closed

May 2010 - Sept 2012 Active Storage Inc. 2295 Jefferson St.
Torrance, CA 90501 Accounting Manager - Jane Wike, CPA

Aug. 2006 - May 2010 International Cabled Connectors - Charles Brian,
2100 E. Valencia Dr. Ste D. Fullerton, CA 92831 CPA
- Completed Degree

April 2005 - Aug. 2006 SJS Enterprises, Inc.
4030 Somerset Blvd. Bellflower, CA 90706 -
Accounts Payable and Receivable Manager - Growth Opportunity

Oct. 2000 - Nov. 2004 Human Designs, Prosthetic and
Orthotics. 2933 Long Beach Blvd. Long Beach, CA 90806
Accounts Receivable Manager - Andrea Ferraro
- Growth Opportunity

From pg. 4

My spouse had a strange relationship with his
biological father, Lucio Gardea. It is possible that
Lucio Gardea was convicted of a felony. However,
I am not sure and he passed away two years
ago.

Applicant's initial V. I. G.

Page 10

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 05-13-2020

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Orthotics and Prosthetics

Nature of MDEG

Nevada Limb & Brace LLC 1505 W. Gwam Parkway #141 Henderson, NV 89074
Name and Address of Business for Which MDEG Administrator Is Requested

Nevada Limb & Brace LLC

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Gardea Vanis Ingrid
Last Name First Name Middle Name

Guzman
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Coastal Fog Ave. Las Vegas, NV 89183
Present Residence Address-Street or RFD City State/Zip

1505 Wigwam Pkwy Suite 141 Henderson, NV 89074
Present Business Address City State/Zip

Administrator/Controller July 2019 - Current
Present Position with the MDEG Dates

Phone: (702) 899-1700 Fax: (702) 899-1813

Email address: vanisg@NULAB1.com

San Salvador, El Salvador
Date of Birth Place of Birth (City, County, State)

44 -- Female
Age Social Security Number or ITIN Sex

Brown Brown 135 lbs. 5-2
Color of Eyes Color of Hair Weight Height

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? ☒ Yes ☐ No

If alien, registration No N/A

If naturalized, certificate . Date 09-17-2004

Place Los Angeles, California, U.S.A. (If naturalized, document must be verified.)

EMPLOYMENT:

1685

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

Oct. Nov.

2000 - 2004 Human Designs P&O 2933 Long Beach Blvd. Long Beach, CA
 Month and Year Name/ Address of Employer/Business No of Employed Hours
 Accounts Receivable Manager - Claims Appeals Patient Financial Support
 Title Description of Duties Name of Supervisor
 Andrea Ferraro

Sept. April

2013 - 2016 Ampro O&P 6877 S. Eastern Ave. Las Vegas, NV 89119
 Month and Year Name/ Address of Employer/Business No of Employed Hours
 Accounting Manager - Appeals - General Accounting Collections - Patient Financial Support
 Title Description of Duties Name of Supervisor
 Karen Jarvis

Month and Year Name/ Address of Employer/Business No of Employed Hours

Title Description of Duties Name of Supervisor

Month and Year Name/ Address of Employer/Business No of Employed Hours

Title Description of Duties Name of Supervisor

Month and Year Name/ Address of Employer/Business No of Employed Hours

Title Description of Duties Name of Supervisor

Month and Year Name/ Address of Employer/Business No of Employed Hours

Title Description of Duties Name of Supervisor

I have ☒ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ☒ I have not ☒ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ☒ I have not ☒ been the subject of an administrative action whether completed or pending.
3. I have ☒ I have not ☒ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

- a) Board Administrative Action:
b)

State: _____

Date: _____

Case Number: _____

- c) Criminal Action:

State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG?

☒ Yes ☒ No

5 .Will you be employed fulltime with the MDEG?

☒ Yes ☒ No

6 .Will you be present at the site of the MDEG during its normal operating hours?

☒ Yes ☒ No

If you answer No to questions 4, 5 or 6 please provide

on.

RAPH

AST



Date of photograph 05-13-2020

I, Vanis Ingrid Gardea, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.

Vanis Ingrid Gardea
Original Signature of Applicant



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY):

2/6/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. IF SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER TOM MOLLOY INSURANCE AGENCY 9708 Gillespie St. Suite A-104 Las Vegas, NV 89123	CONTACT NAME: TOM MOLLOY PHONE (A/C No. Ext.): (702)877-6688 FAX (A/C. No.): (702)877-6242 E-MAIL ADDRESS: tom@tommolloyinsurance.com														
INSURED Nevada Limb & Brace, LLC DBA: Nevada Limb & Brace 1505 Wigwam Pkwy # 141 Henderson, NV 89074	<table border="1"><thead><tr><th>INSURER(S) AFFORDING COVERAGE</th><th>NAIC #</th></tr></thead><tbody><tr><td>INSURER A: KINSALE INSURANCE CO</td><td></td></tr><tr><td>INSURER B: THE HARTFORD INSURANCE COMPANY</td><td></td></tr><tr><td>INSURER C:</td><td></td></tr><tr><td>INSURER D:</td><td></td></tr><tr><td>INSURER E:</td><td></td></tr><tr><td>INSURER F:</td><td></td></tr></tbody></table>	INSURER(S) AFFORDING COVERAGE	NAIC #	INSURER A: KINSALE INSURANCE CO		INSURER B: THE HARTFORD INSURANCE COMPANY		INSURER C:		INSURER D:		INSURER E:		INSURER F:	
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INSURER E:															
INSURER F:															

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDITIONAL INSURED (Y/N)	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR INCLUDES PRODUCT LIAB & PROF LIAB. GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:	Y	Y	020720TM01	2/7/2020	2/7/2021	EACH OCCURRENCE \$ 2,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 50,000 MED EXP (Any one person) \$ PERSONAL & ADV INJURY \$ 2,000,000 GENERAL AGGREGATE \$ 5,000,000 PRODUCTS - COMP/OP AGG \$ 5,000,000
	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO <input type="checkbox"/> OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS <input type="checkbox"/> HIRED AUTOS ONLY <input type="checkbox"/> NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) \$ BODILY INJURY (Per person) \$ BODILY INJURY (Per accident) \$ PROPERTY DAMAGE (Per accident) \$
	UMBRELLA LIAB <input type="checkbox"/> OCCUR EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE DED <input type="checkbox"/> RETENTION \$						EACH OCCURRENCE \$ AGGREGATE \$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in MI) If yes, describe under DESCRIPTION OF OPERATIONS below	Y/N Y	N/A	53WECAF2F1V	2/1/2020	2/1/2021	PER STATUTE <input type="checkbox"/> OTH-ER <input type="checkbox"/> E.L. EACH ACCIDENT \$ 1,000,000 E.L. DISEASE - EA EMPLOYEE \$ 1,000,000 E.L. DISEASE - POLICY LIMIT \$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SALES AND MGF OF PROSTETIC LIMBS AND BRACES.

INSUREDS PREMISES LOCATED AT 1505 WIGWAM PKWY # 141. HENDERSON, NV 89074.

CERTIFICATE HOLDER FOR INFORMATION PURPOSES ONLY	CANCELLATION SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS. AUTHORIZED REPRESENTATIVE
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13

14

14A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Sheffield Pharmaceuticals LLC

Physical Address: 170 Broad St

City: New London State: CT Zip Code: 06320

Telephone Number: 860-442-4451 Fax Number: 860-442-0356

Toll Free Number: N/A

E-mail: anthony.sullivan@sheffieldpharma.com Website: www.sheffieldpharma.com

Facility Manager: Jeff Davis CEO and President

Professional qualifications and experience of facility manager: Jeff Davis has over 25 years of Pharmaceutical Manufacturing experience as well as company financials and Sales

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☒ Hospitals ☒ Wholesalers
☐ Other: Sheffield intends to sell product to third party distributor who is currently licensed in NV

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA?
(If yes, provide a copy of your FDA registration)

Yes ☒ No ☐

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Zeta Pharmaceutical LLC.
Address: 120 Holmes Ave NE, Suite 116 Huntsville, AL 35801

Name: 3CL Beta Packaging Inc.
Address: 1000 CCC Dr Clayton NC 27526

Name: ALBEA AMERICAS, INC
Address: 191 Route 51 North Washington, NJ 07882

Name: CAMPAR TECHNOLOGIES CORP.
Address: 1584 Independence Blvd Sarasota FLA 34234

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☒ No ☐

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

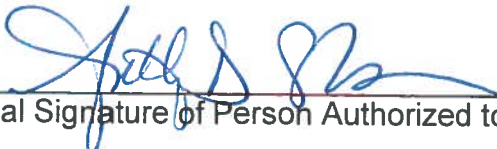
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Anthony D. Sollime CSO and EVP of Regulatory Affairs 3/25/2020
Print Name of Authorized Person Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Connecticut
 Parent Company if any: Sheffield Pharmaceuticals LLC
 Mailing Address: 170 Broad St
 City: New London State: CT Zip: 06320
 Telephone: 860-442-4451 Fax: 860-442-0356
 Contact Person: Anthony Solimine

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

- a) Sue Faria : Mandarin Circle East Sandwich, MA 02537-1041
 Name Business Address
- b) Thomas H Faria Neely Avenue Las Vegas, NV 89178
 Name Business Address
- c) Nancy Faria West Main Road, Apt Middletown RI 0284
 Name Business Address
- d) Diana Faria Sead Dr SE, Unit St Petersburg FL 33701-3957
 Name Business Address

2) Provide the number of shares issued by the corporation.

3) What was the price paid per share? N/A

Company ownership is set
in percentage to each of 5
family member equally 100%
3/25/06

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporation**List of officers and directors**

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

FILED

2014 JUL -8 P 4: 09

UNITED STATES OF AMERICA

CRIMINAL NO. 3:14CR 149 AWT

US DISTRICT COURT
HARTFORD CT

v.

VIOLATION:

THOMAS H. FARIA

33 U.S.C. § 1319(c)(2)(A)
(Clean Water Act)

INFORMATION

The United States Attorney charges:

COUNT ONE

(Knowing Violation of a Requirement Imposed in a Pretreatment
Program Approved Under the Clean Water Act)

The Defendant – Thomas H. Faria

1. At all times relevant to this Information, the defendant, THOMAS H. FARIA, was a resident of Connecticut. In or about April 2003, the defendant became the president and chief executive officer of Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals ("Faria Limited"), and assumed day-to-day management and control over the company. Since on or about April 30, 2008, until on or about May 13, 2014, the defendant held all of the company's voting shares.

Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals

2. At all times relevant to this Information, Faria Limited was and remains a company operating a factory at 170 Broad Street in New London, Connecticut, that manufactures a wide range of over-the-counter pharmaceutical creams, ointments, and toothpastes. Faria Limited

purchased Sheffield Laboratories in 1986 and changed its operating name to Sheffield Pharmaceuticals.

The Clean Water Act and the NPDES Permit Program

3. The Clean Water Act ("CWA") at Title 33, United States Code, Section 1251 et seq., prohibits the discharge of pollutants to waters of the United States, except in a manner consistent with the National Pollutant Discharge Elimination System ("NPDES") permitting program set forth in Section 1342 of the CWA. Under the NPDES permitting program, all publicly owned sewage-treatment systems, commonly known as publicly owned treatment works ("POTWs"), that discharge to waters of the United States must obtain and comply with discharge permits. Because POTWs are designed to treat sewage, not industrial waste, such discharge permits often require the development and implementation of a POTW pretreatment program to treat industrial waste at the factory before the industrial waste reaches the POTW. The purpose of such pretreatment programs is to prevent introducing pollutants into a POTW that may pass through the POTW, may interfere with the POTW's operation, or may otherwise be incompatible with the POTW.

4. The CWA authorizes the Environmental Protection Agency ("EPA") to approve states to administer the NPDES permit program. To receive EPA approval, the state must develop a state pretreatment program that, among other things, incorporates POTW pretreatment program conditions into permits issued to POTWs; requires compliance by POTWs with these incorporated permit conditions; and requires compliance by industrial users with pretreatment standards. A state with an approved state pretreatment program may assume responsibility for implementing the POTW pretreatment program in lieu of requiring the POTW to develop a pretreatment program.

An Industrial Facility in Connecticut Must Have a Permit to Discharge Industrial Wastewater

5. In 1979, the State of Connecticut ("Connecticut") made a formal request to the EPA that Connecticut be approved to administer the NPDES program and to assume responsibility for implementing the POTW pretreatment program in lieu of requiring the POTW to develop a pretreatment program. In its application for pretreatment program approval dated March 27, 1979, the Connecticut Department of Environmental Protection ("CT DEP") stated, "The Department is committed to achievement of its own and the national goals of fishable swimmable waters and elimination of the discharge of pollutants. The treatment of industrial wastes prior to discharge to POTWs is a necessary and significant program element in achievement of those goals." In 1981, the EPA approved Connecticut's pretreatment program, including the request to operate a state-wide pretreatment program. The CT DEP is now named the Connecticut Department of Energy and Environmental Protection ("CT DEEP").

6. Connecticut's pretreatment program prohibits the discharge of industrial wastewater to POTWs without a CT DEEP permit. The failure to obtain a CT DEEP permit prior to discharging industrial wastewater to a POTW constitutes a violation of a requirement of a pretreatment program approved under Title 33, United States Code, Section 1342(b)(8).

7. The CT DEEP tailors wastewater permits for industrial users based on, among other things, the type and quantity of industrial wastewater being discharged by the facility. When applying for a wastewater permit from CT DEEP, an industrial facility must characterize and quantify the pollutants contained in its wastewater based on actual wastewater samples. A CT DEEP permit allows an industrial facility to discharge pollutants to the POTW only within the specific conditions and numeric limitations for pollutants mandated by the permit. Furthermore, CT DEEP permits impose on the industrial facility the obligation to sample and analyze its

wastewater regularly, and to report the results to the CT DEEP each month in a Discharge Monitoring Report ("DMR"). The CT DEEP relies upon the sampling data provided in these monthly DMRs to determine whether the industrial facility is complying with the discharge permit's parameters.

Faria Limited Did Not Have a CT DEEP Permit From 1986 to July 2011. But Still Discharged Industrial Wastewater to the New London POTW Throughout The Entire Period

8. At all times relevant to this matter, the City of New London Water Pollution Control Facility, together with its public sewer system, constituted a POTW ("New London POTW") within the meaning of the CWA and Connecticut's pretreatment program, and as approved by the EPA. The New London POTW discharges to the Thames River in southeastern Connecticut.

9. From in or about 1986 to July 2011, Faria Limited discharged industrial wastewater from its New London manufacturing operations to the New London POTW without a permit and in violation of Connecticut's approved pretreatment program. During this entire time period, Faria Limited lacked a pretreatment system at its factory to treat its industrial wastewater prior to discharge to the New London POTW, performed no regular monitoring of its discharges of industrial wastewater, and submitted no monthly DMRs to the CT DEEP.

The Defendant Knew for Several Years That Faria Limited Did Not Have a Permit From CT DEEP to Discharge Industrial Wastewater to the New London POTW

10. After becoming the company's president and chief executive officer in April 2003, the defendant learned through his own employees that Faria Limited was discharging pollutants in its industrial wastewater, including the toxic metal zinc, without the required permit. The defendant also learned that in order to obtain a permit from CT DEEP, Faria Limited would have to install, at significant expense, a wastewater pretreatment system that would pretreat its industrial wastewater prior to discharging it to the New London POTW.

a. On May 27, 2003, a manager on the Faria Limited production floor sent the following e-mail message, which was copied to the defendant and states in pertinent part:

I strongly suggest we engage an environmental consultant to study this issue. There are several firms that specialize in just this type of permitting. In my experience I have never heard of an industry not needing a discharge permit to discharge into the sanitary sewer. This could potentially be very damaging to the company if it is discovered we are discharging to the sewer without the proper permits and monitoring.

b. Nearly two years later on April 5, 2005, the same manager sent directly to the defendant the following e-mail message and attached a proposal prepared by an environmental consultant to bring Faria Limited into compliance with the CWA and the CT DEEP:

You need to understand a couple of things.

- 1) We are out of compliance with the Clean Water Act. We may continue on for years this way, however once it is recognized we are discharging to the New London POTW and not meeting the pretreatment standards it will mean an immediate shutdown of discharge due to the type of industry we are. Shutdown of our discharge will mean shutting down the factory unless we contract to have our discharge taken away to a disposal facility. This might never happen, or it could happen tomorrow. All it takes is one serious problem at the New London POTW after which the state starts taking a look upstream.
- 2) Criminal penalties could also be levied, and as officers of the company this burden will fall upon you. In my opinion this is probably a slim possibility, but the option exists to the state. But, remember that article I showed you in which [Company X] in Stafford Springs exceeded pretreatment standards when discharging to the local POTW. Multi million dollar fines and criminal prosecution did happen.

I can't stress strongly enough that this should become the top priority in the project list. We need to take immediate action to get this treatment system set up and our permitting completed. To follow the letter of the law we should immediately discontinue all discharge to the New London POTW until this permitting is in place.

11. Under the defendant's leadership and with his knowledge, Faria Limited hired between 2004 and 2007 at least four environmental consulting firms to advise the company regarding its discharge of industrial wastewater to the New London POTW. The consultants of these firms informed Faria Limited that its discharge of industrial wastewater to the public sewage treatment system, without a pretreatment system or CT DEEP permit, was illegal.

a. In a report dated March 31, 2004, that was reviewed by the defendant, one environmental consultant stated: "A discharge permit from the CT DEP is required for cleaning-water discharge; therefore Sheffield is currently out of compliance."

b. In a report dated June 11, 2004, that was forwarded by e-mail to Faria, another environmental consultant stated, among other things: "We understand you are very concerned that going to CT DEP with permit applications, thereby acknowledging some level of noncompliance, might result in some business disruption." This consultant further stated: "It will take time and resources, but the alternative, which includes enforcement action [and] fines . . . will most certainly have a much larger impact on the bottom line."

c. Based on an analysis of samples taken from the factory's own wastewater, the consultant's report dated June 11, 2004, concluded that Faria Limited's industrial wastewater contained levels of zinc far in excess of any concentration permitted by CT DEEP.

12. On April 20, 2011, the CT DEEP conducted an unannounced inspection of Faria Limited. After finding that the company had no wastewater discharge permits, the CT DEEP inspector issued a Notice of Violation and cited Faria Limited for discharging manufacturing and laboratory wastewater without a permit.

13. On or about May 27, 2011, Faria Limited submitted a permit application to CT DEEP, so that Faria Limited could discharge industrial wastewater from its New London facility

into the New London POTW. By July 2011, Faria Limited had installed a wastewater pretreatment system at its factory to pretreat the pollutants contained in its industrial wastewater prior to its discharge to the New London POTW.

14. Based on the foregoing, from at least as early as April 2004 to May 2011, in the District of Connecticut, the defendant, as president and chief executive officer of Faria Limited, knowingly violated and caused to be violated a requirement imposed in a pretreatment program approved under section 1342(a)(3) and 1342(b)(8) of Title 33, United States Code—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit.

All in violation of Title 33, United States Code, Section 1319(c)(2)(A).

UNITED STATES OF AMERICA



DEIRDRE M. DALY
UNITED STATES ATTORNEY



HAROLD H. CHEN
ASSISTANT UNITED STATES ATTORNEY



PETER W. KENYON
SPECIAL ASST. UNITED STATES ATTORNEY



U.S. Department of Justice

United States Attorney

District of Connecticut

FILED

2014 JUL -8 P 4:08

US DISTRICT COURT
HARTFORD CT

Connecticut Financial Center
157 Church Street, 25th Floor
New Haven, Connecticut 06510

(203) 821-3700
Fax (203) 773-5376
www.justice.gov/usao/ct

July 8, 2014

Thomas J. Murphy, Esq.
James T. Cowdery, Esq.
Cowdery & Murphy, L.L.C.
280 Trumbull Street
Hartford, CT 06103

Re: United States v. Thomas H. Faria
Criminal No. 3:14CR149 AWT

Dear Attorneys Murphy and Cowdery:

This letter confirms the plea agreement between your client, Thomas H. Faria (the "defendant"), and the United States Attorney's Office for the District of Connecticut (the "Government" or "this Office") concerning the referenced criminal matter.

THE PLEA AND OFFENSE

The defendant agrees to waive his right to be indicted and to plead guilty to a one-count information charging him with knowingly violating the requirements imposed in a pretreatment program approved under the Clean Water Act. 33 U.S.C. § 1319(c)(2)(A). The defendant understands that to be guilty of this offense, the following essential elements of the offense must be satisfied:

1. From at least as early as April 2004 to May 2011, the defendant violated, or caused a violation of, a requirement imposed in a pretreatment program approved pursuant to 33 U.S.C. § 1342—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit; and
2. The defendant acted knowingly.

THE PENALTIES

This offense carries a maximum penalty of three years of imprisonment and a fine of not less than \$5,000 but not more than \$50,000 per day of the violation. In addition, under 18 U.S.C. § 3583, the Court may impose a term of supervised release of not more than one year to begin at

Thomas J. Murphy, Esq.

July 8, 2014

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the expiration of any term of imprisonment. The defendant understands that should he violate any condition of the supervised release, he may be required to serve a further term of imprisonment of up to one year per violation with no credit for time already spent on supervised release.

The defendant also is subject to the alternative fine provision of 18 U.S.C. § 3571. Under this section, the maximum fine that may be imposed on the defendant is the greatest of the following amounts: (1) twice the gross gain to the defendant resulting from the offense; (2) twice the gross loss resulting from the offense; or (3) \$250,000; or (4) the amount specified in the section defining the offense, which is a fine of not less than \$5,000 but not more than \$50,000 per day of the violation under 33 U.S.C. § 1319(c)(2).

In addition, the defendant is obligated by 18 U.S.C. § 3013 to pay a special assessment of \$100 on each count of conviction. The defendant agrees to pay the special assessment to the Clerk of the Court on the day the guilty plea is accepted.

Unless otherwise ordered, should the Court impose a fine of more than \$2,500 as part of the sentence, interest will be charged on the unpaid balance of the fine not paid within 15 days after the judgment date. 18 U.S.C. § 3612(f). Other penalties and fines may be assessed on the unpaid balance of a fine pursuant to 18 U.S.C. § 3572 (h), (i) and § 3612(g).

Agreement Regarding the Defendant's Involvement in Faria Limited, LLC,
d/b/a Sheffield Pharmaceuticals

On March 7, 2014, the defendant resigned from his position as president and chief executive officer of Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals ("Faria Limited"), and also relinquished his seat on the board of directors. On May 13, 2014, by written amendment to Faria Limited's corporate Operating Agreement, the defendant's 38% equity interest in Faria Limited was converted to Class B – Non Voting shares (or "membership units"). Pursuant to this conversion, the defendant no longer possesses any voting rights to exercise with respect to Faria Limited's operations and management, except that he is entitled to vote if Faria Limited's other equity owners are considering a sale in the future of all, or substantially all, of Faria Limited's membership units, assets, or business. The defendant hereby stipulates that subject to this sole limited exception for the exercise of his voting rights, he shall have no involvement in directing, managing, controlling, or working for Faria Limited in any manner until the Court determines that his term of supervised release has fully expired.

THE SENTENCING GUIDELINES

Applicability

The defendant understands that the Court is required to consider any applicable Sentencing Guidelines as well as other factors enumerated in 18 U.S.C. § 3553(a) to tailor an appropriate sentence in this case and is not bound by this plea agreement. The defendant agrees

Thomas J. Murphy, Esq.

July 8, 2014

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that the Sentencing Guideline determinations will be made by the Court, by a preponderance of the evidence, based upon input from the defendant, the Government, and the United States Probation Office. The defendant further understands that he has no right to withdraw his guilty plea if his sentence or the Guideline application is other than he anticipated, including if the sentence is outside any of the ranges set forth in this agreement.

Acceptance of Responsibility

At this time, the Government agrees to recommend that the Court reduce by two levels the defendant's adjusted offense level under § 3E1.1(a) of the Sentencing Guidelines, based on the defendant's prompt recognition and affirmative acceptance of personal responsibility for the offense. Moreover, should the defendant qualify for a decrease under § 3E1.1(a) and his offense level determined prior to the operation of subsection (a) is level 16 or greater, the Government will file a motion with the Court pursuant to § 3E1.1(b) which recommends that the Court reduce the defendant's Adjusted Offense Level by one additional level based on his prompt notification of his intention to enter a plea of guilty. The defendant expressly understands that the Court is not obligated to accept the Government's recommendations on the reductions.

The above-listed recommendations are conditioned upon the defendant's affirmative demonstration of acceptance of responsibility, by (1) truthfully admitting the conduct comprising the offense(s) of conviction and truthfully admitting or not falsely denying any additional relevant conduct for which the defendant is accountable under Sentencing Guideline § 1B1.3, and (2) truthfully disclosing to the Probation Office personal information requested, including the submission of a complete and truthful financial statement detailing the defendant's financial condition.

In addition, the Government expressly reserves the right to seek denial of the adjustment for acceptance of responsibility if the defendant engages in any acts, unknown to the Government at the time of the signing of this agreement, which (1) indicate that the defendant has not terminated or withdrawn from criminal conduct or associations (Sentencing Guideline § 3E1.1); (2) could provide a basis for an adjustment for obstructing or impeding the administration of justice (Sentencing Guideline § 3C1.1); or (3) constitute a violation of any condition of release. Moreover, the Government reserves the right to seek denial of the adjustment for acceptance of responsibility if the defendant seeks to withdraw his plea of guilty or takes a position at sentencing, or otherwise, which, in the Government's assessment, is inconsistent with affirmative acceptance of personal responsibility. The defendant understands that he may not withdraw his plea of guilty if, for the reasons explained above, the Government does not make one or both of the recommendations or seeks denial of the adjustment for acceptance of responsibility.

Stipulation

Pursuant to § 6B1.4 of the Sentencing Guidelines, the defendant and the Government have entered into a stipulation, which is attached to and made a part of this plea agreement. The

Thomas J. Murphy, Esq

July 8, 2014

Page 4

defendant understands that this stipulation does not set forth all of the relevant conduct and characteristics that may be considered by the Court for purposes of sentencing. The defendant understands that this stipulation is not binding on the Court. The defendant also understands that the Government and the United States Probation Office are obligated to advise the Court of any additional relevant facts that subsequently come to their attention.

Guideline Stipulation

The parties agree that the Guidelines Manual in effect on the date of sentencing is used to determine the applicable Guidelines range.

The Government and the defendant disagree about the Guidelines calculation and the Guidelines range. Consequently, the parties stipulate that all Guidelines calculations, including the calculation of the defendant's total offense level and Guidelines range, shall be resolved at sentencing.

Based on the information currently available, the Government's position regarding the defendant's Guidelines calculation is as follows: The defendant's base offense level under U.S.S.G. § 2Q1.2(a) is 8. Six (6) levels are added because, under U.S.S.G. § 2Q1.2(b)(1)(A), the offense resulted in an ongoing, continuous, or repetitive discharge of a hazardous or toxic substance into the environment. Four (4) levels are added because, under U.S.S.G. § 2Q1.2(b)(4), the offense involved treatment, storage, or disposal without a permit. Two (2) more levels are added because, under U.S.S.G. § 3B1.1(c), the defendant was a leader of the offense. Assuming a three-level reduction under U.S.S.G. § 3E1.1 for acceptance of responsibility, the defendant's total offense level is 17. With a Criminal History Category I and a total offense level of 17, the defendant's Guidelines range would be 24 to 30 months of imprisonment (sentencing table). The fine range is governed by U.S.S.G. § 5E1.2(c)(4). The defendant is also subject to a supervised release term of one (1) year. U.S.S.G. § 5D1.2. The Government reserves its right to amend its position regarding the defendant's Guidelines calculation.

The defendant disagrees with the Government's Guidelines calculation and range, including the application of U.S.S.G. § 2Q1.2 (as opposed to U.S.S.G. § 2Q1.3) and of any aggravating role adjustment under U.S.S.G. § 3B1.1. The Government and the defendant reserve their rights to seek a departure or a non-Guidelines sentence, and both sides reserve their rights to object to a departure or a non-Guidelines sentence. Specifically, the defendant reserves his right to argue at sentencing pursuant to 18 U.S.C. § 3553(a) that the facts of this case provide significant mitigating grounds to support either a downward departure and/or the imposition of a non-Guidelines sentence.

The Government and the defendant reserve their respective rights to seek whatever sentence the parties deem appropriate.

The defendant expressly understands that the Court is not bound by this agreement on any of the Guidelines provisions specified above. The defendant further understands that he will

Thomas J. Murphy, Esq.

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not be permitted to withdraw the plea of guilty in the event he disagrees with the Court's or the Probation Office's Guidelines calculations or Guidelines range.

In the event the Probation Office or the Court contemplates any sentencing calculations different from those argued for by the parties, the parties reserve the right to respond to any inquiries and make appropriate legal arguments regarding the proposed alternate calculations. Moreover, the parties expressly reserve the right to defend any sentencing determination, even if it differs from that argued for by the parties, in any post-sentencing proceeding.

Appeal Rights Regarding Sentencing

The parties reserve their respective rights to appeal and to oppose each other's appeal of the sentence imposed as permitted by 18 U.S.C. § 3742.

Information to the Court

The Government and the defendant reserve their rights to address the Court with respect to an appropriate sentence to be imposed in this case. Moreover, the Government and the defendant will discuss the facts of this case, including information regarding the defendant's background and character, 18 U.S.C. § 3661, with the United States Probation Office. The Government will provide the Probation Officer with access to material in its file, with the exception of grand jury material.

WAIVER OF RIGHTS

Waiver of Right to Indictment

The defendant understands that he has the right to have the facts of this case presented to a federal grand jury, consisting of between sixteen and twenty-three citizens, twelve of whom would have to find probable cause to believe that he committed the offense set forth in the information before an indictment could be returned. The defendant acknowledges that he is knowingly and intelligently waiving his right to be indicted.

Waiver of Trial Rights and Consequences of Guilty Plea

The defendant understands that he has the right to be represented by an attorney at every stage of the proceeding and, if necessary, one will be appointed to represent him.

The defendant understands that he has the right to plead not guilty or to persist in that plea if it has already been made, the right to a public trial, the right to be tried by a jury with the assistance of counsel, the right to confront and cross-examine the witnesses against him, the right not to be compelled to incriminate himself, the right to testify and present evidence, and the right to compel the attendance of witnesses to testify in his defense. The defendant understands that

Thomas J. Murphy, Esq.
July 8, 2014
Page 6

by pleading guilty he waives and gives up those rights and that, if the plea of guilty is accepted by the Court, there will not be a further trial of any kind.

The defendant understands that, if he pleads guilty, the Court may ask him questions about each offense to which he pleads guilty, and if he answers those questions falsely under oath, on the record, and in the presence of counsel, his answers may later be used against him in a prosecution for perjury or making false statements.

Waiver of Statute of Limitations

The defendant agrees that, should the conviction following defendant's plea of guilty pursuant to this plea agreement be vacated for any reason, then any prosecution that is not time-barred by the applicable statute of limitations on the date of the signing of this plea agreement (including any indictment or counts the Government has agreed to dismiss at sentencing pursuant to this plea agreement) may be commenced or reinstated against defendant, notwithstanding the expiration of the statute of limitations between the signing of this plea agreement and the commencement or reinstatement of such prosecution. The defendant agrees to waive all defenses based on the statute of limitations with respect to any prosecution that is not time-barred on the date the plea agreement is signed.

ACKNOWLEDGMENT OF GUILT AND VOLUNTARINESS OF PLEA

The defendant acknowledges that he is entering into this agreement and is pleading guilty freely and voluntarily because he is guilty. The defendant further acknowledges that he is entering into this agreement without reliance upon any discussions between the Government and him (other than those described in the plea agreement letter), without promise of benefit of any kind (other than the concessions contained in the plea agreement letter), and without threats, force, intimidation, or coercion of any kind. The defendant further acknowledges his understanding of the nature of the offense to which he is pleading guilty, including the penalties provided by law. The defendant also acknowledges his complete satisfaction with the representation and advice received from his undersigned attorney. The defendant and his undersigned counsel are unaware of any conflict of interest concerning counsel's representation of the defendant in the case.

SCOPE OF THE AGREEMENT

The defendant acknowledges that this agreement is limited to the undersigned parties and cannot bind any other federal authority, or any state or local authority. The defendant acknowledges that no representations have been made to him with respect to any civil or administrative consequences that may result from this plea of guilty because such matters are solely within the province and discretion of the specific administrative or governmental entity involved. Finally, the defendant acknowledges that this agreement has been reached without regard to any civil tax matters that may be pending or which may arise involving him.

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COLLATERAL CONSEQUENCES

The defendant understands that he will be adjudicated guilty of each offense to which he has pleaded guilty and will be deprived of certain rights, such as the right to hold public office, to serve on a jury, to possess firearms, and in some states, the right to vote. Further, the defendant understands that if he is not a citizen of the United States, a plea of guilty may result in removal from the United States, denial of citizenship, and denial of admission to the United States in the future. The defendant understands that pursuant to section 203(b) of the Justice For All Act, the Bureau of Prisons or the Probation Office will collect a DNA sample from the defendant for analysis and indexing. Finally, the defendant understands that the Government reserves the right to notify any state or federal agency by which he is licensed, or with which he does business, as well as any current or future employer of the fact of his conviction.

SATISFACTION OF FEDERAL CRIMINAL LIABILITY; BREACH

The defendant's guilty plea, if accepted by the Court, will satisfy the federal criminal liability of the defendant in the District of Connecticut as a result of his participation in violating a requirement imposed in a pretreatment program approved pursuant to the Clean Water Act—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit, which forms the basis of the information in this case. The defendant understands that if, before sentencing, he violates any term or condition of this agreement, engages in any criminal activity, or fails to appear for sentencing, the Government may void all or part of this agreement. If the agreement is voided in whole or in part, the defendant will not be permitted to withdraw his plea of guilty.

NO OTHER PROMISES

The defendant acknowledges that no other promises, agreements, or conditions have been entered into other than those set forth in this plea agreement, and none will be entered into unless set forth in writing, signed by all the parties.

Thomas J. Murphy, Esq.
 July 8, 2014
 Page 8

This letter shall be presented to the Court, in open court, and filed in this case.

Very truly yours,

DEIRDRE M. DALY
 UNITED STATES ATTORNEY


 HAROLD H. CHEN
 ASSISTANT UNITED STATES ATTORNEY



 PETER W. KENYON
 SPECIAL ASSISTANT U.S. ATTORNEY

The defendant certifies that he has read this plea agreement letter and its attachment(s) or has had it read or translated to him, that he has had ample time to discuss this agreement and its attachment(s) with counsel and that he fully understands and accepts its terms.


 THOMAS H. FARIA
 The Defendant

7/8/14
 Date

I have thoroughly read, reviewed and explained this plea agreement and its attachment(s) to my client who advises me that he understands and accepts its terms.


 THOMAS J. MURPHY, ESQ.
 Attorney for the Defendant

7/8/14
 Date


 JAMES T. COWDERY, ESQ.
 Attorney for the Defendant

7-8-14
 Date

Thomas J. Murphy, Esq.
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STIPULATION OF OFFENSE CONDUCT

The defendant, Thomas H. Faria ("Faria" or "the defendant"), and the Government stipulate to the following offense conduct that gives rise to the defendant's agreement to plead guilty to the information:

Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals ("Faria Limited") was and is a company with a factory at 170 Broad Street in New London, Connecticut, that manufactures a wide range of over-the-counter pharmaceutical creams, ointments, and toothpastes. Faria Limited purchased Sheffield Laboratories in 1986 and changed its operating name to Sheffield Pharmaceuticals.

Faria, the company's president and chief executive officer, assumed control over the company in April 2003 after his father's death. As president and chief executive officer, Faria has been responsible for Faria Limited's operations since April 2003. In addition, Faria held all of the company's voting shares from April 30, 2008, until May 13, 2014.

The City of New London Water Pollution Control Facility, together with the New London public sewer system, constituted a publicly owned treatment works ("POTW") within the meaning of the Clean Water Act and Connecticut's pretreatment program as approved by the Environmental Protection Agency. Under the Clean Water Act, Connecticut's pretreatment program prohibits the discharge of industrial wastewater to POTWs without a permit issued by the Connecticut Department of Energy and Environmental Protection ("CT DEEP"). The failure to obtain a CT DEEP permit prior to discharging industrial wastewater to a POTW constitutes a violation of a requirement of a pretreatment program approved under Title 33, United States Code, Section 1342(b)(8).

From at least as early as April 2003 to July 2011, Faria Limited discharged industrial wastewater from its manufacturing operations to the New London POTW without a permit and in violation of Connecticut's approved pretreatment program. During this time period, Faria Limited lacked an approved wastewater treatment system and performed no regular monitoring of its discharges of industrial wastewater pursuant to a CT DEEP permit.

After becoming the company's president and chief executive officer in April 2003, Faria learned through his own employees that Faria Limited was discharging industrial wastewater without the permit required by the Clean Water Act. Despite knowing that Faria Limited needed to apply for and obtain a wastewater permit from CT DEEP, Faria continued to operate the factory and to discharge industrial wastewater to the New London POTW without a permit.

The parties stipulate that from at least as early as April 2004 to May 2011, the defendant, as president and chief executive officer of Faria Limited, knowingly violated and caused to be violated a requirement imposed in a pretreatment program approved under section 1342(a)(3) and 1342(b)(8) of Title 33, United States Code—that is, the discharge of industrial wastewater into the New London POTW without a permit.

Thomas J. Murphy, Esq.

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The written stipulation above is incorporated into the preceding plea agreement. The defendant and the Government reserve their rights to present additional relevant offense conduct to the attention of the Court in connection with sentencing. Both parties agree that although this stipulation provides a sufficient factual basis for the guilty plea, both parties will provide the Court with additional relevant evidence for sentencing. Specifically, the defendant will submit materials that provide mitigating circumstances for the offense conduct, whereas the Government will submit materials that provide aggravating circumstances for the offense conduct.




THOMAS H. FARIA

The Defendant



HAROLD H. CHEN

ASSISTANT U.S. ATTORNEY



THOMAS J. MURPHY, ESQ.

Attorney for the Defendant



PETER W. KENYON

SPECIAL ASST. U.S. ATTORNEY



JAMES T. COWDERY, ESQ.

Attorney for the Defendant

Page 1

UNITED STATES DISTRICT COURT
District of Connecticut

UNITED STATES OF AMERICA

JUDGMENT IN A CRIMINAL CASE

v.

CASE NO. 3:14CR149 AWT
USM NO: 22573-014

THOMAS H. FARIA

Harold H. Chen
Peter West Kenyon
Assistant United States Attorneys

Thomas P. Murphy, Esquire
James T. Cowdery, Esquire
Defendant's Attorneys

THE DEFENDANT pled guilty to **Count 1 of an Information**. Accordingly, the defendant is adjudged guilty of the following offense:

<u>Title & Section</u>	<u>Nature of Offense</u>	<u>Offense Concluded</u>	<u>Count</u>
33:1319(c)(2)(A)	Knowing violation of a requirement imposed in a pretreatment program approved under the Clean Water Act	July 2011	1

The following sentence is imposed pursuant to the Sentencing Reform Act of 1984. The court concluded that a "non-Guidelines sentence," as opposed to a "Guidelines sentence," see United States v. Crosby, 397 F.3d 103, 112 n.6 (2d Cir. 2005), was appropriate in this case.

PROBATION

The defendant shall be placed on probation for a total term of 3 years. In determining the advisory Guidelines range, the court departed pursuant to Guidelines §2Q1.3(b)(4). The court then imposed a non-Guidelines sentence after concluding that such a sentence was necessary in order for the court to place proper weight on the fact that (i) the defendant's dominant motive for committing the offense and (ii) the defendant's post-offense acknowledgment of the wrongfulness of his conduct are mitigating factors that outweigh (iii) the need to impose a sentence that serves the purposes of general deterrence and promoting respect for the law.

Because the defendant is currently an Oregon resident, he will be supervised in the District of Oregon during his term of probation.

The mandatory and standard conditions of probation, as attached, are imposed. In addition, the following special conditions are imposed:

1. The defendant shall pay the fine that is being imposed in this case, at a rate of not less than \$1,000 per month.
2. The defendant shall perform 300 hours of community service at the rate of 100 hours per year.

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CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments as follows.

Special Assessment: \$100.00, due immediately
Fine: \$30,000.00, to be paid at the rate of not less than \$1,000 per month, during the defendant's period of probation, on the 10th day of each calendar month, commencing in April, 2015.
Restitution: \$0.00

It is further ordered that the defendant will notify the United States Attorney for this district within 30 days of any change of name, residence or mailing address until all fines, restitution, costs and special assessments imposed by this judgment are paid.

February 13, 2015

Date of Imposition of Sentence

/s/ AWT
 Alvin W. Thompson
 United States District Judge
 Date: February 17, 2015

Judgment received by U.S. Marshal at _____ on _____.

Print name _____
 Signature _____
 Deputy Marshal

**CERTIFIED AS A TRUE COPY
 ON THIS DATE _____
 ROBERTA D. TABORA, Clerk
 BY: _____
 Deputy Clerk**

CONDITIONS OF PROBATION

In addition to the Standard Conditions listed below, the following indicated (■) Mandatory Conditions are imposed:

MANDATORY CONDITIONS

- (1) The defendant shall not commit another federal, state or local offense;
- (2) For a felony, the defendant shall (A) make restitution, (B) give notice to victims of the offense pursuant to 18 U.S.C. section 3555, or (c) reside or refrain from residing, in a specified place or area, unless the court finds on the record that extraordinary circumstances exist that would make such a condition plainly unreasonable, in which event the court shall impose one or more of the discretionary conditions set forth under 18 U.S.C. section 3563(b);
- (3) The defendant shall not unlawfully possess a controlled substance;
- (4) For a domestic violence crime as defined in 18 U.S.C. section 3561(b) by a defendant convicted of such an offense for the first time, the defendant shall attend a public, private, or non-profit offender rehabilitation program that has been approved by the court, in consultation with a State Coalition Against Domestic Violence or other appropriate experts, if an approved program is available within a 50-mile radius of the legal residence of the defendant;
- (5) The defendant shall refrain from any unlawful use of a controlled substance and submit to one drug test within 15 days of release on probation and at least two periodic drug tests thereafter for use of a controlled substance;
- (6) The defendant shall (A) make restitution in accordance with 18 U.S.C. sections 2248, 2259, 2264, 2327, 3663, 3663A, and 3664; and (B) pay the assessment imposed in accordance with 18 U.S.C. section 3013;
- (7) The defendant shall notify the court of any material change in the defendant's economic circumstances that might affect the defendant's ability to pay restitution, fines or special assessments;
- (8) If the court has imposed a fine, the defendant shall pay the fine or adhere to a court-established payment schedule;
- (9) (A) In a state in which the requirements of the Sex Offender Registration and Notification Act (see 42 U.S.C. §§ 16911 and 16913) do not apply, a defendant convicted of a sexual offense as described in 18 U.S.C. § 4042(c)(4)(Pub. L. 105-119, § 115(a)(8), Nov. 26, 1997) shall report the address where the defendant will reside and any subsequent change of residence to the probation officer responsible for supervision, and shall register as a sex offender in any State where the person resides, is employed, carries on a vocation, or is a student; or
- (B) In a state in which the requirements of Sex Offender Registration and Notification Act apply, a sex offender shall (i) register, and keep such registration current, where the offender resides, where the offender is an employee, and where the offender is a student, and for the initial registration, a sex offender also shall register in the jurisdiction in which convicted if such jurisdiction is different from the jurisdiction of residence; (ii) provide information required by 42 U.S.C. § 16914; and (iii) keep such registration current for the full registration period as set forth in 42 U.S.C. § 16915;
- (10) The defendant shall cooperate in the collection of a DNA sample from the defendant.

While on probation, the defendant also shall comply with all of the following Standard Conditions:

STANDARD CONDITIONS

- (1) The defendant shall not leave the judicial district or other specified geographic area without the permission of the court or probation officer;
- (2) The defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
- (3) The defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
- (4) The defendant shall support the defendant's dependents and meet other family responsibilities (including, but not limited to, complying with the terms of any court order or administrative process pursuant to the law of a state, the District of Columbia, or any other possession or territory of the United States requiring payments by the defendant for the support and maintenance of any child or of a child and the parent with whom the child is living);
- (5) The defendant shall work regularly at a lawful occupation unless excused by the probation officer for schooling, training, or other acceptable reasons;
- (6) The defendant shall notify the probation officer at least ten days prior to any change in residence or employment, or if such prior notification is not possible, then within five days after such change;
- (7) The defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, or administer any controlled substance, or any paraphernalia related to any controlled substance, except as prescribed by a physician;
- (8) The defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered, or other places specified by the court;
- (9) The defendant shall not associate with any persons engaged in criminal activity, and shall not associate with any person convicted of a felony unless granted permission to do so by the probation officer;
- (10) The defendant shall permit a probation officer to visit the defendant at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view by the probation officer;
- (11) The defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
- (12) The defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
- (13) The defendant shall pay the special assessment imposed or adhere to a court-ordered installment schedule for the payment of the special assessment.

Upon a finding of a violation of probation, I understand that the court may (1) revoke supervision and impose a term of imprisonment, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

These conditions have been read to me. I fully understand the conditions and have been provided a copy of them.

(Signed) _____
Defendant

_____ Date

U.S. Probation Officer/Designated Witness

_____ Date

Drug Establishments Current Registration Site

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](https://twitter.com/intent/tweet?text=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)



e [EMAIL \(MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](mailto:?subject=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&body=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

New Search (default.cfm)

Search Results for **Sheffield**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sheffield Pharmaceuticals LLC	1210513	151177797	MANUFACTURE	170 Broad Street, New London, Connecticut (CT) 06320, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

[Previous](#) [Next](#)

Data Current through: Thursday, Oct 17, 2019

[Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)](#)

Verified
11/14/20
NB



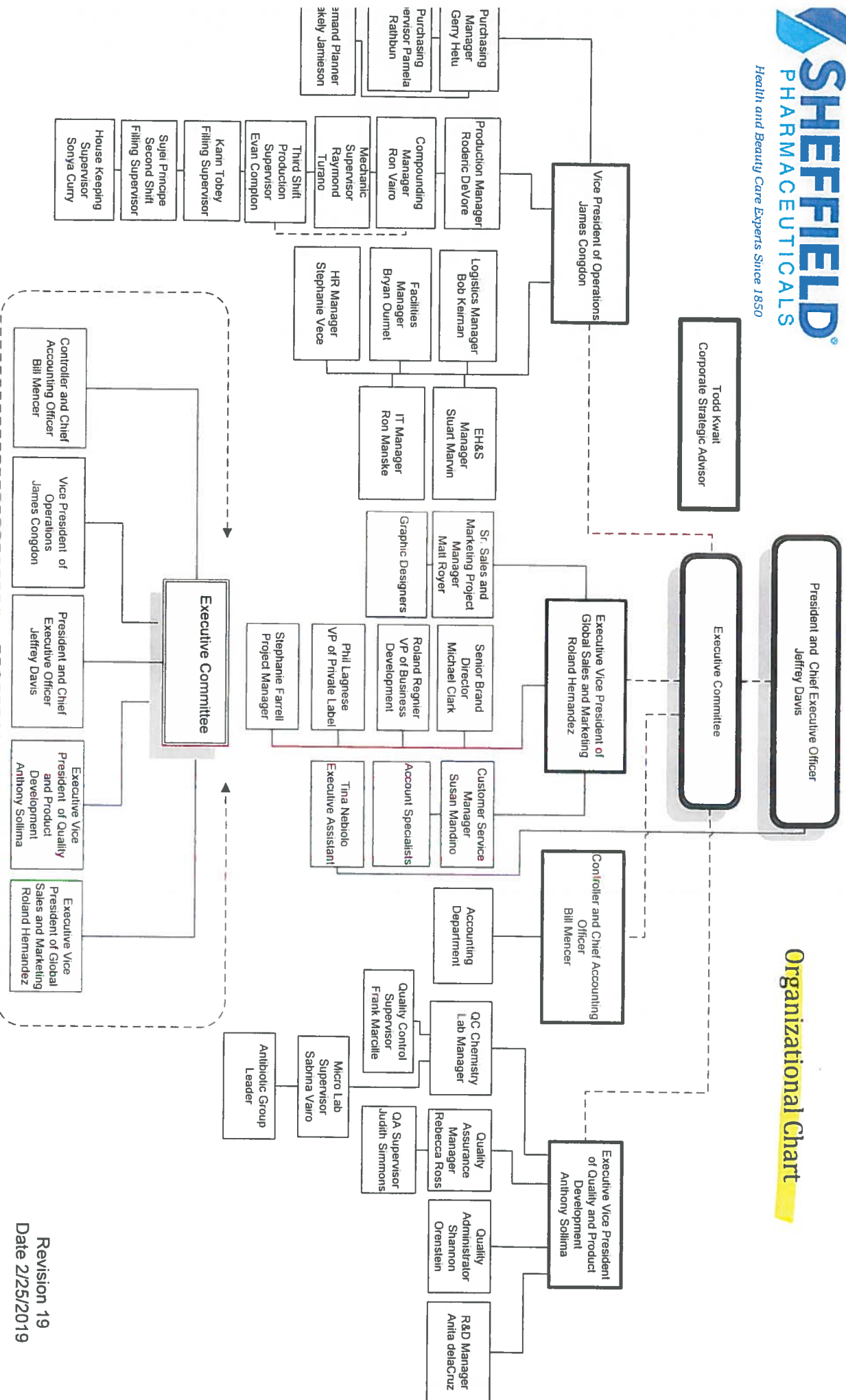
Owners	% Ownership
Sue Faria –Voting member of LLC Marshview Circle East Sandwich, MA 02537-1041	16
Diane Faria- Beach Drive SE, Unit 2003 St. Petersburg, FL 33701-3957	16
Gail Faria- Lagoon Drive Fort Meyers, FL 33905-2500	14
Nancy Faria - West Main Road, Apt Middletown RI 02842	16
Thomas H. Faria - Neath Avenue Las Vegas, NV 89178	38

Sheffield Pharmaceutical Officers

Jeffrey Davis CEO and President	N/A
Anthony Sollima CSO and EVP of Regulatory Affairs	N/A

Jeffrey Davis
3/27/2020

Organizational Chart



NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. NV5212592

Application/License No. _____

Sheffield Pharmaceuticals, LLC, doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
170 Broad Street New London, CT 06320, as
Address of Applicant/Principal
PRINCIPAL, and Merchants Bonding Company (Mutual), a
Surety Company
 corporation organized under the laws of the state of Iowa
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
6700 Westown Parkway, West Des Moines, IA 50266 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of **TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00)**, for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 30, 2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of March, 2020.

APPLICANT/PRINCIPAL

SURETY

COMPANY

Jeff Davis
Sheffield Pharmaceuticals, LLC
Authorized Representative

Jeffrey Davis, President & CEO

Russell C Comer II
Merchants Bonding Company (Mutual)
Surety Company's Representative

Russell C Comer II, Attorney-in-fact
print name



SIGNED and SEALED in the presence of:

Anthony Sollima
Witness Anthony Sollima, Chief Scientific Officer

SIGNED and SEALED in the presence of:

Jessica Mendonca
Witness Jessica Mendonca

William D. Mencer
Witness William D. Mencer, Controller

Denise Chianese
Witness Denise Chianese

Countersigned by:

1721

MERCHANTS
BONDING COMPANY™
POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Russell C Corner II

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

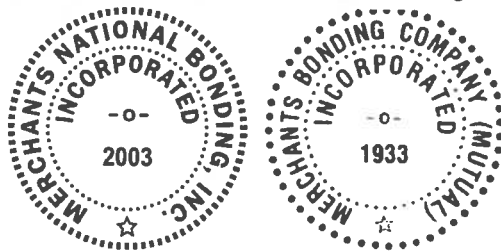
"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 30th day of March, 2020.

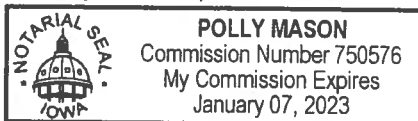


MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.

By *Larry Taylor*
President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 30th day of March, 2020, before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.



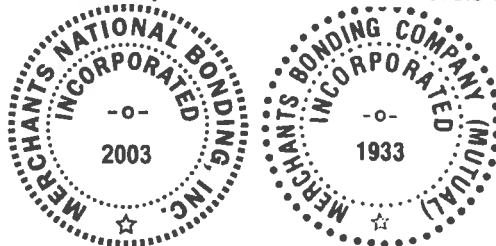
Polly Mason

Notary Public

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 30th day of March, 2020.



William Warner Jr.
Secretary

MERCHANTS BONDING COMPANY™

MERCHANTS BONDING COMPANY (MUTUAL) • P.O. BOX 14498 • DES MOINES, IOWA 50306-3498
PHONE: (800) 678-8171 • FAX: (515) 243-3854

ADDENDUM TO BOND

This Addendum is in reference to the bond(s) to which it is attached.

Merchants Bonding Company (Mutual) ("Merchants") deems the digital or electronic image of Merchants' corporate seal below affixed to the bond(s) to the same extent as if a raised corporate seal was physically stamped or impressed upon the bond(s). The digital or electronic seal below shall have the same force and effect as though manually fixed to the bond(s).

All terms of the bond(s) remain the same.

Signed and effective March 23, 2020.

MERCHANTS BONDING COMPANY (MUTUAL)



By: _____

Larry Taylor

Larry Taylor, President

Office of the Secretary of the State of Connecticut

I, the Connecticut Secretary of the State, and keeper of the seal thereof,
DO HEREBY CERTIFY, that articles of organization for

SHEFFIELD PHARMACEUTICALS, LLC

a domestic limited liability company, were filed in this office on September 29, 1999.

Articles of amendment for FARIA LIMITED LLC, changing its name to SHEFFIELD
PHARMACEUTICALS, LLC, were filed on August 12, 2014.

Articles of dissolution have not been filed, and so far as indicated by the records of this office such
limited liability company is in existence.



Secretary of the State

Date Issued: March 25, 2020

Office of the Secretary of the State of Connecticut

I, the Connecticut Secretary of the State, and keeper of the seal thereof,
DO HEREBY CERTIFY, that articles of organization for

SHEFFIELD PHARMACEUTICALS, LLC

a domestic limited liability company, were filed in this office on September 29, 1999.

Articles of amendment for FARIA LIMITED LLC, changing its name to SHEFFIELD
PHARMACEUTICALS, LLC, were filed on August 12, 2014.

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limited liability company is in existence.



Secretary of the State

Date Issued: March 25, 2020



STATE OF CONNECTICUT

DEPARTMENT OF REVENUE SERVICES

03/25/2020

SHEFFIELD PHARMACEUTICALS, LLC
170 BROAD ST

NEW LONDON, CT 06320-5313

CT Tax Registration #: 9852971000

Status Letter

To Whom It May Concern,

Based on the information currently available, the State of Connecticut, Department of Revenue Services (DRS) records indicate that the entity listed above has filed all of its tax returns and paid all taxes that were reported due.

This status letter is valid until: **04/24/2020**

In providing this letter, DRS is **not** making any representations that it has conducted an audit examination or otherwise concluded that the information reported on the tax return(s) is correct. In the future, DRS may determine that additional tax returns were required or, to the extent allowed by law, make an assessment against the taxpayer and its successors or assigns.

This is not a Tax Clearance Certificate under Connecticut General Statutes §§12-294, 12-424, 12-546, or 12-707.

Sincerely,
Department of Revenue Services

DRS-033 (New 07/16)

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions regarding this registration can be emailed to the Drug Control Division at dcp.drugmanufacturers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information current. The email on your account will be used for all correspondence from this office.

You can update your address and email address or print a duplicate certificate by logging into your account with your User Id and Password at www.elicense.ct.gov. If you need your User Id and/or Password, please email dcp.online@ct.gov.

Mailing address:

SHEFFIELD PHARMACEUTICALS
FARIA LIMITED, LLC D/B/A SHEFFIELD
LABORATORIES
170 BROAD ST
NEW LONDON, CT 06320-5313

Email on file to be used for receiving all notices from this office:

anthony.sollima@sheffieldpharma.com

STATE OF CONNECTICUT ♦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

SHEFFIELD PHARMACEUTICALS

170 BROAD ST

NEW LONDON, CT 06320-5313

has satisfied the qualifications required by law and is hereby issued a

MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: No Rx Legend Drugs: Yes Non Rx Legend Drugs: Yes Medical Devices: Yes Cosmetics: Yes

Medical Gases/Oxygen: No

Durable Medical Equipment (DME): No

Number of Chemists: 14

Registration #: CSM.0000094

Effective Date: 08/05/2019

Expiration Date: 06/30/2020

verify online at www.elicense.ct.gov

Michelle Seagull, Commissioner

ACCOMPLISHED OPERATIONS EXECUTIVE

- Highly accomplished executive leader with experience defining the strategic direction and growth of a cGMP compliant pharmaceutical company; responsible for shepherding the organization through a period of massive growth, from \$6MM in annual revenue to over \$43MM today.
- After becoming CEO in 2016, led and managed the debt restructure and recapitalization of Sheffield Pharmaceuticals and returned the company to profitability after multi-year losses,
- Maintains executive responsibility for all facets of operations, spanning Sales & Marketing, Finance, Regulatory affairs, Manufacturing, Supply Chain, Logistics, Environmental Health and Safety, Engineering, and Facilities; leverages competencies in Lean Manufacturing, Logistics, Global Sourcing, Corporate Strategy Development & Execution, Environmental Health & Safety, and regulatory requirements to achieve all corporate objectives.
- Experienced in the oversight of teams of Pharmaceutical professionals dedicated to product quality, safety and job ownership.
- Skilled in matters of corporate finance and the performance of due diligence in support of M&A transactions; assumes an active role in direct sales, as well as the management of quoting and bidding processes.
- Successfully leverages a winning combination of excellent management skills, team building expertise, and a "hands-on approach" to deliver results that exceed customer expectations.

Core Skills and Competencies

Corporate Executive Leadership – Sales and Marketing – Finance – Corporate Strategy - Operations Management
 Training & Development – Inventory Management – Production Systems – OSHA Compliance – FDA compliance
 Process Control Improvement – Equipment Procurement – Purchasing - cGMP Environments – EPA Regulations
 Lean Manufacturing – Logistics – Environmental Health & Safety - Due Diligence – M&A Transactions

Career Achievements

- **SHEFFIELD PHARMACEUTICALS.** Led and managed a \$16 million debt restructure and recapitalization in 2016, and returned the company to sustained profitability after Multiyear losses in 2016
- **SHEFFIELD PHARMACEUTICALS.** Led and managed Sheffield's first branded product launch, establishing a successful national CPG brand with distribution in over 25,000 retail doors
- **SHEFFIELD PHARMACEUTICALS.** Responsible for 600% growth and the transformation of the company from a small toiletries manufacturer to a cGMP compliant pharmaceutical manufacturer, building revenue from \$6MM to over \$43MM.
- **SHEFFIELD PHARMACEUTICALS.** Creates optimal strategies to achieve corporate goals using skills and knowledge in Lean Manufacturing, Finance, Sales and Marketing, Logistics, Global sourcing, Corporate Strategy Development & Execution, Environmental Health & Safety, and regulatory requirements
- **SHEFFIELD PHARMACEUTICALS.** Led the due diligence and execution of the acquisition of Lee Pharmaceuticals, a \$7MM company, in California; managed the relocation and integration of a 100,000 square foot factory to Connecticut within 6 weeks.
- **PHOENIX ENVIRONMENTAL.** Gained invaluable expertise in the use of Gas Chromatograph and High Performance Liquid Chromatography techniques, as well as wet chemistry techniques.
- **DAVIS PHARMACEUTICALS.** Coordinated and led training for new employees to build competencies in materials handling and safety.

Relevant Professional Experience

SHEFFIELD PHARMACEUTICALS, New London, CT

(1997-Present)

PRESIDENT & CHIEF EXECUTIVE OFFICER (2016 TO PRESENT)

A demonstrated record of success and achievement at this leading pharmaceutical company, marked by a promotion to a position of increased influence, authority, and accountability. Served as Operations Manager from 2004 to 2014 before promotion to an executive role as COO in 2014 and CEO in 2016.

- Designs and deploys corporate Vision, Mission, and Strategy, with the goal of maximizing sustainable business growth while overseeing a \$40MM operating budget.
- Oversees all operations and business activities to ensure they produce the desired results and are consistent with the overall vision, strategy and mission
- Communicates with Board of Directors

CHIEF OPERATING OFFICER (2014 TO 2016)

As Chief Operating Officer, fulfills a key leadership role in a direct and indirect capacity over multiple functions, including Sales, Sales Support, Quality, Procurement, Logistics, HR, Engineering, and Finance. Advanced to this role to provide support to a new CEO and serve a major role in operations management and as a member of the executive leadership team.

- Leverages expertise in Lean Manufacturing, Logistics, Global sourcing, Corporate Strategy Development & Execution, Environmental Health & Safety, and regulatory requirements to build optimal strategies to achieve corporate goals.
- Led Multi-year effort to Automate all production operations
- Led the due diligence and acquisition of a \$7MM company in California, managing the relocation and integration of a 100,000 square foot factory to Connecticut within 6 weeks.
- Eliminated 10% of freight costs through a strategic partnership with a 3PL to serve the needs of a key account.
- Reduced energy costs by 25% through the implementation of a \$3MM consolidated heat and power system.
- Lowered Out of Stock incidents by 50% while simultaneously reducing obsolescence by 20% through a new sales forecasting and production planning system.

PRODUCTION MANAGER (1997 TO 2014)

Leads all vision, strategy, and execution for first and second shift production at this leading pharmaceutical company, with a focus on maintaining compliance with FDA, OSHA, EPA, and GMP requirements governing manufacturing operations. Leads the management of all inventory, while assuming a hands-on role hiring and training new employees.

- Serves as the architect of standard operating procedures governing production processes and maintenance.
- Serves an integral role addressing and resolving process control issues; works closely with production personnel to resolve production issues with the potential to impact productivity and output.
- Envisioned, developed, and deployed validation methods for new product processing and cleaning.
- Responsible for all purchasing and installation of production equipment.
- Contributed additional service and expertise facilitating the development of methods of manufacture and new product development.

PHOENIX ENVIRONMENTAL, Manchester, CT

(1993-1997)

GC/HPLC ANALYST

Led a full spectrum of analysis responsibilities at this provider of high quality testing services for soils, water, sludge, and solids, gaining invaluable expertise in the operation and maintenance of a variety of laboratory equipment.

- Leveraged the use of Gas Chromatograph and High Performance Liquid Chromatography techniques, as well as wet chemistry techniques, to analyze soil and water samples.
- Analyzed metals using atomic absorption.

Early Career

Quality Control Analyst and Production Supervisor, DAVIS PHARMACEUTICALS, Plainfield, CT (1986-1994)

Education

Bachelor of Science Degree in Environmental Science – Eastern Connecticut State University

Cum Laude, GPA 3.69

Laboratory Assistant in the Geographic Information Systems Laboratory

Master of Science in Operations Management- Rensselaer Polytechnic Institute

Technical Proficiencies

Microsoft Office Suite, Various ERP software, Microsoft SharePoint, SAP B1,

14B

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALE LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler or ☒ Ownership Change (Provide current license number if making changes: WH 02274)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Sun Pharmaceutical Industries, Inc.

Physical Address: 29 Dunham Road

City: Billerica State: MA Zip Code: 01821

Telephone Number: 781-687-1219 Fax Number: 781-275-2634

Toll Free Number: 800-221-7554

E-mail: Susan.Tennent@sunpharma.com Website: www.sunpharma.com

Facility Manager: Daniel O'Brien

Professional qualifications and experience of facility manager: See Attached Resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☒

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☒ No ☐

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: West Pharmaceutical Services

Address: 530 Herman O. West Drive, Exton, PA 19341

Name: Nipro PharmaPackaging

Address: 1200 North 10th Street, Millville, NJ 08332

Name: Alcami Carolins

Address: 4620 Creekstone Drive, Durham, NC 27703

Name: VWR Inc.

Address: 100 Matsonford Road, Radnor, PA 19087

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?

Yes ☒ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?

Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?

Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Daniel O'Brien
Print Name of Authorized Person

13 May 2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Sun Pharmaceutical Industries, Inc.

Mailing Address: 2 Independence Way

City: Princeton State: NJ Zip: 08540

Telephone: 609-720-9200 Fax: 609-514-1155

Contact Person: Zvi Albert, CFO

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

- a) Not Applicable - 100% owned by Sun Pharmaceutical Industries, Inc.
- | | |
|------|------------------|
| Name | Business Address |
|------|------------------|
- b) _____
- | | |
|------|------------------|
| Name | Business Address |
|------|------------------|
- c) _____
- | | |
|------|------------------|
| Name | Business Address |
|------|------------------|
- d) _____
- | | |
|------|------------------|
| Name | Business Address |
|------|------------------|

- 2) Provide the number of shares issued by the corporation. N/A
- 3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporationList of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

The attached summary document provides the explanation of disciplinary actions for Sun Pharmaceutical Industries, Inc. Please note that these actions pertain to the parent company, not this facility location.

C. J. Praveen
June-08-2020

Praveen Devakadaksham, Director-Regulatory Affairs & Business Continuity

Sun Pharmaceutical Industries, Inc.

(predecessor company being Caraco Pharmaceutical Laboratories, Ltd)

(a) FDA/2009

On June 25, 2009, FDA, in conjunction with the Dept of Justice, issued a Warrant of Arrest in rem for the seizure of all product manufactured at the Detroit, MI manufacturing location, alleging that the product was adulterated as it was manufactured under conditions not meeting cGMP. Caraco entered in a Voluntary Consent Decree on Sept 29, 2009. This applied only to product manufactured at the 1150 Elijah McCoy, Detroit, MI 48202 facility and did not impact any product held for sale which was manufactured by a third party. No fines were imposed as a part of the Voluntary Consent Decree. Caraco proceeded to remediate the issues presented by the FDA with the aid of consultants. Caraco received permission from the FDA to re-start manufacturing operations at its 1150 Elijah McCoy, Detroit, MI 48202 facility in August of 2012 and has subsequently been classified as an acceptable manufacturing operation during FDA inspections conducted in 2013 and 2014. Post classified for operation by FDA, due to business consolidation, the site was closed and no more in operation and deregistered from USFDA facility established list in the fiscal year 2015-16.

(b) Maine Pharmacy Board/2010

On June 3, 2010, Maine Board of Pharmacy, during its board meeting, preliminarily denied Caraco Pharmaceutical Laboratories, Ltd in Wixom, MI an application for a wholesale distributor license. It was determined that Caraco Pharmaceutical Laboratories, Ltd had a restricted FDA permit. Pursuant to the board's Rule Chapter 12, section 4 (1), (3), (5), and (6), if the applicant had a license from any other jurisdiction suspended, revoked, cancelled, or otherwise restricted for any reason the board had the right to deny application. The matter was forwarded to the Maine Department of Attorney General. The Attorney General found that Caraco Pharmaceutical Laboratories, Ltd accurately responded to questions on its application and Caraco was not required by law or rule of the board to report the FDA warning since the FDA warning is different from the disciplinary action of a "warning" under Maine Pharmacy Laws and legally was not a matter that needed to be reported in response to license/ disciplinary questions in the application. At the end of the FDA's inspection of Caraco's facilities in Wixom, MI and Detroit, MI, it was noted that Caraco may resume manufacturing operation as reflected in a letter from the FDA to Caraco dated August 27, 2012. Maine Board of pharmacy granted a wholesale distributor license (WH70001485) to the Wixom, MI facility.

(c) Florida/2012

On August 28, 2012, the Florida Department of Business & Professional Regulation found Caraco Pharmaceutical Laboratories, Ltd located at wixom, MI (license# 26:213) in violation of Section 499.0121 of FL Statutes (2010) and Rule 61F-12.012 of the FL Administrative Code for failure to provide a complete audit trail of all transaction regarding the receipt and distribution of Prescription Drugs. Caraco Pharmaceutical Laboratories, Ltd failed to include the recipient's specific Florida license number on the packing slips. Enhancements were made to the internal data interface and implemented an enhanced packing slip which now accompanies the physical shipment. A fine of \$10,000 was imposed and paid on September 6, 2012. The license was not encumbered.

(d) **Georgia/2014**

On June 10, 2014, the Georgia Board of Pharmacy cited Caraco Pharmaceutical Laboratories, Ltd (license #PHWH002689) at the facility in Wixom, Michigan for shipping without a valid permit. The license was not renewed and consequently lapsed in June 2013. The facility continued to ship into Georgia past expiration. A fine was paid for the violation (docket# 2014-0061} and the license was re-instated.

(e) **Alabama/2014**

On September 15, 2015 an order issued by the Alabama State Board of Pharmacy in response to Sun Pharmaceutical Industries, Inc.'s initial application for licensure with Alabama State for the facility located at 270 Prospect Plains Road, Cranbury, NJ 08512. The fine was paid and permit is granted. Please note that this order was issued due to a sister Sun site, located at 31060 Oak Creek Dr., Wixom, MI 48393, having received a violation from the state of Georgia in June 2014.

(f) Refer most recent settlement from ALABAMA (As separate attachment)

IN THE MATTER OF:)	BEFORE THE ALABAMA STATE
)	
SUN PHARMACEUTICAL)	BOARD OF PHARMACY
INDUSTRIES, INC.)	
)	CASE NO: 19-L-0144
Private Label Distributor Applicant)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Sun Pharmaceutical Industries, Inc. (hereinafter referred to as "Sun") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Sun through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows

1. The Board finds that Sun has violated Code of Alabama (1975) § 34-23-32(a) and/or (f) by distributing drug products in the State of Alabama during 2018 and/or 2019 without first having obtained your permit.

2. Sun's Application for a Private Label Distributor – Virtual shall be granted subject to compliance with the terms of this Consent Order.

3. Sun shall pay to the Board an administrative fine in the amount of Twenty-One Thousand dollars (\$21,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of

payment to the Board shall not be dischargeable in bankruptcy and Sun shall not attempt to discharge the same in any bankruptcy proceeding.

4. That Sun expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Sun further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

5. By execution of this Consent Order, Sun hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and complaint.

6. That Sun agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

7. That Sun acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Sun acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this

Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 3rd day of October, 2019.

SUN PHARMACEUTICAL INDUSTRIES, INC.

BY: 

ITS: Chief Executive Officer


Luther Maxwell Dorr, Jr., attorney for Sun
Pharmaceutical Industries, Inc.

DONE this the 8th day of October, 2019.

ALABAMA STATE BOARD OF PHARMACY

By: 

Kenny Sanders, R.Ph., President

By: 

James S. Ward
Its Attorney

WARD & COOPER, LLC.
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF OWNERSHIP, WHICH MERGES:

"PHARMALUCENCE, INC.", A DELAWARE CORPORATION,

"INSITE VISION INCORPORATED", A DELAWARE CORPORATION,

"MUTUAL PHARMACEUTICAL COMPANY, INC.", A DELAWARE CORPORATION,

WITH AND INTO "SUN PHARMACEUTICAL INDUSTRIES, INC." UNDER THE NAME OF "SUN PHARMACEUTICAL INDUSTRIES, INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE ON THE THIRTIETH DAY OF MARCH, A.D. 2020, AT 4:26 O'CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF OWNERSHIP IS THE FIRST DAY OF APRIL, A.D. 2020 AT 12:01 O'CLOCK A.M.



7893212 8100M
SR# 20202465390

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 202687150
Date: 03-31-20

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SUN PHARMACEUTICAL INDUSTRIES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF MARCH, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SUN PHARMACEUTICAL INDUSTRIES, INC." WAS INCORPORATED ON THE ELEVENTH DAY OF MARCH, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.



7893212 8300

SR# 20202087743

You may verify this certificate online at corp.delaware.gov/authver.shtmlA handwritten signature in black ink, appearing to read "JBULLOCK", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 202570546

Date: 03-12-20

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7



1743

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors
SCHEDULES VI			

ISSUED TO

SUN PHARMACEUTICAL INDUSTRIES, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

NEW

831014



CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors
SCHEDULES VI			

ISSUED TO

SUN PHARMACEUTICAL INDUSTRIES, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

NEW

Dan O'Brien

Mobile: 603-882-1234 | Worcester, MA 01601
 Email: dan@danobrien.com
 dan@danobrien.com

Work Experience

Site Head // 2018 -> Now

Responsible for lyophilized and terminally sterilized parenteral drug manufacturing, packaging, and distribution operations for SUN Pharma Billerica site as well as topical dermatology production, packaging, and distribution at SUN Pharma Wilmington site.

Senior Director of Engineering // 2014 -> 2018

Responsible for all aspects of Pharmaceutical Engineering at Pharmaceutical's two aseptic lyophilisation facilities, maintaining production at an older classic cleanroom facility while completing migration and initial product launch from new Isolator facility.

Director Manufacturing/Engineering // 2007 -> 2014

Responsible for parenteral manufacturing operations as well as engineering improvements and capability upgrades including multiple line lyophilizer installations ranging from traditional operator loading/unloading and loading systems. Scoped, designed and executed projects ranging from \$2 million to \$40 million in capital cost. Provided oversight for multiple successful FDA/FDA inspections and worked with regulatory agencies prior to multiple product launches.

Profile

Over 20 years of experience in pharmaceutical manufacturing and engineering. Strong background in aseptic processing, lyophilization, and packaging operations. Proven ability to lead teams and manage complex projects.

Expertise

Pharmaceutical Engineering
 Lyophilization
 Aseptic Processing
 Parenteral Manufacturing
 Cleanroom Management
 FDA/FDA Inspections
 Project Management

Education

BS Operations, Northeastern University

MS Operations, Worcester Polytechnic Institute

Post Graduate Study Aseptic Technology,
 University of Tennessee

Drug Establishments Current Registration Site

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDE
R/DRLS/GETDRLS.CFM\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=
HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](https://twitter.com/intent/tweet/?text=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)



 [EMAIL \(MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDA
TA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](mailto:?subject=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&body=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

New Search (default.cfm)

Search Results for **Sun Pharmaceutical Industries, Inc.**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sun Pharmaceutical Industries, Inc.	3009395771	139261648	ANALYSIS; LABEL; MANUFACTURE; PACK;	29 Dunham Rd, Billerica, Massachusetts (MA) 01821, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

[Previous](#)[Next](#)

Data Current through: Wednesday, Apr 8, 2020

[Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)](#)

Verified
MS
6/9/20

Drug Establishments Current Registration Site

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](https://twitter.com/intent/tweet?text=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

in [LINKEDIN \(HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM&TITLE=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&SOURCE=FDA\)](https://www.linkedin.com/sharearticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&title=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&source=fda)

p [PIN IT \(HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM&DESCRIPTION=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE\)](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm&description=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE)



e [EMAIL \(MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](mailto:?subject=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&body=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

PRINT

New Search (default.cfm)

Search Results for **Sun Pharmaceutical Industries, Inc.**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sun Pharmaceutical Industries, Inc.	3009395771	139261648	ANALYSIS; LABEL; MANUFACTURE; PACK;	29 Dunham Rd, Billerica, Massachusetts (MA) 01821, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

[Previous](#)[Next](#)

Data Current through: Tuesday, Jun 9, 2020

[Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)](#)

Sun Pharmaceutical Industries, Inc.
29 Dunham Road Billerica, MA 01821

Corporate Officers

Abhay Gandhi
Chief Executive Officer, North America
2 Independence Way
Princeton, NJ 08540
Abhay.Gandhi@sunpharma.com

Zvi Albert
Vice President - Finance & Treasurer
2 Independence Way
Princeton, NJ 08540
Zvi.Albert@sunpharma.com

Michele Visosky
Vice President - Head of Human Resources, North America
3 Skyline Drive, Suite 120
Hawthorne, NY 10532
Michele.Visosky@sunpharma.com

Daryl LeSueur
Vice President - Head of Operations, North America Topicals, Liquids and Injectables
14 Terminal Road
New Brunswick, NJ 08901
Daryl.LeSueur@sunpharma.com

Jayesh Shah
Vice President - Procurement
1 Commerce Drive
Cranbury, NJ 08512
Jayesh.Shah@sunpharma.com

Please note that the updated home state (Massachusetts) license for Sun Pharmaceutical Industries, Inc. is expected to be received shortly. We have attached the current Pharmalucence, Inc. license and will forward the updated license showing the new company name as soon as it arrives.

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114



CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO

PHARMALUCENCE, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

MBW

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

RENEWAL

835913



CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO

PHARMALUCENCE, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

MBW

RENEWAL

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

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ISSUED TO

PHARMALUCENCE, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

MBW

COMMISSIONER OF PUBLIC HEALTH

FILE COPY

RENEWAL

835913



NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane

Reno, NV 89509

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0512872

Application/License No. _____

Sun Pharmaceutical Industries, Inc., doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
29 Dunham Road, Billerica, MA 01821, as
Address of Applicant/Principal
PRINCIPAL, and Harco National Insurance Company, a
Surety Company
 corporation organized under the laws of the state of Illinois
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Newark Center, 20th Floor Newark, NJ 07102 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of Twenty Five Thousand and 00/100 Dollars (25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 7, 2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this
7 day of May, 2020.

APPLICANT/PRINCIPAL

Sun Pharmaceutical Industries, Inc.

[Signature]
 Authorized Representative

SURETY COMPANY

Harco National Insurance Company

[Signature]
 Surety Company's Representative
 Mary Y. Volmar, Attorney-in-fact
 print name

SIGNED and SEALED in the presence of:

[Signature]
 Witness

[Signature]
 Witness

SIGNED and SEALED in the presence of:

[Signature]
 Witness Krystal Karnes

[Signature]
 Witness Bonnie Rice

Countersigned by:

N/A
 Nevada Resident Agent

POWER OF ATTORNEY

Bond # 0512872

HARCO NATIONAL INSURANCE COMPANY**INTERNATIONAL FIDELITY INSURANCE COMPANY**

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

KATHY L. DELGRECO, RACHEL A. CHAVERIAT, MICHELLE LUTE-HEATHERLY, SANDRA KING, JESSICA FREDERICK, JULIE KARNES, REBECCA J. HOBBS, BONNIE L. RICE, MARIAH SMITH, MARY Y. VOLMAR, ANDREA ALMAN, JOY M. WILLIAMS, CAROLYN E. WHEELER, VICKI NORRIS, LORETTA M. JONES, SANDY
Knoxville, TN

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

***RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2018



STATE OF NEW JERSEY
County of Essex

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

STATE OF ILLINOIS
County of Cook



On this 31st day of December, 2018, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.



IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, May 07, 2020

Irene Martins, Assistant Secretary



State of Nevada
Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

RE: Notification of Merger of Pharmalucence, Inc. License #WH02274 into Sun
Pharmaceutical Industries, Inc.

Dear Sir/Madam:

This notification is to advise you that Pharmalucence, Inc., a SUN PHARMA Company, an FDA approved facility engaged in manufacturing and distribution of prescription drug products under license # WH02274 has merged into its parent company, Sun Pharmaceutical Industries, Inc., effective April 1, 2020.

Although Pharmalucence has changed its name to Sun Pharmaceutical Industries, Inc., the company's location, corporate officers, company management, designated representative, facility operations, and procedures & policies will not change. Pharmalucence was previously a wholly owned subsidiary of Sun Pharmaceutical Industries, Inc. Therefore, we kindly request that the current permit be transferred from Phamalucence to Sun Pharmaceutical Industries, Inc. at 29 Dunham Road, Billerica, MA 01821.

Enclosed is an application form, as required for this merger. If you have any questions or require additional information, you may contact me as the Designated Representative at 781-687-1242 (email: daniel.obrien@sunpharma.com), or contact my colleague Praveen Devakadaksham, Director-Regulatory Affairs & Business Continuity at 781-687-1232 (email: praveen.devakadaksham@sunpharma.com).

Sincerely,

A handwritten signature in blue ink, appearing to read "Daniel O'Brien".
05 June 2020

Daniel O'Brien
Site Head

14C

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☒ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Zydus Pharmaceuticals (USA) Inc.

Physical Address: 73 Rate 31 North

City: Pennington State: NJ Zip Code: 08534

Telephone Number: 609-730-1900 Fax Number: 609-730-1998

Toll Free Number: _____

E-mail: lpastor@zydususa.com Website: www.zydususa.com

Facility Manager: Louis M. Pastor Jr.

Professional qualifications and experience of facility manager: A.V. P. Trade operations
16yrs experience in managing pharmaceutical operations for generic companies

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☐ Other: Pharmacy warehouses, mail order facilities

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☒ Controlled Substances (include copy of DEA) (via a 3PL)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA?

(If yes, provide a copy of your FDA registration)

Yes ☒ No ☐

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: _____ N/A
Address: _____

Name: _____ N/A
Address: _____

Name: _____ N/A
Address: _____

Name: _____ N/A
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____ N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Keenley, CEO + president
Print Name of Authorized Person Date 1/7/2020

Board Use Only

Date Processed: _____

Amount: 500.00

Page 5

Establishment Inspection Report

Zydus Pharmaceuticals USA Inc

Pennington, NJ 08534-3601

FEI: 3008444937

EI Start: 05/09/2014

EI End: 05/15/2014

REPORT LIMITED TO SUMMARY OF FINDINGS

This surveillance Establishment Inspection (EI) of Zydus Pharmaceuticals USA, Inc. was initiated pursuant to NWJ FY'14 workplan and the Memo dated 10/1/13 from CDER, Office of Compliance, Division of Safety Compliance (DSC), Office of Scientific Investigations and FACTS Assignment Identification #8711891, Operation Identification #7016138. It was conducted in accordance with Compliance Program (CP) 7353.001, Postmarketing Adverse Drug Experience (PADE) Reporting Inspections.

The previous EI from 2/10-22/11 was classified VAI (Voluntary Action Indicated) and resulted in a one point FDA Form 483 for not ensuring adverse drug experience information from foreign affiliates were received and reviewed for reporting to FDA.

On 5/9/14, I, Investigator Loretta Nemchik, presented my credentials and issued an FDA Form 482, Notice of Inspection, to Prashant J. Desai, Vice-President of Operations, at Zydus Pharmaceuticals USA, Inc. Mr. Desai stated he had the authority to receive the Notice and is responsible for business development and all technical operations including Regulatory Affairs (RA) and the supply chain in the United States. Joseph Renner, Chief Executive Officer (CEO), was not available at the initiation of the EI. Mr. Desai reports to Mr. Renner (**Exh 1, Organization chart**). Mr. Renner reports to Pankaj Patel, the Chairman and Managing Director of the firm's **parent company, Cadila Healthcare Ltd., headquartered in India (Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, Gujarat, India)**. Also in attendance was Srinivas Gurram, Head of Regulatory Affairs at Zydus USA. Mr. Gurram is responsible for all RA and Pharmacovigilance (PV) activities in the U.S. and coordinates RA and PV activities between Cadila headquarters and FDA. Mr. Gurram administratively reports to Mr. Desai and has dotted line reporting responsibility to Mr. K. Anand, President of Global QA & RA for Cadila Healthcare. Mr. Anand reports to Mr. P. Patel (**Exh 2, Global Pharmacovigilance Organization Structure chart**).

Zydus Pharmaceuticals USA continues to perform PV reporting of all 15-day ADE reports for drugs approved for market in the United States (**Exh 3, Total ANDA Filing and Approval Status for the US Market list**). Periodic Adverse Drug Experience Reports (PADERs) and Annual Reports are compiled and submitted by the global headquarters (**Exh 4, Global PV contact information**). The firm identified two major changes that occurred since the previous EI: 1) implementation of a global PV system on 2/28/11; and 2) a new subsidiary, Neshor Pharmaceuticals USA LLC (St. Louis, MO). The current EI covered ADE reporting from 5/1/12 to 5/1/14. Per assignment instructions, Warfarin Sodium Tablets USP [ANDA 40-663] and Metformin Hydrochloride [ANDA 77-064] were the primary focus of the review. Written procedures, 15-day reports, periodic reports, complaints, training records, vendor agreements, co-marketing safety agreements and ANDA annual reports were reviewed along with corrections to the previous FDA Form 483.

I observed the correction made in response to the previous FDA Form 483 appeared adequate. I identified no significant objectionable conditions during the current EI and issued no FDA Form 483. However, at close-out with Mr. Renner I discussed two examples of inaccurate awareness

Establishment Inspection Report

Zydus Pharmaceuticals USA Inc
 Pennington, NJ 08534-3601

FEI: 3008444937
 EI Start: 05/09/2014
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dates, ten PADERs in 2012 submitted late, an unclear reporting responsibility in one Safety Agreement and one serious, unexpected literature case where the article submitted was not in English.

Written Procedures. I observed the firm has written procedures to cover the surveillance, receipt, evaluation and reporting of PADE reports to FDA. I collected copies of local and global procedures including: Adverse Drug Experience (ADE) Reporting Responsibilities Between The Medical Affairs Company (TMAC) and Zydus Pharmaceuticals USA Inc.; Pharmacovigilance Data Exchange Between Global PV Cell and Local Affiliates; and Case Processing on PvNET (**Exh 5, SOP-202-A-04; Exh 6, CHL/GPV/SOP/011 version 01; Exh 7 CHL/PV/WI-022 version 00**). I also collected a list of procedures related to global PV (**Exh 8**). The procedures collected appeared adequate.

Domestic PADEs. Standard Operating Procedure (SOP) 202-A-04 (**Exh 5**) outlines the ADE collection, processing, follow-up and reporting process. As identified during the previous EI, the firm contracts with The Medical Affairs Company (TMAC) located at 125 Town Park Drive, Suite 450, Kennesaw, GA to receive, evaluate, process, and follow-up on all domestic ADEs (**Exh 9, TMAC contact information**). Upon receipt TMAC enters the information into the IRMS (Information Request Management System) database which assigns a unique identification number (firm [ZYD], year [14], AE and three digit sequential number). TMAC classifies the report as either a 15-day or periodic report and generates a MedWatch 3500A form which is sent via e-mail to Zydus USA's RA Department (Mr. Gurram or Dhaval Desai, RA Analyst). The RA Department submits a paper copy of the completed MedWatch form to FDA for 15-day reports or submits the periodic report information to the global headquarters for inclusion in the periodic report. Hardcopy source documents are maintained by TMAC. If Zydus USA directly receives a report of an adverse event the RA Department forwards the information to TMAC who processes it as described above. On a monthly basis TMAC prepares a report of all ADEs and forwards it to the RA Department for reconciliation.

Mr. Gurram provided lists of ADE cases from 5/1/12 to 5/1/14 for all products approved in the U.S. According to Mr. Gurram the list was generated from the information entered into the TMAC database. I estimated there were 160 ADEs from 5/1/12 to the end of 2012; 351 ADEs from 2013; and 135 ADEs thus far in 2014. Per assignment instructions, I focused on two products, Warfarin Sodium Tablets USP (ANDA 40-663) and Metformin Hydrochloride (ANDA 77-064). I also focused on serious and unexpected event reports for all products during this time period. I reviewed a total of 34 ADEs (8 metformin, 10 warfarin and all serious, unexpected ADEs from 2013). I observed no significant deficiencies. I observed two ADEs with inaccurate initial receipt dates but this did not cause any late reporting to FDA (**Exh 10, ZYD-13-AE-172 case documents; Exh 11, ZYD-13-AE-004 case documents**).

Foreign PADE Reporting. SOP 202-A-04 (**Exh 5**) and global PV procedures CHL/GPV/SOP/011 version 01 (**Exh 6**) and CHL/PV/WI-022 version 00 (**Exh 7**) outline the ADE collection, processing,

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follow-up and reporting process for ADEs from foreign sources. Non-U.S. ADEs are received by the parent company or its local affiliates (e.g., Zydus France, Zydus Healthcare Brazil, Zydus Pharma Japan) and are sent to global PV. Upon receipt global PV enters the information into the PvNET database which assigns a unique identification number (country of origin [FR], Zydus, six digit automatically generated number). Only global PV has entry access to the PvNET database. Global PV classifies the report and if serious and unexpected and the same active ingredient is approved for marketing in the U.S. global PV sends the report to the RA Department at Zydus USA. The RA Department then forwards the information to TMAC who processes it as described under the domestic PADE heading above. Source documents are scanned into the PvNET database. On a monthly basis global PV prepares and sends a reconciliation report to Zydus USA.

I asked Mr. Gurram if the firm had received any foreign spontaneous cases that were reportable in the United States from 5/1/12 to 5/1/14. He stated the firm had not received any. I requested global PV to perform a search of the PvNET database and generate a list of all serious and unexpected ADEs from foreign sources between 1/1/13 to 5/1/14 that were reportable in the United States. I observed the list provided contained only three literature cases from Zydus Spain (**Exh 12**). I reviewed the three cases and observed that case ES-ZYDUS-002056-01 (**Exh 13**) did not contain a copy of the article translated to English. I informed Mr. Gurram at the time and Mr. Renner at close-out that the PADE Compliance Program states that literature articles should be submitted in English. I also observed that the other two cases ES-Zydus-002186 and ES-Zydus-001463 did not contain a copy of the articles. Mr. Gurram stated that the full articles are not always available.

Since I observed that the list contained no spontaneous foreign cases reportable in the U.S., I informed the firm that I was going to request that global PV perform a database search for all serious cases submitted from Zydus France from 1/1/13 to the present. Although I intended to watch the search process remotely via a computer link, upon my return to the firm the following day Mr. Gurram stated that due to the time difference global PV already performed the search and that there was one spontaneous, reportable case (FR-Zydus-003413, Mirtazapine) from Zydus France. This case was received by global PV on 5/12/14 and Zydus USA was in the process of submitting it to FDA. I requested that global PV perform another search of the database so I could observe the search process remotely via a computer link. I requested a source country of France and the same time period. I then requested and watched global PV filter the results to include only spontaneous (source = company) events. I selected four cases (FR-Zydus-002505, FR-Zydus-002517, FR-Zydus-002524, FR-Zydus-002526) involving drugs approved for marketing in the U.S. to review and observed no serious and unexpected events.

Scientific Literature Reports. According to SOP 202-A-04 (**Exh 5, pg 12**), Global PV performs literature searches on a weekly basis then enters any cases found into the PvNET database. Serious, unexpected cases for U.S. reporting are sent on a MedWatch form via e-mail to the Zydus USA RA Department who does the reporting to FDA by paper submission.

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Mr. Gurram provided a copy of the search performed by Global PV for reportable literature cases from 1/1/13 to 5/1/14. I did not review any individual cases for reporting to FDA. However, I reviewed three literature cases from a previous search done to evaluate the receipt and reporting of ADEs from foreign sources and observed that the one case containing a copy of the literature article did not include an English translation of the article.

Postmarketing/IND Studies. Mr. Gurram stated the firm does not do any post-marketing studies. However, I observed that SOP 202-A-04 addresses how to handle adverse events pertaining to clinical trials (**Exh 5, pgs 12 & 13**).

Periodic Safety Reports. SOP 202-A-04 addresses PADER preparation and submission (**Exh 5, pgs 16-18**). I observed there is also a global PV procedure that addresses PADERs (**Exh 8**) but did not request it for review. Periodic reports are compiled and submitted electronically to FDA by global PV. The RA Department at Zydus USA composes a cover letter that is submitted with each PADER.

Mr. Desai provided a list that identifies the dates PADERs were filed in 2012, 2013 and 2014 for all products approved for marketing in the United States (**Exh 14, PADER list**). I estimated there were 285 PADERs filed during this time period. I observed 10 of these were filed late and all 10 were in the May-June 2012 time period (**Exh 15, Cover letters corresponding to late PADERs**). I brought this to the firm's attention. Mr. Gurram stated that the firm had a problem submitting the information electronically during that time period and global PV needed to scan all of the information onto a disc and send the disc to FDA. He attributed the delays to the increased time it took to scan the information. I suggested if a delay occurs in the future the cover letter submitted with the PADER should reflect the reason for the delay.

I reviewed the electronic versions of five randomly selected PADERs. I reviewed the contents and observed no deficiencies. I also selected 17 non-serious or expected ADE cases from the ADE case lists previously provided and verified they were reported in PADERs.

ANDA Annual Reports. The ANDA Annual Reports are also compiled and submitted electronically to FDA by global PV. I reviewed the content and submission dates for the 2012 and 2013 ANDA Annual Reports for metformin and warfarin. I observed no deficiencies.

Waivers. Mr. Gurram stated the firm had no waivers from FDA.

PV Agreements. Zydus Pharmaceuticals USA Inc. is the distributor of multiple products for which it is not the marketing authorization (MHA) holder (**Exh 16, Distributor non-application holder product list**). Mr. Gurram stated that the Zydus name is on the label for each of the distributed products. I reviewed the Quality Agreements the firm has with Emcure (acetazolamide), Abbvie/Abbott (clarithromycin, divalproex, fenobibrate, fenofibric acid, paricalcitol, potassium chloride), and Navinta (famotidine). I observed no deficiencies with the agreements made with

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Emcure and Abbvie/Abbott. However, I informed Mr. Gurram at the time of my review and Mr. Renner at close-out that the agreement with Navinta did not directly state who was responsible for reporting ADEs to FDA (**Exh 17 pg 11, Navinta Quality Agreement dated 2/12/10**). Mr. Renner stated the firm would review the agreement and update it for clarity if necessary. Mr. Gurram stated the firm has no PV/Quality Agreement with Nasur (oxycodone, potassium chloride) since it is a subsidiary of Zydus USA. Mr. Gurram stated that there is no agreement between Zydus USA and global PV at Cadila. However, there is an SOP that governs PV data exchange (**Exh 6**).

I also reviewed the Master Services Agreement between TMAC and Zydus USA (**Exh 18**). I observed no deficiencies.

Complaint Files. Standard Operating Procedure (SOP) 203-A-03 (**Exh 19**) outlines the complaint receipt, review, processing, follow-up, investigation and reporting process. The firm contracts with TMAC to handle receive and categorize complaints as a complaint and/or an ADE. Investigating and reporting the results is the responsibility of the RA Department at Zydus USA in association with Cadila Healthcare Ltd., the manufacturer of Zydus USA's marketed drug products. If a complaint claims ineffectiveness of the drug product TMAC processes it as both an ADE and a complaint. All complaints are investigated. TMAC typically requests return of the product. If the complainant returns the product and the quantity returned is sufficient the manufacturing facility tests the product to ensure it meets release specifications. If the product is not returned or the quantity returned is not sufficient but the lot number is known the manufacturing site tests a retain. If the lot number is not known no testing is performed by the manufacturing site. The manufacturing site sends the results of the complaint investigation to the RA Department of Zydus USA who communicates the results to the complainant.

I requested and reviewed the list of open product complaints. I observed that any complaint on the list that claimed ineffectiveness also had an ADE number. I correlated the ADE numbers on the open complaint list to the ADE lists provided by the firm. I observed no deficiencies. I observed three complaints since the previous EI in the FACTS database flagged as follow-up at the next EI. None involved unlisted (unexpected) events and therefore did not require a 15-day report.

ADMINISTRATIVE DATA

Inspected firm: Zydus Pharmaceuticals USA Inc
 Location: 73 Route 31 N
 Pennington, NJ 08534-3601
 Phone: 609-730-1900
 FAX: 609-730-1999
 Mailing address: 73 Route 31 N
 Pennington, NJ 08534-3601

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Dates of inspection: 5/9/2014, 5/12/2014, 5/13/2014, 5/14/2014, 5/15/2014

Days in the facility: 5

Participants: Loretta Nemchik, Investigator

EXHIBITS COLLECTED

1. Zydus Pharmaceuticals USA Inc. Organizational Chart, 1 pg
2. Global PV Organization Chart, 1 pg
3. Product list, 22 pgs
4. Global PV contact information, 1 pg
5. Adverse Drug Experience (ADE) Reporting Responsibilities between the Medical Affairs Company (TMAC) and Zydus Pharmaceuticals USA Inc. SOP 202-A-04 effective 12/20/13, 74 pgs
6. Pharmacovigilance Data Exchange Between Global PV Cell and Local Affiliates, SOP CHL/GPV/SOP/011 version 01, 9 pgs
7. Case Processing on PvNET, SOP CHL/PV/WI-022 version 00, 39 pgs
8. List of global PV procedures, 2 pgs
9. TMAC contact information, 2 pgs
10. ADE case ZYD-13-AE-172 selected pages, 4 pgs
11. ADE case ZYD-13-AE-004 selected pages, 7 pgs
12. ADEs from foreign affiliates 1/1/13-4/30/14, 1 pg
13. ADE case ES-Zydus-002056-01 selected pages, 10 pgs
14. 2012-2014 PADER submission list, 16 pgs
15. Submission cover letters of late PADERs, 11 pgs
16. List of distributed non-MHA products, 4 pgs
17. Quality Agreement between Zydus USA and Navinta, 17 pgs
18. Master Services Agreement between Zydus USA and TMAC, 10 pgs
19. Product Complaint Handling Responsibilities Between the Medical Affairs Company (TMAC) and Zydus Pharmaceuticals USA Inc. SOP 203-A-03 effective 12/20/13, 45 pgs

ATTACHMENTS

FDA Form 482, Notice of Inspection, dated 5/9/14 issued to Prashant J. Desai, 3 pgs

CDER, Office of Compliance Assignment Memo dated 10/1/13, 3 pgs

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Pennington, NJ 08534-3601

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05/15/2014



Loretta Nemchik, Investigator



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Jersey District Office
Central Region
Voorhees Resident Post
1020 Laurel Oak Road – Suite 203
Voorhees, NJ 08043
Telephone: 856-783-1398

June 19, 2014

Mr. Joseph Renner, CEO
Zydus Pharmaceuticals USA Inc.
73 Route 31 N.
Pennington, NJ 08534-3601

*Pushout
Shini
Mike
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Dear Mr. Renner,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at the above address on May 9th, 2014 through May 15th, 2014 by Investigator Loretta Nemchick on behalf of the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21CFR Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to contact:

Louise Miranda
U.S. Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, New Jersey 07054
Telephone: 973-331-4903

Sincerely,

Nerizza B. Guerin
Supervisory Consumer Safety Officer

NBG/gjp
Attachment

WARNING LETTER

Cadila Healthcare Limited

MARCS-CMS 584856 – OCTOBER 29, 2019

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Pankaj R. Patel

Chairman

Cadila Healthcare Limited

Zydus Tower, Satellite Cross Roads

Ahmedabad 380015 Gujarat

India

Issuing Office:

Center for Drug Evaluation and Research

10903 New Hampshire Avenue,

Silver Spring, MD 20993

United States

Warning Letter 320-20-05

October 29, 2019

Dear Mr. Patel:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Cadila Healthcare Limited, FEI 3002984011, at 419 & 420 8a Village-Moraiya, Ahmedabad, from April 22 to May 3, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP,

your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your May 24, 2019 response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following.

1. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).

Your cleaning procedure for non-dedicated equipment, including your (b)(4), is inadequate. Our investigators observed multiple (b)(4), used in the production of potent and non-potent compounds, marked as clean and containing residues of what appeared to be different products. The residues were observed on the back of the (b)(4), after product change-over cleaning. The (b)(4) system of your equipment interacts with the interior of the equipment in which products are processed.

Significant equipment flaws and cleaning deficiencies resulted in cross-contamination between your drug products. For example, you lacked provisions for inspecting or cleaning the area behind the (b)(4).

After our inspection, your firm observed residues in additional non-dedicated equipment and confirmed the recovery of multiple active ingredients through swab samples and visible (b)(4) residues collected from product-contact surfaces. For example:

- Equipment ID #CH/PM/013 – (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/PP/028 – (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/TS/013 - (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/MC/TAB/1999/19 - (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/MC/TAB/2004/176 - (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.

After our inspection, your firm also tested reserve samples of selected batches to assess the potential for cross contamination. Your testing confirmed the presence of active ingredients manufactured in numerous samples tested, including but not limited to:

- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets

- Appropriate improvements to your cleaning validation program with special emphasis on incorporating conditions identified as worst case in your drug manufacturing operation. This should include but not be limited to identification and evaluation of all worst-case:

- drugs with higher toxicities
- drugs with higher drug potencies
- drugs of lower solubility in their cleaning solvents
- drugs with characteristics that make them difficult to clean
- swabbing locations for areas that are most difficult to clean
- maximum hold times before cleaning

In addition, describe the steps that must be taken in your change management system before introduction of new manufacturing equipment or a new product.

- A summary of updated SOPs that ensure an appropriate program is in place for verification and validation of cleaning procedures for products, processes, and equipment. Also, include a copy of your cleaning validation report once completed.

2. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your investigations into failures during periodic qualification of the (b)(4) cycles are inadequate. For example, investigation DC/2018/381 was initiated on June 9, 2018 for a failure during periodic requalification of the (b)(4) used for (b)(4) Injection (b)(4) ml in (b)(4) ml vial. The required F_0 was not achieved and there was significant (b)(4) variation for at least (b)(4). You concluded that the root cause was improper (b)(4). As part of the impact assessment, you evaluated the qualification reports for other products that utilize the same (b)(4) and concluded that there was no impact on other (b)(4) products. Therefore, you did not extend the CAPA to other products.

However, in March 2019, you initiated investigation DC/2019/190 and DC/2019/195 because of another failure during the periodic requalification of the same (b)(4) used for the (b)(4) of (b)(4) Injection (b)(4) ml in (b)(4) ml vial. Again, several sensors did not achieve the required F_0 , and one did not reach the (b)(4) temperature. In addition, at the end of the incubation, the biological indicators at multiple locations in the (b)(4) showed microbiological growth. This resulted in the recall of (b)(4) batch of (b)(4) Injection, USP, (b)(4) mg per (b)(4) ml ((b)(4) mg per ml), due to lack of (b)(4) assurance.

In this instance you also concluded that the root cause was improper (b)(4). There was no assurance that your assessment of other (b)(4) products using this (b)(4) was thorough and that adequate CAPA were identified and implemented. In addition, your investigation did not sufficiently address why your originally validated cycle parameters were not met and why the process fell out of a state of control.

Your response adds that there has been some drift in the calibration of the built-in (b)(4) that control the (b)(4) cycle since 2017. However, your response lacks an assessment of the adequacy of the (b)(4) calibration standards, as you acknowledge in the response that the variation observed is within your established acceptance criteria. Also, calibration of (b)(4) was verified as part of your original investigation.

According to your firm's investigation report there have been seven deviations during the periodic requalification of this (b)(4) in the past two years. Recurrent failures suggest that you have not adequately identified the root cause and lack

- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets

As a result of these inspectional findings your firm initiated a recall of numerous batches manufactured in your (b)(4) #CH/TS/013 (dedicated to potent compounds).

In your response, you committed to corrective and preventive actions (CAPA) for non-dedicated equipment, including revisions to cleaning procedures, mechanical changes to equipment to prevent (b)(4), cleaning validation for all processing equipment, and further testing to analyze reserve samples of batches manufactured using (b)(4) to quantify the potential carryover of previous products.

Your firm's review concluded that the significant cross-contamination identified by your firm does not represent a risk to patients.

Your response is insufficient. Your response stated that any potential residue that enters the (b)(4) and contaminates the next drug product can produce a nearly uniform distribution in the (b)(4) and that (b)(4) steps minimize localization of carryover residue. Your rationale is not scientifically sound in that cross-contamination cannot be assumed to be uniformly distributed.

In addition, your response described failure modes that may have contributed to the accumulation of residues in the (b)(4). But you failed to explain when the cross-contamination involving numerous products started and why it had not been detected. Your response also stated that testing for cross-contamination in the products provides good assurance that any carryover is detected. However, reserve sample testing alone is insufficient to mitigate associated risks. The extent of the cross-contamination found suggests a lack of assurance that products meet appropriate standards for identity, quality, purity and safety.

In response to this letter provide the following:

- Your CAPA plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment/facility infrastructure, and improved systems for ongoing management review.
- A comprehensive, independent retrospective assessment of your cleaning effectiveness to evaluate the scope of cross-contamination hazards and recalls initiated to determine if additional batches were affected. This should include, but not be limited to:
 - Identification of any inadequacies of cleaning procedures and practices for each piece of manufacturing equipment used to manufacture more than one product.
 - Any updates to your investigation regarding the identity of residues, other manufacturing equipment that may have been improperly cleaned, and an assessment whether additional cross-contaminated products may have been released for distribution.
- A CAPA plan based on the retrospective assessment, that includes appropriate remediations to your cleaning processes and practices, and timelines for completion. Provide a detailed summary of vulnerabilities in your process for lifecycle management of equipment cleaning. Describe improvements to your cleaning program, including enhancements to cleaning effectiveness; improved ongoing verification of proper cleaning execution for all products and equipment; and all other needed remediations.

conditions.

In response to this letter, provide the following:

- A risk assessment of all contamination hazards with respect to your aseptic processes, equipment, and facilities, including an independent assessment that includes, but is not limited to:
 - All human interactions within the (b)(4) area
 - Equipment placement and ergonomics
 - Air quality in the (b)(4) area and surrounding room
 - Facility layout
 - Personnel Flows and Material Flows (throughout all rooms used to conduct and support sterile operations)
- A comprehensive, independent retrospective review of all batches that remain within expiry in the U.S. market, which incorporates the knowledge of hazards gained from your risk assessment. Include any additional actions you intend to initiate because of the retrospective review.

4. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

Your environmental and personnel monitoring program is deficient. For example, your procedures allowed personnel performing aseptic interventions (e.g., (b)(4)) in the (b)(4) area to have (b)(4) colony-forming units (CFU) on their (b)(4) without triggering an appropriate investigation. During our inspection, a firm official indicated that your firm does not consider the (b)(4) to be an (b)(4) intervention and operators are only held to ISO 7 limits.

The (b)(4) step in your operation is a critical aseptic intervention, and it is manually intensive. Our inspection noted significant aseptic technique breaches during performance of this intervention.

Your firm's response is inadequate. We acknowledge your commitment to conduct a protocol-based assessment to evaluate the adequacy of limits of viable monitoring based on the classification of the area and the criticality of the operation. However, your response did not include a retrospective review of your personnel monitoring data to identify the instances in which operators held to ISO 7 limits conducted activities in the (b)(4) area, and if the (b)(4) limits were exceeded. Growth observed on (b)(4) samples taken from personnel performing any activities within the (b)(4) area should, at a minimum, lead to trending and assessment, and could trigger further actions and investigation.

In response to this letter, provide the following for products that remain within expiry in the U.S. market:

- A risk assessment of personnel and environmental monitoring data since April 2017, including but not limited to identification of adverse trends or acute findings, and any potential impact on marketed products. Place special emphasis on data from your aseptic processing rooms, as well as any adverse trends that indicate any loss of environmental control in your facility's overall suite of cleanrooms.
- A detailed update to the CAPAs implemented and their current status in light of your decision to permanently close down the injectable manufacturing lines that serve the U.S. market.
- Describe how your firm will ensure continued accountability and responsibility for all products remaining in distribution from this facility (e.g. complaint evaluation, stability testing, handling of reserve samples, post-marketing reporting activities, OOS investigations and document retention). State who will be performing these duties and procedures that will be followed for all marketed products.

Cessation of Sterile Drug Manufacturing for U.S. Marketed Products

(b)(4) assurance.

In response to this letter provide the following:

- A comprehensive retrospective, independent review of all batches (b)(4) with this (b)(4) that were distributed in the U.S. market and remain within expiry. This review should include, but not be limited, to:
 - Review of your (b)(4) parameters, including time and (b)(4) settings to ensure a (b)(4) assurance level of (b)(4) or more.
 - Evaluations of F-value and Z-value data and any related assumptions; (b)(4); D-value determinations and population enumerations for each biological indicator lot; and commercial batch data to determine whether (b)(4) cycles used for your products were complete/adequate.
- A comprehensive and independent assessment of your system for investigating deviations, and failures. Your CAPA plan should include, but not be limited to, improvements in investigations, root cause analysis, written procedures, staff competencies (e.g., evaluating potential root causes), and quality unit oversight. Also, include your process for evaluating CAPA plan effectiveness.

3. Your firm failed to follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

Poor Aseptic Behavior

Operators displayed poor aseptic practices during aseptic set-up and filling operations. For example:

- Operators leaned over the open bag of sterilized stoppers. These bags are subsequently introduced into the stopper chute. Also, the operator's hands passed over the sterile stopper chute and over sterilized stoppers already added into the chute. Notably, your procedures specifically prohibit personnel leaning over the product or sterilized containers and closures.
- Operators used (b)(4) Restricted Access Barrier Systems ((b)(4)RABS) (b)(4) to pick up sterile forceps and remove fallen vials. During that intervention, the (b)(4) extend over open vials without clearing them. According to your procedures, (b)(4)RABS (b)(4) are sterilized only (b)(4). Your firm's staff confirmed that these (b)(4) cannot be considered sterile during this extended use period.

Inadequate Cleanroom Design and Smoke Study Deficiencies

Your stopper chute leans (b)(4) of the filling line during stopper loading operations thereby creating turbulence as the air flows (b)(4) filters (b)(4) the chute.

In addition to this inadequate design, your smoke studies performed for your (b)(4) areas also lacked simulation of multiple critical interventions that occur during aseptic manufacturing operations.

Thorough smoke studies are essential to evaluate the effects of such interventions on unidirectional airflow and to ensure design modifications are made wherever necessary.

The (b)(4) area is critical because sterile product is exposed and therefore vulnerable to contamination. Your aseptic filling process should be designed, and operations executed, to prevent contamination hazards to your sterile product. The flawed design of the filling line and execution of the aseptic operations promoted influx of contamination into the critical filling areas.

Your firm's response is inadequate. You did not provide a thorough evaluation of all batches produced under inadequate

In your October 2, 2019 communication, you informed the FDA that you would permanently cease production of injectable drug products for the United States. It is important to note that full remediation of the related CGMP violations cited will be necessary if you decide to resume the manufacturing of injectable drug products at this site, or if any successor firm assumes responsibility over the site's operation in the future. In your response include your action plan for transferring any of your injectable drug products to other facilities. Notify this office in writing if you decide to revisit your decision and resume manufacturing injectable drugs for the U.S. in the future.

Additional Guidance on Aseptic Processing

See FDA's guidance document *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice* to help you meet the CGMP requirements when manufacturing sterile drugs using aseptic processing at <https://www.fda.gov/media/71026/download> (<https://www.fda.gov/media/71026/download>).

Repeat Violations at Facility

In previous warning letters (WL 320-11-015 and 320-16-05), FDA cited similar CGMP violations. You proposed specific remediation for these violations in your response. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b). This also allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new drug applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in the FDA refusing admission of articles manufactured at Cadila Healthcare Limited, 3002984011, at 419 & 420 8a Village-Moraiya, Ahmedabad, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (<mailto:CDER-OC-OMQ-Communications@fda.hhs.gov>) or mail your reply to:

Rebecca Parrilla, M.S.

Compliance Officer

U.S. Food and Drug Administration

White Oak Building 51, Room 4235

10903 New Hampshire Avenue

Silver Spring, MD 20993

Please identify your response with FEI 3002984011.

Sincerely,

/S/

Francis Godwin

Director

Office of Manufacturing Quality

Office of Compliance

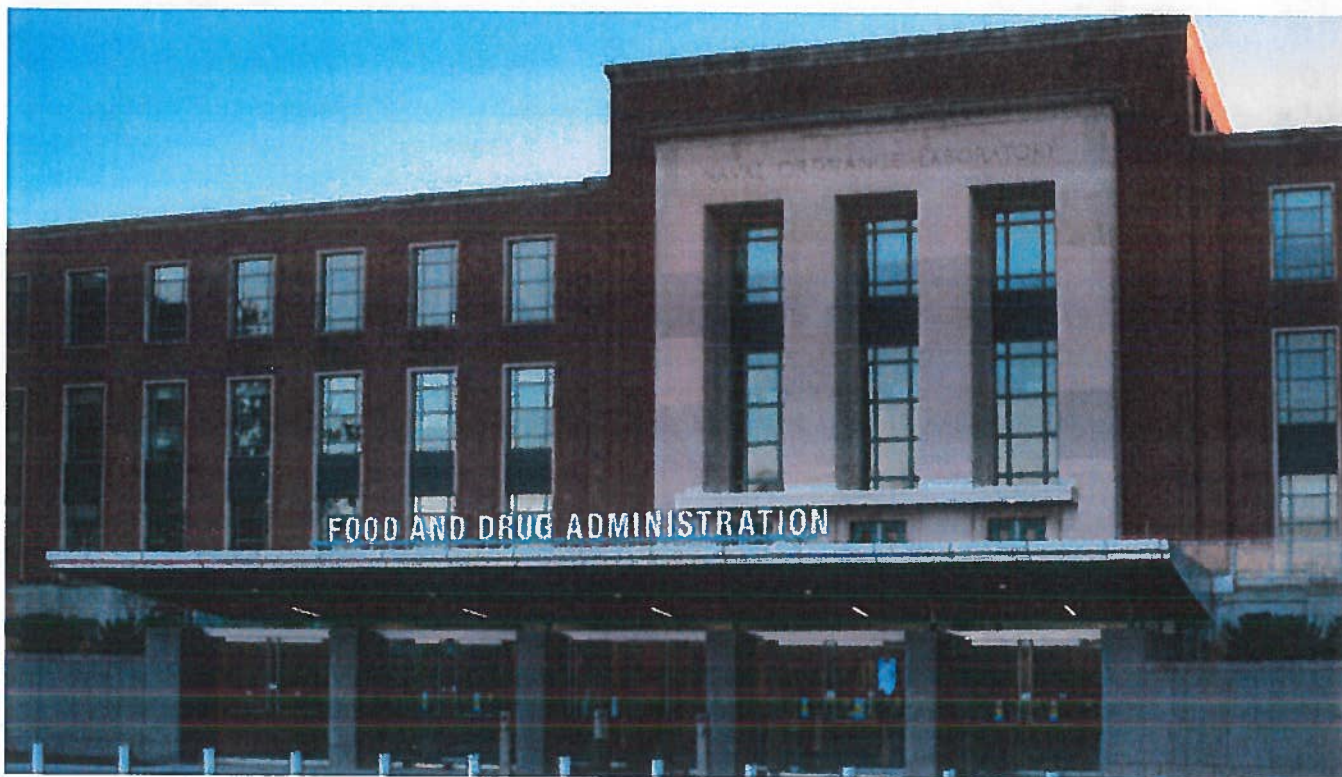
Center for Drug Evaluation and Research

[More Warning Letters \(/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters\)](#)

FDA slams another Indian drug maker for serious quality problems

By [Ed Silverman](#)² [@Pharmalot](#)³

January 6, 2016



India's Cadila Healthcare has run into trouble with the FDA. *FDA*

If there is a surefire way to arouse the concerns of Food and Drug Administration inspectors, try this: take a notebook listing manufacturing problems, place it in plastic bags along with other paperwork, and toss them in a nearby scrap yard where the inspectors can find them.

Here's another approach: leave "unofficial notebooks," which are used to track manufacturing activities, lying around an office so the inspectors can read how bacteria is present in the water system, but become puzzled when the problem is not cited in official company records.

These were just two of several “serious breaches” of good manufacturing practices the FDA cited in a Dec. 23, 2015, [warning letter](#)⁴ sent to Cadila Healthcare, one of India’s largest drug makers. The letter followed agency inspections of two manufacturing plants in India between August and December 2014.

[Related:](#) ⁵

[Review of FDA oversight of Asian drug plants requested by lawmakers](#) ⁵

What else concerned the FDA?

There were problems with the [potency of warfarin](#) made at one plant and Cadila agreed to temporarily suspend production. But after running tests, the company resumed production in November 2014. Yet in June 2015, Cadila acknowledged to the FDA that problems with some lots of warfarin were subsequently found, but had been shipped anyway.

Meanwhile, nine consumer complaints were lodged by way of pharmacies and distributors over potential product mix-ups. But while Cadila conceded some drugs were made on adjacent production lines, the company never completed its investigation. [Were mix-ups caused by inadequate cleaning, unsuitable equipment, material flow, or something else?](#) Cadila didn’t know, which made it hard to fix the problem.

There’s more. [Several batches of active pharmaceutical ingredients failed an analysis](#), but Cadila never explored why this occurred. The drug maker also failed to prevent unauthorized access or changes to data. FDA inspectors noted a lab manager could delete data from software and, in fact, one file was deleted. But an audit trail function was never activated and Cadila did not have records of any changes.

For its part, Cadila issued a [statement](#)⁶ to the Bombay Stock Exchange last week to maintain that it takes “quality and compliance matters very seriously

... and is working hard to ensure that the commitments made to the FDA are fully completed.” The drug maker also insisted its products are safe and effective and that no products shipped to the United States are made with ingredients from the plant where the analyses failed.

“This has a theme found in a lot of warning letters, especially warning letters issued to Indian companies,” said Vince Suneja, chief executive of [TwoFour Insight Group](#)⁷, a consulting firm that works with Indian drug makers. “There’s a failure to properly investigate problems and a lack of adequate controls for data.”

Indeed, as we have noted previously, this is only the latest instance in which the FDA has scolded an Indian drug maker or ingredients supplier for quality control problems. Over the past several years, in fact, there has been mounting concern over the safety of the pharmaceutical supply chain after the agency cited several companies for production failures.

The most notable example was Ranbaxy Laboratories, which is now owned by Sun Pharmaceutical. The drug maker has been a poster child for manufacturing problems. Last year, Ranbaxy paid a \$500 million fine to US authorities as part of a settlement that included pleading guilty to two charges of violating drug safety laws that, for example, involved manipulating data.

[Related:](#) ⁸

[**French proposal for ‘Made in EU’ labels threatens to divide drug industry**](#)⁸

Several companies have also been hit with so-called import alerts in which the FDA bans products made at a specific facility. The crackdown, however, has alarmed Indian drug makers. They have complained the FDA has singled them out for especially tough inspections, which occur too frequently and haphazardly, depriving them of the opportunity to make substantive changes.

The ongoing problems prompted several congressional lawmakers last month

to ask⁵ the US Government Accountability Office to review FDA oversight of foreign manufacturing plants.

Last year, the FDA began considering a new approach to inspecting manufacturing facilities in India. The plan is to “allow our inspectors to document where a firm’s quality management system exceeds what would be required to meet regulatory compliance,” FDA officials wrote in a [blog post](#)⁹. “To put it simply: the inspections can yield also carrots, and not just sticks.”

The FDA has also begun working with the Indian government to bolster domestic oversight. Right now, the agency has three inspectors who work in the country, but others regularly travel there as well, so the total number varies. India’s drug makers, however, are angry over the FDA scrutiny, which has led to a series of [import alerts](#)¹⁰ that ban products from being shipped to the US.

About the Author



[Ed Silverman](#)²

Pharmalot Columnist, Senior Writer

Ed covers the pharmaceutical industry.

ed.silverman@statnews.com¹¹
[@Pharmalot](#)³

Links

1. <https://www.statnews.com/category/the-regulars/pharmalot/>
2. <https://www.statnews.com/staff/ed-silverman/>
3. <https://twitter.com/Pharmalot>
4. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm479712.htm>
5. <https://www.statnews.com/pharmalot/2015/12/21/drugs-fda-congress/>
6. http://zyduscadila.com/wp-content/uploads/2015/12/Warning_Letter_US_FDA.pdf
7. <http://twofourinsight.com/>

8. <https://www.statnews.com/pharmalot/2015/11/19/pharmalot-drug-labels-france-sanofi/>
9. <http://blogs.fda.gov/fdavoices/index.php/2015/03/from-new-jersey-to-new-delhi-a-global-focus-on-quality/>
10. http://www.accessdata.fda.gov/cms_ia/countrylist.html
11. <https://www.statnews.com/pharmalot/2016/01/06/fda-warning-letter-cadila>
[/mailto:ed.silverman@statnews.com](mailto:ed.silverman@statnews.com)
12. <https://www.statnews.com/tag/drug-makers/>
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UndoCutCopyFormat PainterClipboard

Font

Alignment

General

Conditional Formatting

Styles

Cells

Editing

1	Code	Firm Name
7114	68284	Hexal AG
7115	68285	Ridley Inc.
7116	68289	Jazeera Pharmaceutical
7117	68292	Carib Supply St. Croix, Inc.
7118	68294	Copima SL
7119	68304	Biodomeade Hardware and Supply
7120	68305	Sigma-Aldrich Corporation
7121	68306	B4 Brands LLC
7122	68308	Mayne Pharma Inc.
7123	68319	Glatt Pharmaceutical Services GmbH & Co. KG
7124	68324	CAMBRIDGE MAJOR LABORATORIES EUROPE B.V.
7125	68327	Cover FX Skin Care, Inc.
7126	68330	Cephazone Pharma LLC
7127	68343	Montani Cosmetics Inc.
7128	68345	PSS World Medical, Inc.
7129	68352	Oxy Respiratory & Home Medical Equipment Specialists, Inc. dba Oxy Respiratory & HME Specialist, Inc.
7130	68354	Blowed Pharmaceuticals, Inc.
7131	68356	LemaPharm Lens Inc.
7132	68359	Ningbo Renjian Pharmaceutical Group Co., Ltd.
7133	68362	Shenzhen Happy Pharmaceuticals Ltd
7134	68367	LINGYUN COUNTY PHARMACEUTICAL FACTORY GUANGXI
7135	68368	Barron Laboratories Pty Limited
7136	68371	The Pharmacy Counter, LLC dba ProMedica Home Medical Equipment
7137	68372	ThermiPhos UK Ltd.
7138	68374	Sarnachully Pharmaceutical Co. Ltd.
7139	68382	Zydus Pharmaceuticals (USA) Inc
7140	68387	Keltman Pharmaceuticals
7141	68391	BUWC
7142	68393	MDR Fitness Corp.
7143	68400	Myrcene Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc
7144	68403	CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
7145	68404	Alkaloids Private Limited
7146	68405	Physician Therapeutics LLC
7147	68411	Aledian Corporation
7148	68415	Biomedix Inc.
7149	68418	Biocortex, Inc.
7150	68419	American Medical Gas LLC
7151	68421	Critas First Aid & Safety

Verified
MS
A7/2020

January 7th, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

To whom it may concern:

Zydus Pharmaceuticals USA Inc. imports controlled (CIV) and non-controlled prescription drugs from our FDA approved manufacturing facilities in India for distribution in the USA. The finished dosages imported are stored at our 3PL warehouse, Eversana Life Sciences Services, LLC, 4580 Mendenhall Road, Memphis, TN 38141. Zydus markets and sells these products to Pharmacy warehouses, Distributors and wholesalers.

The State of New Jersey does not require inspection of our corporate headquarters location in Pennington, NJ.

Sincerely,



Louis Pastor
AVP, Trade Operations

Corporate Officers	Title	DOB	Address
Michael Keenley	CEO, President		Route N., Pennington, NJ 08534
Ravi Yadavar	CFO, Treasurer		Route N., Pennington, NJ 08534
Crystal Fisher	Treasurer		Route N., Pennington, NJ 08534



NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0739049

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 - "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of \$20.00 shall accompany such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:
73 ROUTE 31 NORTH PENNINGTON, NJ 08534.

Reg. No.
5003171

ZYDUS PHARMACEUTICALS USA INC
ATTN: STUART D. GROW, SR EXE.
73 ROUTE 31 NORTH
PENNINGTON, NJ 08534-

ISSUED PURSUANT TO

N.J.S.A. 24:6B

EXPIRES: January 31, 2021

Establishment Copy

**STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING**

ZYDUS PHARMACEUTICALS (USA) INC.
0100915422

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on November 18, 2003.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

JOSEPH D RENNER
73, ROUTE 31 NORTH
PENNINGTON, NJ 08534



*IN TESTIMONY WHEREOF, I have
hereunto set my hand and affixed
my Official Seal at Trenton, this
18th day of December, 2019*

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6103368802

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 13BSBIH8903

Application/License No. _____

Zydus Pharmaceuticals USA, Inc., doing or intending to do business as a
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
73 NJ-31, Pennington, NJ, 08534, as
Address of Applicant/Principal
 PRINCIPAL, and Hartford Fire Insurance Company, a
Surety Company
 corporation organized under the laws of the state of Connecticut
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06155 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 4/1/20.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

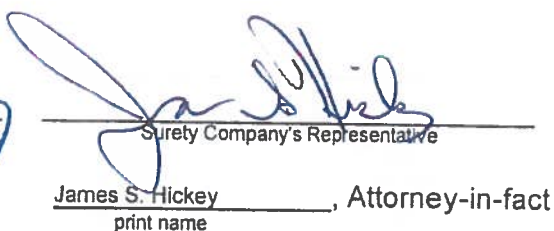
In witness whereof, each party to this bond has caused it to be executed on this 26th day of March, 2020.

APPLICANT/PRINCIPAL

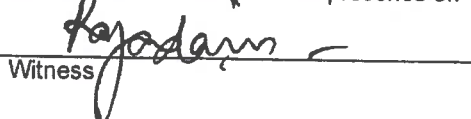
SURETY

COMPANY


Authorized Representative


Surety Company's Representative
James S. Hickey, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:


Witness


Witness

SIGNED and SEALED in the presence of:


Witness


Witness

Countersigned by:

n/a
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:

THE HARTFORD

BOND, T-11

One Hartford Plaza

Hartford, Connecticut 06155

Bond.Claims@thehartford.com

call: 888-266-3488 or fax: 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: LINK INSURANCE SERVICES

Agency Code: 13-651708

- ☒ Hartford Fire Insurance Company, a corporation duly organized under the laws of the State of Connecticut
- ☐ Hartford Casualty Insurance Company, a corporation duly organized under the laws of the State of Indiana
- ☐ Hartford Accident and Indemnity Company, a corporation duly organized under the laws of the State of Connecticut
- ☐ Hartford Underwriters Insurance Company, a corporation duly organized under the laws of the State of Connecticut
- ☐ Twin City Fire Insurance Company, a corporation duly organized under the laws of the State of Indiana
- ☐ Hartford Insurance Company of Illinois, a corporation duly organized under the laws of the State of Illinois
- ☐ Hartford Insurance Company of the Midwest, a corporation duly organized under the laws of the State of Indiana
- ☐ Hartford Insurance Company of the Southeast, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint James S. Hickey

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 13BSBIH9903

Naming Zydus Pharmaceuticals USA, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.



Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA

COUNTY OF SEMINOLE

SS. Lake Mary

On this 13th day of February, 2020, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.



Jessica Ciccone

Jessica Noelle Ciccone
My Commission #FF029702
Expires June 20, 2021

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of March 26, 2020.

Signed and sealed in Lake Mary, Florida.



Keith D. Dozois

Keith D. Dozois, Assistant Vice President



The National Association of Boards of Pharmacy®
hereby awards

Verified-Accredited Wholesale Distributors®
Accreditation

to

Evensana Life Science Services, LLC

located at

4580 Mendenhall Road, Memphis, TN 38144

This facility has met all the Verified-Accredited Wholesale Distributors (VAWD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAWD section of the NABP website, located at www.nabp.pharmacy.

Carmen A. Calzone, Executive Director/Secretary

October 17, 2018 - October 16, 2021

Period of Accreditation

National Association of Boards of Pharmacy | 1600 Techamville Drive, Mount Prospect, IL 60056 | www.nabp.pharmacy

Louis M. Pastor Jr.
1 Lower Mountain Rd
Furlong, PA 18925

PROFESSIONAL EXPERIENCE

Zydus Pharmaceuticals USA Inc, Pennington, NJ

December 2013-Present

A.V.P. Trade Operations

- Manage day to day interactions with Third Party Logistics provider handling warehousing and distribution activities
- Manage chargebacks department
- Manage day to day sales operations including product allocation, inventory management, reporting and forecasting
- Take a lead role in government contracting and negotiations
- Participate in Business Development activities including contract review and negotiation
- Manage state licensing compliance

CorePharma, LLC, Middlesex NJ

March 2009-December 2013

Amedra Pharmaceuticals LLC, Horsham PA

Director, Sales Administration

- Create product launch plans to meet and exceed market share and profitability targets
- Identify market and pricing opportunities to grow current products
- Manage all day to day sales operations functions including contracts, returns, rebates, customer service, forecasting, chargebacks and Medicaid
- Work closely with Finance to develop and adjust accrual method for rebates, Medicaid, returns and chargebacks
- Develop sales strategies and growth incentive programs to grow market share on current products
- Participate in contract negotiations to acquire mature brands and other generic product opportunities
- Responsible for developing and executing the strategy to bring Sales, Marketing and Distribution functions from 3rd party logistics provider back to CorePharma.
- Set-up all internal operations to support new warehousing and distribution functions
- Work with contract manufacturers and Supply Planning on new launches and forecasting

Cadista Pharmaceuticals, Horsham PA

February 2006-March 2009

Sr. Manager, Sales Administration

- Manage strategic customer contract negotiations, proposal developments and pricing
- Lead weekly production planning and monthly Sales and Operations Planning meetings
- Spearheaded seamless transition from third party distribution to internal distribution resulting in annual savings of over \$500k
- Maintain superior service levels with all customers through accurate forecasts and production schedules
- Responsible for gathering and reporting monthly sales data to Global Management Team
- Work closely with CFO to ensure adequate accruals are maintained and rebates are accounted for accurately
- Federal Government liaison for Veterans Administration Contract and Federal Supply Schedule

Sandoz Inc, Princeton NJ

October 2003-February 2006

Pricing Analyst

- Performed profitability analysis on proposals
- Partnered with Rebates, Chargebacks and Collections to resolve contract and pricing disputes
- Monitored Siebel approval process of contracts and pricing to ensure timely customer responses
- Coordinated data analysis for contract renewals
- Determined contractual and financial impact of price increases
- Performed business reviews for RFP's ensuring competitive pricing among classes of trade and adherence to the Robinson-Patman Act
- Managed the implementation of price changes and new product offers in response to customer requests

Business Systems Analyst

- Business Warehouse and SAP liaison for Sales and Marketing-*Recognized with a Galaxy Award*
- Created ad hoc sales reports for various functional areas
- Identified areas of improvement within SAP and partnered with IT to implement the changes
- Developed and analyzed reports to improve customer service levels
- Worked with various areas to enhance and develop current systems

Corporate Account Representative

- Maintained and developed relationships with strategic clients by managing day to day activities- *Recognized with a Galaxy Award for outstanding customer focus and performance*
- Supported internal and external auditors
- Ensured SOX compliance with regard to order processing

Commerce Bank, NA, Flemington, NJ

April 1999-October 2003

Assistant Branch Manager, Certified Consumer Lender

- Supervised operation of the branch to ensure the highest level of customer service
- Responsible for employee development and retention
- Performed daily and monthly audits
- Lead monthly meetings
- Responsible for employee performance reviews
- Oversaw the loan process to ensure timely completion of loan applications

SKILLS

- Microsoft Word, Excel, PowerPoint and Access, Lotus Notes, SAP, Business Warehouse, Siebel, Baan, Outlook

EDUCATION

Rider University, Lawrenceville NJ
Bachelor of Science in Marketing
 Major- Marketing
Cum Laude

14D

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
 Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership
☐ Publicly Traded Corporation – Pages 1,2,3,4 ☒ Partnership – Pages 1,2,3,7,8
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: APNAR PHARMA LP

Physical Address: 4820 LANIER RD

City: CHINO State: CA Zip Code: 91710

Telephone Number: 844-283-9825 Fax Number: 909-525-4142

Toll Free Number: _____

E-mail: dharmeshpatel@apnarpharma.com Website: www.apnarpharma.com

Facility Manager: DHARMESH PATEL

Professional qualifications and experience of facility manager: Pharmacist

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate)

Yes ☐ No ☒

Licensed as Manufacturer by the FDA?
(If yes, provide a copy of your FDA registration)

Yes ☐ No ☒

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: KAISER PERMANENTE

Address: 300 PULLMAN STREET, LIVERMORE, CA, 94551

Name: MCKESSON CORPORATION

Address: 6555 STATE HIGHWAY 161, IRVING, TX 75037

Name: CARDINAL HEALTH

Address: 7000 CARDINAL PLACE, DUBLIN, OH, 43017

Name: AMERISOURCE BERSEN

Address: 500 INNOVATION DRIVE, MN, 55379

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALE LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

DHARMESH PATEL
Print Name of Authorized Person

03/24/2020
Date

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership:

General _____

Limited X

List names of 4 largest partners and percentage of ownership:

Name: DHARMESH PATEL %: 70Name: UMESH PATEL %: 24Name: DIPAK SURESH PATEL %: 6

Name: _____ %: _____

Partnership Name: APNAR PHARMA LPMailing Address: LANIER ROADCity, State Zip Code: CHINO, CA, 91710Telephone Number: _____ Fax Number: 909-525-4142Contact Person: DHARMESH PATEL

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NIA

Include with the application for a partnership

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

State of California
Secretary of State
CERTIFICATE OF STATUS

ENTITY NAME: APNAR PHARMA, LP

FILE NUMBER: 201400800012
FORMATION DATE: 01/02/2014
TYPE: DOMESTIC LIMITED PARTNERSHIP
JURISDICTION: CALIFORNIA
STATUS: ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California,
hereby certify:

The entity is authorized to exercise all of its powers, rights and
privileges in California.

This certificate relates to the status of the entity on the Secretary
of State's records and does not reflect documents that are pending
review or other events that may affect status.

No information is available from this office regarding the financial
condition, status of licenses, if any, business activities or
practices of the entity.



IN WITNESS WHEREOF, I execute this
certificate and affix the Great Seal
of the State of California this day of
June 24, 2020.

ALEX PADILLA
Secretary of State

FSB

State of California
Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME: APNAR PHARMA, LP

FILE NUMBER: 201400800012
FORMATION DATE: 01/02/2014
TYPE: DOMESTIC LIMITED PARTNERSHIP
JURISDICTION: CALIFORNIA
STATUS: ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California,
hereby certify:

The records of this office indicate the entity is authorized to
exercise all of its powers, rights and privileges in the State of
California.

No information is available from this office regarding the financial
condition, business activities or practices of the entity.



IN WITNESS WHEREOF, I execute this
certificate and affix the Great Seal
of the State of California this day of
December 31, 2019.

A handwritten signature in black ink, appearing to read "Alex Padilla".

ALEX PADILLA
Secretary of State

CFG



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



April 9, 2020

APNAR PHARMA LP
4820 LANIER RD
CHINO CA 91710

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: APNAR PHARMA LP

License Type: WHOLESALER

License Number: WLS 7576

Status: ACTIVE

Issue Date: 05/06/2019

Expiration Date: 01/01/2021

Address of Record: 4820 LANIER RD CHINO CA 91710

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Barbera Schleicher
Public Inquiry Analyst
(916) 518-3081
Barbera.Schleicher@dca.ca.gov



Visit our website at www.pharmacy.ca.gov



CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100



Wholesale Drug Permit

LICENSE NO. WLS 7576
RECEIPT NO. 00700181

VALID UNTIL MAY 01, 2021

APNAR PHARMA LP
4820 LANIER RD
CHINO CA 91710

03/12/20

03/12/20 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

FORM WPHWLS (05/30/19) WLS

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 10105323

Application/License No. _____

Apnar Pharma LP DBA Apnar Pharma LP, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
4820 LANIER RD CHINO, CA 91710
Address of Applicant/Principal
PRINCIPAL, and Hudson Insurance Company, a
Surety Company
corporation organized under the laws of the state of Delaware
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1035 Greenwood Blvd, Suite 265 Lake Mary, FL 32746
Address of Surety
as

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 3/30/2020 12:00:00 AM
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this _____ day of _____, 20____.

APPLICANT/PRINCIPAL

SURETY COMPANY

Authorized Representative

Surety Company's Representative

Matt Bocklage, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

SIGNED and SEALED in the presence of:

Witness

Witness

Witness

Witness

Countersigned by:

Nevada Resident Agent



10105323

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Matt Bocklage
of the State of MO

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

One Hundred Thousand Dollars (\$100,000.00)

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly

on this 6th day of February, 20 20 at New York, New York.



Attest:
Dina Daskalakis
Corporate Secretary

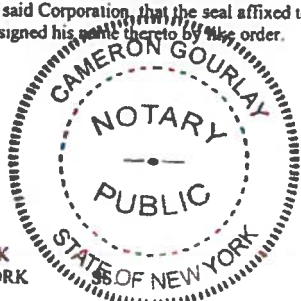
HUDSON INSURANCE COMPANY

By: **Michael P. Cifone**
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 6th day of February, 20 20 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of HUDSON INSURANCE COMPANY, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by my order.

(Notarial Seal)



CAMERON GOURLAY
Notary Public, State of New York
No. 01GO6372305
Qualified in New York County
Commission Expires June 4, 2022

STATE OF NEW YORK
COUNTY OF NEW YORK

CERTIFICATION

The undersigned **Dina Daskalakis** hereby certifies

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOLVED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

In witness the hand of the undersigned and the seal of said Corporation this 30th day of March, 20 20



By: **Dina Daskalakis**
Corporate Secretary

DHARMESH PATEL

Rice Ave ,Chino Ca

Work Experience

- **1999 to 2002** Rite Aid Pharmacy, Newport Beach, California
 Pharmacy Technician
- 2002 to 2004** Rite aid, Newport Beach, California
 Intern Pharmacist
- 2004 to 2006** Family Pharmacy, Long Beach, California
 Pharmacist in Charge
- 2006 to 2010** Community Pharmacy, Bakersfield, California
 Pharmacist in Charge
- 2010 to 07/2011** Caring Pharmacy, Riverside, California
 Pharmacist in charge
- 2015//03/24 to 01/01/2012** – Parkview medical plaza pharmacy, Riverside, California
 pharmacist in charge.
- 2015/03/25/ to current** -Pharmacist and CEO at APNAR PHARMA, chino, California

Responsibilities

- Responsible for pharmacy operations which included ordering and inventory control of pharmaceutical drugs.
- Supervised seven employees including their workflows.
- Responsible to increase company's production
- Build strong pipeline of drugs .and monitoring all small to big projects.

Certification: Certified in immunization. Certified in compounding medicines by PCCA.



PHARMA LP

4820 LANIER RD ,CHINO CA 91710

Date :04/02/2020

To: Nevada Board Of Pharmacy

RE: List of employees handling the drugs on a daily basis

Employee Names;

Sandy Samperio

Agustin Hernandez

Neel Patel

Sincerely,

Signature

Dharmesh Patel

President/Pharmacist

Date

04/2/2020

0 www.apnarpharma.com Q dharmesh.patel@apnarpharma.com @ 844-283-9825

Corporate Office: Apnar Pharma LP 4820 LANIER RD, Chino, CA, 91710, USA.

15

15A

NEVADA STATE BOARD OF PHARMACY

Monte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New OUTSOURCING FACILITY

☒ Ownership Change (Provide current license number if making changes:) OUT Pending

☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☒ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Optum Compounding Services, LLC

Physical Address: 24416 N. 19th Ave, Ste. 200

City: Phoenix State: AZ Zip Code: 85085

Telephone: (877) 358-9030 Fax: (623) 869-7151

Toll Free Number: (877) 358-9030 (Required per NAC 639.708)

E-mail: orxpharmlic@optum.com Website: www.avella.com/sourceb (anticipated to change)

Supervising Pharmacist: Christopher Dinoffria Nevada License #: Pending

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral

☐ ☒ Sterile Compounding

☐ ☒ Non Sterile Compounding

☒ ☐ Mail Service Sterile Compounding

☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

Page 2

FEI Number (From FDA application): 3012890460

Please provide the name of the facility as registered with the FDA and the registration number:
Optum Compounding Services, LLC & 3012890460

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A - facility will not use a DBA

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Christopher Dinoffria Nevada License Number: Pending

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Karen Peterson

Print Name of Authorized Person

7/20/2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: AZ (State of Organization for the LLC)Parent Company if any: Optum Pharmacy 801, Inc. (sole member of the LLC)Address: 24416 N. 19th Ave, Ste. 200City: Phoenix State: AZ Zip: 85085Telephone: (623) 742-1700Fax: (623) 742-1705Contact Person: Christopher Dinoffria

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) No individual owners

Name

Address

b)

Name

Address

c)

Name

Address

d)

Name

Address

2) Provide the number of shares issued by the corporation. N/A - LLC3) What was the price paid per share? N/A - LLC4) What date did the corporation actually receive the cash assets? No cash assets received; intracompany acquisition of 503B asset on 07/29/2020

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Optum Compounding Services, LLC**Officer and Ownership Information****Officers:**

Name	Title
Jeffrey Grosklags	Manager
Michael Zeglinski	Manager, CEO & President
Peter Gill	Treasurer
Karen Peterson	Secretary
Heather Lang	Assistant Secretary
David Oberg	Assistant Secretary

The facility is wholly owned by:

Optum Compounding Services, LLC

FEIN: 20-3253658

24416 N. 19th Ave., Ste. 200

Phoenix, AZ 85085

The sole member of Optum Compounding Services, LLC is:

Optum Pharmacy 801, Inc.

FEIN: 13-4318552

24416 N. 19th Ave., Ste. 100

Phoenix, AZ 85085

STATE OF ARIZONA



Office of the CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

OPTUM COMPOUNDING SERVICES, LLC

ACC file number: 23101764

was incorporated under the laws of the State of Arizona on 06/30/2020, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: 07/10/2020



Matthew Neubert, Executive Director

Disciplinary Action History



Optum Pharmacy 801, Inc. (fka Avella of Deer Valley, Inc.)

Colorado Board of Pharmacy, 2010. Colorado Board of Pharmacy issued a Stipulation and Final Agency Order inclusive of a \$5500 fine to Avella of Deer Valley, Inc. for failing to submit required data or zero reports, regarding controlled substances, to the Colorado Electronic Prescription Drug Monitoring Program.

Colorado Board of Pharmacy, 2011. Colorado Board of Pharmacy issued a Stipulation and Final Agency Order inclusive of a \$11,000 fine to Avella of Deer Valley, Inc. for failing to submit required data or zero reports, regarding controlled substances, to the Colorado Electronic Prescription Drug Monitoring Program.

Colorado Board of Pharmacy, 2014. Colorado Board of Pharmacy issued a Stipulation and Final Agency Order inclusive of a \$1,000 fine to Avella of Deer Valley, Inc. for failing to submit required data or zero reports, regarding controlled substances, to the Colorado Electronic Prescription Drug Monitoring Program for the December 1 through December 10, 2013 reporting period.

Hawaii Board of Pharmacy, 2015. Hawaii Board of Pharmacy and Avella of Deer Valley, Inc. entered into a Settlement Agreement for Avella's failing to report Colorado Board of Pharmacy disciplinary actions in a timely manner. Settlement agreement included \$2,500 payment for administrative costs.

Colorado Board of Pharmacy, 2015. Colorado State Board of Pharmacy issued a Stipulation and Final Agency Order in Case No. 2014-3990 to Avella Deer Valley for distributing prescription drug product to a veterinarian intended for in-office use for an animal-patient, without first obtaining a patient specific prescription.

Please note, although the California Board of Pharmacy does not consider a citation disciplinary action, we are disclosing the citation in an abundance of caution.

California Board of Pharmacy, 2018. California Board of Pharmacy issued a citation to Avella of Deer Valley for shipping non-patient specific sterile drug preparations to facilities in California without obtaining the required documentation from the prescribers to meet the requirements for office administration, and for not obtaining a license with the board as an outsourcing facility prior to shipping non-patient specific sterile drug preparations into this state. The non-patient specific sterile drug products were made in Avella of Deer Valley, Inc.'s FDA licensed 503b facility located in suite 16 of the same premises as Avella of Deer Valley, Inc, (NRP 991) and (NSC 99593), which according to board records is located in suite 12.

Pending Action Summary

The California Board of Pharmacy filed an Accusation against Avella of Deer Valley, Inc. and its shareholder Apothecary Holdings Inc. on August 6, 2019. The Accusation sets forth alleged violations of current Good Manufacturing Practices observed during inspections conducted in July 2017 and June 2018, prior to the time that the current owners acquired and took over the operations of the facility in August 2018. A subsequent inspection conducted in July 2019 did not identify any deficiencies requiring corrective action. Based on that inspection and other efforts undertaken by the new owners, the California Board has agreed to continue the hearing that was scheduled for later this summer, to allow the parties the opportunity to discuss settlement.

Karen Peterson

Karen Peterson

STATE OF ILLINOIS

)

) ss.

COUNTY OF

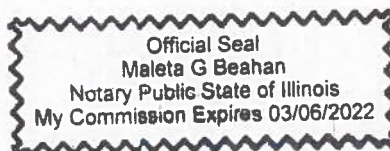
)

On this 13th day of July, 2020 before me, Maleta G Beahan, Notary Public, personally appeared Karen Peterson, personally known to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Maleta G. Beahan

Notary Public



Optum Compounding Services, LLC
f/k/a Avella of Tucson II, Inc.
f/k/a Apothecary Shop of Tucson II, Inc.

STOCK LEDGER

Certificate #	Issued To	No. of Shares	Date of Certificate	Transferred To	No. of Shares	Date of Transaction/ Cancellation	Location of Original	Notes
The Corporation is authorized to issue 1,000,000 Common Shares, no par value								
1	John D. Musil	100,000	8/3/2005	Apothecary Holdings, Inc.	100,000	12/31/2008	Cancelled	
2	Apothecary Holdings, Inc.	100,000	12/31/2008	Apothecary Holdings, Inc.	100,000	6/30/2020	Cancelled	8/16/2018 Acquired as part of Avella acquisition when OptumRx Holdings, LLC acquired Apothecary Holdings, Inc. and all of its subsidiaries. No stock certificates or stock ledger provided at time of closing.

MEMBERSHIP LEDGER

Membership Unit	Issued To	Membership %	Date of Certificate	Transferred To	Membership %	Date of Transaction/ Cancellation	Location of Original	Notes
6/30/2020 Avella of Tucson II, Inc. converted to a corporation and was renamed Optum Compounding Pharmacy, LLC.								
Uncertificated	Apothecary Holdings, Inc.	100	6/30/2020					6/30/2020 Assumption and Contribution Agreement whereby Apothecary Holdings, Inc. contributed, assigned, conveyed and delivered 100% of its right, title and interest in Optum Compounding Pharmacy, LLC to Avella of Deer Valley, Inc.
Uncertificated	Avella of Deer Valley, Inc.	100	6/30/2020		100	6/30/2020	Uncertificated	



ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
<http://www.azpharmacy.gov>

Receipt Date: 05/29/2020
Receipt Number: 202083551
Receipt Amount \$: 1000.00

Manufacturer - 503B Outsourcer

Issued to:

PERMIT NO
M001629
Optum Compounding Services, LLC
Optum Compounding Services, LLC
24416 N. 19TH AVE STE. 200
PHOENIX, AZ 85085

EXPIRES
10/31/2021

Optum Compounding Services, LLC
24416 N. 19TH AVE STE. 200
PHOENIX, AZ 85085

Lam Gaudin
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749



WALLET CARD

NAME: Optum Compounding Services, LLC
LICENSE NUMBER: M001629
EXPIRES: 10/31/2021

<http://www.azpharmacy.gov>

- Your license must be available for inspections during business hours.
- Permit holder(s) must display permit in the location to which it is issued.
- Please note it is your responsibility to keep this license/permit current.

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C. R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

7/18/2020

<https://azbop.igovsolution.net/online/ProfileData/uaj5Oc2eNLsZXikjlj9mg==>**Arizona State Board of Pharmacy**

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007

Mailing Address: P.O. Box 18520, Phoenix, AZ 85005

(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov**CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :**

This document is not a license/permit but serves as the primary source of verification.

Name :	Optum Compounding Services, LLC
Address :	24416 N. 19th Ave Ste. 200 Phoenix AZ 85085
License No :	M001629
Permit Type :	Manufacturer
Sub Type :	503B Outsourcer
Date Issued :	06/30/2020
Expiration Date :	10/31/2021
Status :	OPEN
Discipline :	No

Kam GandhiExecutive Director
Arizona State Board of Pharmacy

Date: 07/18/2020

8/14/2020

Registered Outsourcing Facilities | FDA

Registered Outsourcing Facilities

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 8/7/2020

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility ¹	Date of Most Recent Registration as an Outsourcing Facility ¹	End Date of Last FDA Inspection Related to Compounding ²	Was a Form FDA-483 issued? ³	Other Action, if Any, Based on Last Inspection ^{4,5}	Intends to Compound Sterile Drugs From Bulk Drug Substances ⁶
Advanced Pharmaceutical Technology, Inc., Elmsford, NY	Marco Persichillo 914-358-5260	2/26/2019	11/18/2019	Not yet inspected	N/A	N/A	Yes
AnazaoHealth Corporation, Las Vegas, NV	Jaclyn Wong 800-995-4363 Ext=3120	9/23/2014	10/22/2019	9/19/2019	Yes (https://www.fda.gov/media/132898/download)	Open ⁷	Yes
Apollo Care, Columbia, MO	Jarred Dudding 573-441-8900	9/14/2017	12/11/2019	3/13/2018	Yes (/media/112143/download)	Warning Letter - 3/20/2019	Yes
AptiPharma, LLC, Loveland, CO	Jennifer Travis 970-685-1078	2/7/2020	2/7/2020	Not yet inspected	N/A	N/A	No
ASP CARES, San Antonio, TX	Jacqueline Esqueda 210-417-4567	2/14/2017	12/3/2019	8/23/2018	Yes (/media/120742/download)	Open	Yes
Athenex Pharma Solutions, LLC, Clarence, NY	Michael Scribner 888-629-8593	4/10/2017	10/25/2019	8/28/2019	Yes (https://www.fda.gov/media/132333/download)	Open ⁷	Yes
Atlas Pharmaceuticals, Phoenix, AZ	Nickolaus Banda 480-208-1855	11/8/2016	11/22/2019	9/26/2017	Yes (/media/108456/download)	Warning Letter - 9/11/2018 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/atlas-pharmaceuticals-llc-564139-09102018)	Yes
Optum Compounding Services, LLC, formerly registered as Avella of Deer Valley, Inc., Phoenix, AZ	Christopher Dinoffria 877-794-0404	6/21/2016	12/11/2019	4/20/2018	Yes (/media/112827/download)	Open	Yes
BayCare Integrated Service Center, LLC dba BayCare Central Pharmacy, Temple Terrace, FL	Kenneth Jozefczyk 813-901-6339	6/4/2019	12/7/2019	12/10/2019	Yes	Yes	No
BPI Labs LLC, Largo, FL	Chandra Kasireddy 727-471-0850	3/4/2019	12/3/2019	Not yet inspected	N/A	N/A	Yes
Brookfield Medical/Surgical Supply, Inc., Brookfield, CT	James Cangelosi 203-775-0862	1/12/2015	1/16/2020	12/21/2018	Yes (https://www.fda.gov/media/120806/download)	Open	Yes
BSO LLC, Lakewood, CO	David W. Hill 303-589-8677	11/24/2015	10/17/2019	9/20/2019	Yes (https://www.fda.gov/media/132339/download)	Open ⁷	Yes
Central Admixture Pharmacy Services, Inc., Allentown, PA	Wm. John Brandon 205-945-1955 Ext=106	2/28/2014	10/18/2019	8/22/2018	Yes (https://www.fda.gov/media/120740/download)	FMD-145 Issued 6/17/2020	Yes
Central Admixture Pharmacy Services, Phoenix, AZ	Wm. John Brandon 205-945-1955 Ext=106	3/29/2018	10/18/2019	4/26/2019	No	FMD-145 Issued 6/3/2020 (https://www.fda.gov/media/139371/download)	Yes
Central Admixture Pharmacy Services, Inc. San Diego, CA	Wm. John Brandon 205-945-1955 Ext=106	6/4/2014	10/18/2019	9/11/2018	Yes (/about-fda/central-admixture-pharmacy-services-inc-san-diego-ca-483-issued-09112018)	FMD-145 Issued 5/27/2020 (https://www.fda.gov/media/139369/download)	No


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Accredited Drug Distributors

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Current list of 1 Verified-Accredited Wholesale Distributors²

¹ NABP Accreditation is valid for 3 years
² Facilities listed with "Recertification - In Progress" remain active throughout the recertification process

Name	Address	Accreditation Date
Chon Distributors, Inc.	24411 N. 19th Ave. Phoenix, AZ 85085	12/23/15

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Chon processing



CTM processing
 The National Association of Boards of Pharmacy®
 hereby awards

Verified-Accredited Wholesale Distributors®
 Accreditation

to

Avella of Deer Valley, Inc 38

located at

24416 N 19th Ave, Phoenix, AZ 85085

This facility has met all the Verified-Accredited Wholesale Distributors (VAWD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAWD section of the NABP website, located at www.nabp.pharmacy.

C. Catzone

Carmen A. Catzone, Executive Director/Secretary

December 13, 2019 - December 12, 2022

Period of Accreditation

National Association of Boards of Pharmacy | 1600 Fechenville Drive, Mount Prospect, IL 60056 | www.nabp.pharmacy

Christopher J. Dinoffria, Pharm.D.

N. 51st St.
 Scottsdale, AZ 85254
 (480) 6 – cell

EDUCATION	Midwestern University College of Pharmacy Doctor of Pharmacy	2005-2008
	University of Arizona Bachelor of Science – Chemistry Minor – Math & Physics	1996-97, 1998-2001
LICENSURE	Pharmacist License	
	Arizona Board of Pharmacy	2008
	Mississippi Board of Pharmacy	2012
	Alabama Board of Pharmacy	2014
	Arkansas Board of Pharmacy	2014
	Kentucky Board of Pharmacy	2014
	Louisiana Board of Pharmacy	2014
	Maryland Board of Pharmacy	2014
	Nebraska Board of Pharmacy	2014
	Oregon Board of Pharmacy	2014
	Oklahoma Board of Pharmacy	2014
	Tennessee Board of Pharmacy	2014
	Virginia Board of Pharmacy	2014
	West Virginia Board of Pharmacy	2014
	Michigan Board of Pharmacy	2015
	Massachusetts Board of Pharmacy	2015
	New York Board of Pharmacy	2016
	Texas State Board of Pharmacy	2016
	Kansas Board of Pharmacy	2018
	Pharmacist Non-Resident Registration	
	Idaho Board of Pharmacy	2014
	Iowa Board of Pharmacy	2018
EXPERIENCE	Director, Compliance	2018-Present
	Optum Compounding Services (formerly Avella of Deer Valley, Inc. #38) 24416 N. 19 th Ave. Phoenix, AZ 85085 (623) 238-7073 Responsible for compliance to state and federal regulations governing the operation of a duly-licensed outsourcing facility under Section 503B of the Food, Drug, & Cosmetic Act. Serves as Pharmacist-in-Charge/Designated Representative for all licensure held by the facility. Provides directional guidance on state and federal statutes as they relate to outsourcing facility operations, as well as oversight pertaining to product safety, including surveillance, process, recalls, and reporting. Responsible for all government liaison activities relating to outsourcing facility operations, including interactions with state regulators, FDA, CDC, DEA, OSHA, EPA, and DHHS.	

Christopher J. Dinoffria, Pharm.D.

0 N. 51st St.
Scottsdale, AZ 85254
(480) cell

om

Director, Compliance
Avella
24416 N. 19th Ave.
Phoenix, AZ 85085
(623) 238-7073

2015-2018

Responsible for executing Avella's Corporate Compliance Program under the direction of the Chief Compliance Officer and Chief Executive Officer. Subject-matter expert for all Avella locations, ensuring they operate appropriately within the bounds of applicable regulatory requirements. Point of contact and subject-matter expert for all regulatory, corporate standard and/or professional practice questions. Provides regulatory input for Quality Assurance department. Collaborates with all site Pharmacists-in-Charge to ensure regulatory compliance and adherence to corporate standards of practice, including multi-state licensure, regulatory body inspection, safe and proper handling and distribution of medications to end-users and disaster-recovery contingencies

Pharmacist-in-Charge – Avella of Deer Valley

2011-2015

Pharmacist of record for the National Mail order facility while managing growth from annual revenue to \$240 million from \$80 million. Responsible for all regulatory and compliance matters involved in conducting business nationally, including clinical expertise as well as logistics requirements necessary for safe and proper handling and nationwide fulfillment of specialty medications. Maintains permits and licensure requirements for all 50 states. Oversees largest compounding facilities within Avella, with capabilities to supply sterile and non-sterile compounded medications nationally. Manages pharmacist activities and workflow to ensure standards of practice and proper dispensing procedures as dictated by multi-state regulations including Responds to regulatory agency inspection inquiries when applicable.

Clinical Pharmacist – Avella of Deer Valley

2008-2011

Clinical Pharmacist for specialty pharmacy's national mail order facility. Helped develop distribution policies and medication therapy management system to coordinate drug utilization and implementation to ensure proper adherence and persistency of medications for national specialties including transplant, HIV, oncology, fertility, ophthalmology, sports medicine and extemporaneous sterile and non-sterile compounding. Closely involved in REMS programs monitoring limited-distribution medications. Acting subject-matter reference for pediatric therapeutics. Involved with strategic drug information gathering/implementation both internally for colleagues and externally for specialty practices.

ACTIVITIES

VAWD Accreditation (503B Outsourcing Facility)

2019

Led accreditation application process in order to obtain VAWD accreditation for 503B Outsourcing Facility through NABP

Registered Outsourcing Facility

2013-Present

Provided regulatory oversight of construction, installation, and maintenance of three cGMP-compliant facilities for compounding of sterile products in compliance with Drug Quality and Security Act of 2013; led efforts for facilities

Christopher J. Dinoffria, Pharm.D.

N. 51st St.

Scottsdale, AZ 85254

(480) - cell

in order to obtain national licensure for nation-wide distribution

- Adjunct Assistant Professor 2014-2015
 Midwestern University: College of Pharmacy - Glendale
 PPRA 1433 – Introduction to Specialty Pharmacy
 Designed to develop confidence and competence to efficiently and effectively provide pharmaceutical care in a specialty pharmacy environment. Focus includes lecture series on 4 unique disease states commonly found in specialty pharmacy, and the role specialty pharmacists play in providing comprehensive clinical care within those disease states.
- URAC Accreditation (Specialty & Mail-Service) 2012-2013
 Assisted in drafting, editing and implementing policies and procedures for the facility in compliance with accreditation by the Utilization Review Accreditation Commission (URAC) as both Specialty Pharmacy and Mail-Service Pharmacy to ensure the company is conducting business in a manner consistent with national standards.
- PCAB Accreditation (Sterile & Non-Sterile Compounding) 2009
 Assisted in drafting, editing and implementing compounding methods, policies and procedures for facility in accordance with the Pharmacy Compounding Accreditation Board (PCAB) designed to recognize compounding pharmacies that meet or exceed the high quality standards established by the United States Pharmacopeia (USP) for both sterile and non-sterile compounding.
- SKILLS**
- Pharmacy Regulatory Specialist 2015
 CE certificate program, administered by Pharmaceutical Education Consultants, focusing on regulatory standards governing the practice of pharmacy.
- Limited Drug Distribution 2008-Present
 Oversight of facility operations in dispensing drugs with restricted distribution networks or REMS programs limiting end-user access for safety, post-marketing, clinical, financial and/or adherence concerns, as well as safe and proper storage, handling and fulfillment of medication to end-users throughout the country
- Cold Chain Technologies Training 2014
 Pre-qualified packaging solution employed by Avella's national distribution centers designed to ensure safe and proper handling and fulfillment of medications
- RevAssist Certified Counselor 2010
- Pharmaceutical Compounding 2001-present
 Trained in extemporaneous compounding of pharmaceutical formulations in order to provide medication options to patients that are unable to be solved with commercially available products. Fluent in formulations including oral, topical, transmucosal, transdermal and sterile dosage forms for many therapeutic needs such as Pediatrics, Hormone Replacement, Pain Management, Ophthalmology, and Veterinary Medicine.

Christopher J. Dinoffria, Pharm.D.

N. 51st St.

Scottsdale, AZ 85254

(480) il

RESEARCH EXPERIENCE	Research Assistant, University of Arizona Assisted in laboratory research of natural products designed to extract and isolate compounds for pharmaceutical testing	2000-2001
PROFESSIONAL ORGANIZATIONS	Phi Delta Chi Fraternity	2007
AWARDS	Pharmacist of the Year – Mail Order The Apothecary Shop	2011
	Rookie Preceptor of the Year Midwestern University: College of Pharmacy – Glendale	2011
SPECIAL PROJECTS	Medication Utilization Review Evaluated administration and efficacy of injectable Ibuprofen Lysine to induce closure of the Patent Ductus Arteriosus in premature infants.	December 2007

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206

Reno, NV 89521

(775) 850-1440

Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107255232

Application/License No. WH02302 (CHOW processing)

Optum Compounding Services, LLC, doing or intending to do business as
Applicant/Principal
 pharmaceutical wholesaler, whose address for purposes of service is
24416 N. 19th Ave, Suite 200, Phoenix, AZ 85085, as
Address of Applicant/Principal
 PRINCIPAL, and Travelers Casualty and Surety Company of America, a
Surety Company
 corporation organized under the laws of the state of CT
State of Incorporation
 and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Tower Square, Bond/5PB, Hartford CT 06183 as
Address of Surety

SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 20, 2020.
Effective Date

WHEREAS, the provisions of Nevada Revised Statute (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of \$25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are imposed pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

- (1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
- (2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
- (3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
- (4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
- (5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
- (6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
- (7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this
17th day of August, 2020.

APPLICANT/PRINCIPAL
 Optum Compounding Services, LLC



 Authorized Representative

SURETY COMPANY
 Travelers Casualty and Surety Company of America



 Surety Company's Representative

Sandra M. Winsted, Attorney-in-fact
 print name

SIGNED and SEALED in the presence of:

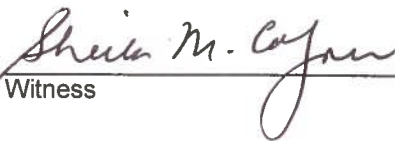


 Witness

SIGNED and SEALED in the presence of:



 Witness K. Hannigan



 Witness



 Witness Jessica B. Dempsey

Countersigned by:



 Nevada Resident Agent Non-Resident Agent
 Susan Ann Welsh



**Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company**

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Sandra M. Winsted** of **Chicago** Illinois, their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this 3rd day of February, 2017.



State of Connecticut

City of Hartford ss.

By: _____

Robert L. Raney, Senior Vice President

On this the 3rd day of February, 2017, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

In Witness Whereof, I hereunto set my hand and official seal.

My Commission expires the 30th day of June, 2021



Marie C. Tetreault
Marie C. Tetreault, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her, and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this

17 day of August 2020



Kevin E. Hughes
Kevin E. Hughes, Assistant Secretary

**To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which the power is attached.**



411 East Wisconsin Avenue
Suite 2400
Milwaukee, Wisconsin 53202-4426
414.277.5000
Fax 414.271.3552
www.quarles.com

Attorneys at Law in
Chicago
Indianapolis
Madison
Milwaukee
Naples
Phoenix
Scottsdale
Tampa
Tucson
Washington, D.C.

Writer's Direct Dial: 414.277.5303
E-Mail: Elizabeth.Gebarski@quarles.com

August 21, 2020

VIA UPS OVERNIGHT

Mr. Mark Sedar
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

**RE: Change of Ownership, Name, and Officers and Address Update
Avella of Deer Valley, Inc. #38 – Phoenix, AZ
Wholesaler License No.: WH02302
Outsourcer License No.: Application Pending**

Dear Mr. Sedar:

This will follow-up on our June 29, 2020 notice letter. Please be advised that there was a sale of assets of Avella of Deer Valley, Inc. #38 related to the FDA Registered 503B Outsourcing Facility in an intracompany change of ownership to Optum Compounding Services, LLC. The new owner of the 503B Outsourcing Facility, Optum Compounding Services, LLC, is now wholly owned by the prior owner, Avella of Deer Valley, Inc. (NKA Optum Pharmacy 801, Inc.). The enclosed organizational chart shows the facility's ownership structure before and after the intracompany change.

As a result of this intracompany change, there was a change in the facility's name, federal tax identification number, and officers. The facility discontinued use of any and all DBAs. It is not using any DBA going forward. The facility did not move, but updated its address to include a suite number. The effective date was July 29, 2020.

Per our July 15, 2020 discussion, this change application is due within 30 days of the change; but, because the license will expire in October, we are submitting the application prior to August 25, 2020. In addition, as we discussed on August 20, 2020, we are enclosing an updated new Outsourcing Facility (503B) license application to reflect the new ownership. **We request that you please put the Wholesaler application on the October Agenda and that the Outsourcing Facility (503B) application currently on the October Agenda be replaced with the enclosed.**

Mr. Mark Sedar
Nevada State Board of Pharmacy
August 21, 2020
Page 2

The application, supporting documents, and fees are enclosed. The pharmacist in charge's Nevada license application is pending. Because the facility is FDA registered and VAWD certified, we have not enclosed fingerprints or a list of employees. Should you have any questions or require additional information, please contact me at 414-277-5303 or Elizabeth.Gebarski@quarles.com. Thank you for your consideration.

Very truly yours,



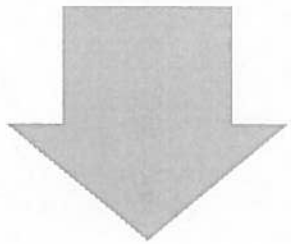
Elizabeth R. Gebarski

Enclosures

Intracompany Transfer

Before

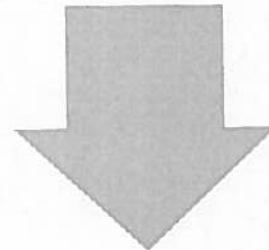
Apothecary Holdings, Inc.
26-3913051



Avella of Deer Valley, Inc.
13-4318552

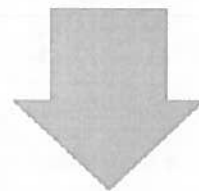
After

Apothecary Holdings, Inc.
26-3913051



Optum Pharmacy 801, Inc.*
(fka Avella of Deer Valley, Inc.)
13-4318552

**Name change effective 07/29/2020*



Optum Compounding Services, LLC
20-3253658



Via Email to kmangosing@pharmacy.nv.gov

September 30, 2020

Nevada State Board of Pharmacy
985 Demonte Ranch Pkwy, Suite 206
Reno, NV 89521
775-850-1440

Re: Optum Compounding Services, LLC f/k/a Avella of Deer Valley, Inc. #38
24416 N. 19th Ave., Suite 200, Phoenix, AZ 85085
Outsourcing Facility Application

To Whom It May Concern:

With this letter, I am providing authorization for Christopher Dinoffria, Supervising pharmacist, to appear and speak before the Nevada Board of Pharmacy on behalf of Optum Compounding Services, LLC f/k/a Avella of Deer Valley, Inc. #38.

Thank you,

A handwritten signature in blue ink that reads "Karen E. Peterson".

Karen E. Peterson
Secretary

15B

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☐ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Imprimis NJOF, LLC

Physical Address: 1705 Route 46, Suite 6B

City: Ledgewood State: NJ Zip Code: 07852

Telephone: (844) 446-6979 Fax: (855) 405-4669

Toll Free Number: (844) 446-6979 (Required per NAC 639.708)

E-mail: imprimisnjof@imprimisrx.com Website: www.imprimisrx.com

Supervising Pharmacist: Kathleen A. Fucillo Nevada License #: 20055

exp
10/31/21

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral

☒ ☐ Sterile Compounding

☒ ☐ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding

☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 5.27.2020

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY**Page 2**FEI Number (From FDA application): 3013024146Please provide the name of the facility as registered with the FDA and the registration number:
Imprimis NJOF, LLC - Reg. # 080431967Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Kathleen A. Fucillo Nevada License Number: 20055A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/AThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Heidi Morales on behalf of Sanjay Samudre
Original Signature of Person Authorized to Submit Application, no copies or stamps

Sanjay Samudre, VP - Mfg. & Technical Services
Print Name of Authorized Person

5/15/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY**Page 4****OWNERSHIP IS A PUBLICLY TRADED COMPANY**

State of Incorporation: Delaware
Parent Company if any: Harrow Health, Inc. / fka Imprimis Pharmaceuticals, Inc.
Corporation Name: Imprimis NJOF, LLC (applicant)
Address: 12264 El Camino Real, Suite 350 (mailing address)
City: San Diego State: CA Zip: 92130
Telephone: (844) 446-6979 Fax: (862) 244-4340
Contact Person: John Saharek (President)

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 01/11/2006 (Delaware)
Registration number issued: CIK#0001360214
Stock Exchange: NASDAQ

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. (see attached)

List of officers and directors. (see attached)

BEFORE THE NORTH DAKOTA
STATE BOARD OF PHARMACY

IN THE MATTER OF IMPRIMIS NJOF,)
)
)
)
)

RESPONDENT.

Admin No. 2018-10-20

STIPULATION AND SETTLEMENT AGREEMENT
AND PROPOSED RECOMMENDATION OF SANCTIONS

COMES NOW, MARK J. HARDY, R. Ph., PharmD, Executive Director of the North Dakota State Board of Pharmacy, hereinafter called "the Board" and Chairman and member of the investigating committee of the North Dakota State Board of Pharmacy, and IMPRIMIS NJOF, sometimes hereafter referred to as "Respondent", located at 1705 Route 46, Suite 6B, Ledgewood, NJ 07852, and hereby stipulate and agree to enter into the Stipulation and Settlement Agreement and Recommendation of Sanctions, as follows:

RECITALS

- A. Respondent, IMPRIMIS NJOF, is an out of state out-sourcing facility located at 1705 Route 46, Suite 6B, Ledgewood, NJ 07852.
- B. Respondent, IMPRIMIS NJOF, does not hold an out-sourcing facility permit to distribute wholesale prescription drugs, medical gases, or medical equipment in this state.
- C. That a Complaint and Statement of Charges was served upon the Respondent based upon allegations that Respondent made unauthorized shipments of non-patient specific prescription medications to eye clinics located in the State of



proceedings based upon the Complaint and Statement of Charges can be resolved on a stipulated basis without the need for a hearing under the North Dakota Administrative Agency's Practices Act, Chapter 28-32 of the North Dakota Century Code.

NOW, THEREFORE, it is hereby Stipulated and Agreed to by and between the parties as follows:

- A. Respondent agrees to be subject to the jurisdiction of the Board.
- B. Respondent expressly waives formal hearing for all facts and legal conclusions referenced herein and any and all procedures before the Board relative to said facts and conclusions to which it might otherwise be entitled by law.
- C. That as Executive Director of the board and Chairman of the investigating committee, Mark J. Hardy, R.Ph. PharmD, received information regarding the possible unauthorized distribution non-patient specific prescription medication to ophthalmologists located in the State of North Dakota. Respondent, IMPRIMIS NJOF, is not licensed as a outsourcing facility under chapter 43-15.3 NDCC in the State of North Dakota and correspondence from Pramod Sharma, Ph.D, Vice-President, Quality, with IMPRIMIS NJOF, admitted that IMPRIMIS NJOF, does not hold a outsourcing facility permit but shipped drug orders to clinics in North Dakota at least 232 times within the past two years.
- D. In the event the Board, in its discretion, does not approve this Stipulation and Proposed Recommendation of Sanctions, it shall be deemed withdrawn and of no evidentiary value and shall not be introduced or relied upon by either party, nor disclosed to any third party and the Board shall not be considered prejudiced against the Respondent in any way.



occurring after the date of the Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions which is not related to the facts, circumstances and requirements therein.

The parties agree that this agreement is the recommendation Mark J. Hardy, R.Ph., PharmD, will present to the Board and that the Board may reject this recommendation after the presentation to the Board. In the event the Board in its discretion does not approve this Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions, it shall be deemed withdrawn and of no evidentiary value and shall not be introduced or relied on by either party nor disclosed to any third party and the Board shall not be considered prejudiced toward Respondent in any way.

This Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions was read in its entirety by Respondent prior to its execution. Respondent understands all of the provisions and has had the opportunity to review the Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions with its attorney and Respondent affirms it was entered into freely and voluntarily by it. The Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies from this Stipulation.



Dated this 13th day of March, 2019.

IMPRIMIS NJOF

~~IMPRIMIS NJOF~~



Mark Baum, CEO

STATE OF NEW JERSEY

)

(ss

COUNTY OF

)

On this _____ day of March, 2019, before me, a notary public in and for said county and state, personally appeared MARK BAUM, CEO, known to me to be the person described in and who executed the foregoing Stipulation and Proposed Recommendation of Discipline and acknowledged to me that she executed the same.

(SEAL)


Notary Public

My commission expires:

See attached

Dated this 21st day of March, 2019.

NORTH DAKOTA STATE BOARD
OF PHARMACY

By 
Mark J. Hardy, R.Ph., PharmD
Executive Director, Chairman and
Member of Investigating Committee
1906 East Broadway Avenue
PO Box 1354
Bismarck, ND 58502-1354
701-328-9535

Dated this 21st day of March, 2019.

David A. Lindell
Special Assistant Attorney General
Counsel for North Dakota State Board of Pharmacy
PO Box 427
Washburn, ND 58577
701-462-8566

STATE OF NORTH DAKOTA)
)
) (ss
COUNTY OF BURLEIGH)

On this 21st day of March, 2019, before me, a notary public in and for said county and state, personally appeared MARK J. HARDY, R. Ph., PharmD, Executive Director of the North Dakota State Board of Pharmacy, known to me to be the person described in and who executed the foregoing Stipulation and Proposed Recommendation of Discipline and acknowledged to me that he executed the same.

(SEAL)

KATHY R. ZAHN
Notary Public
State of North Dakota
My Commission Expires April 12, 2023

My commission expires:



NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 389, Trenton, New Jersey 08625-0389

0739016

1841

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of \$20.00 shall accompany such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

1705 ROUTE 46, SUITE 6B LEDGEWOOD, NJ 07852

Reg. No. IMPRIMIS NJOF, LLC
5005097 1705 ROUTE 46, SUITE 6B
LEDGEWOOD, NJ 07852

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2021

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 4/30/2020

Registration Number: 5005097 **Registered as:** Manufacturer and Wholesale

Parent Company Name: IMPRIMIS NJOF, LLC

Trade Name:

Original Issue Date: 01/11/2017 **Expiration Date:** 01/31/2021

Current Issue Date: 01/16/2020

Disciplines: No

Heidi Morales

Subject: FW: FY2020 Outsourcing Facility Invoice - Imprimis NJOF, LLC

-----Original Message-----

From: DoNotReply_CDERS@fda.hhs.gov <DoNotReply_CDERS@fda.hhs.gov>

Sent: Thursday, November 14, 2019 2:08 PM

To: Brad Bingham <bbringham@imprimisrx.com>

Cc: CDERCollections@fda.hhs.gov; Compounding@fda.hhs.gov; EDRLS@fda.hhs.gov

Subject: FY2020 Outsourcing Facility Invoice - Imprimis NJOF, LLC

Good Afternoon,

We have received the establishment registration fee for Imprimis NJOF, LLC, in the amount of \$18,288. Effective January 01, 2020, your facility located at 1705 Route 46, Suite 6B Ledgewood, NJ 07852 is now registered as a human drug outsourcing facility through December 31, 2020.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:

<https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FDrugs%2FGuidanceComplianceRegulatoryInformation%2FPharmacyCompounding%2Fdefault.htm&data=02%7C01%7Chmorales%40imprimisrx.com%7C6452cead221642fc762d08d769523439%7C3ee10f8a0392483a87fda18c1f4b557b%7C0%7C0%7C637093674090873378&sdata=3USBo9wFe%2BtM1oiX1sYFtwrjmyzwYuZPFXSmCcrq4RE%3D&reserved=0>

CQA User Fee Staff

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY "HARROW HEALTH, INC." IS DULY
INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD
STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS
OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF MAY, A.D. 2020.



4092296 8300

SR# 20203762303

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBullock", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Authentication: 202920290

Date: 05-12-20

IMPRIMIS NJOF, LLC

Imprimis NJOF, LLC Directors & Officers	Harrow Health, Inc. Directors & Officers
John Saharek- President Jole Deal- Secretary Sanjay Samudre – VP (Manufacturing & Technical Services)	Mark L. Baum- CEO and Board member Andrew R. Boll- CFO Robert J. Kammer- Chairman of the Board Teresa F. Sparks- Board member Richard Lindstrom- Board member Anthony Principi- Board member

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

HARROW HEALTH, INC.

Form: 10-K

Date Filed: 2020-03-13

Corporate Issuer CIK: 1360214

15C

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ **New OUTSOURCING FACILITY**

☐ Ownership Change (Provide current license number if making changes:) OUT _____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4 ☐ Partnership – Pages 1-3 & 6
☒ Non Publicly Traded Corporation – Pages 1-3 & 5 ☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: KRS GLOBAL BIOTECHNOLOGY, INC.

Physical Address: 791 PARK OF COMMERCE BLVD

City: BOCA RATON State: FL Zip Code: 33487

Telephone: 888-502-2050 Fax: 866-480-3322

Toll Free Number: 888-502-2050 (Required per NAC 639.708)

E-mail: PHARMACY@KRSBIO.COM Website: KRSBIO.COM

Supervising Pharmacist: SCOTT STANISLAW Nevada License #: 19917

OK
10/31/21

SERVICES PROVIDED

Yes/No

- ☒ ☐ Parenteral
☒ ☐ Sterile Compounding
☒ ☐ Non Sterile Compounding
☒ ☐ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only

Date Processed: 5.12.2020

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

Page 2

FEI Number (From FDA application): 3006412304

Please provide the name of the facility as registered with the FDA and the registration number:

KRS GLOBAL BIOTECHNOLOGY, INC. 3006412304

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.

NONE

Please provide the name and Nevada license number of the supervising pharmacist:

Name: SCOT STANISLAW Nevada License Number: 19917A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/AThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☒ No ☐
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☒ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

ELSA KERPI, PRESIDENT

Print Name of Authorized Person

05/06/2020

Date



APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: FLORIDAParent Company if any: NONE

Address: _____

City: _____ State: _____ Zip: _____

Telephone: 561-430-2360 Fax: 561-430-2360Contact Person: SCOTT STANISLAW, RPh.

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) CLEVELAND DIABETES CARE, INC. 10752 DEERWOOD PARK BLVD SUITE 111 JACKSONVILLE, FL 32256 (100%)

Name Address

b) _____

Name Address

c) _____

Name Address

d) _____

Name Address

- 2) Provide the number of shares issued by the corporation.
- 100

- 3) What was the price paid per share?
- \$28.00

- 4) What date did the corporation actually receive the cash assets?
- 11/08/2019

- 5) Provide a copy of the corporation's stock register evidencing the above information
- ATTACHED

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

ATTACHEDList of officers and directorsATTACHED



791 Park of Commerce Blvd.
Suite 600
Boca Raton, FL 33487
888.242.7996
www.gbtbio.com

May 7, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

Re: Out-of-State Outsourcing Facility Application

To Whom it May Concern,

With respect to the licensing questions 2, 3 and 5, please find our response below. These matters have been previously reported under our Pharmacy Permit PH02535.

Colorado - 2009-2010: There were two issues which were clerical in nature. They were related to bi-monthly zero reporting of controlled substances. The matters were settled and closed.

Missouri - 2009-2010: We shipped office use medication which was not permitted. We were placed on probation which was successfully completed on December 31, 2014.

DEA - 2010-11: We voluntarily surrendered our DEA Registrations. In 2014, we re-applied and received a Pharmacy and Manufacturer Registration, as our business had changed servicing hospitals.

Nebraska - December 2013: We had a non-resident pharmacy application denied based upon the two disciplines mentioned above. We were, years prior, previously licensed in the state.

Alabama -August 2, 2016: KRS was disciplined based on a 2015 Warning Letter from the FDA. The observations in the letter were addressed and the corrections completed several years ago. There has been no further communication from the FDA on this matter. We have disputed the validity of this Alabama action and the matter is under appeal.

California: In August 2017, the California Board of Pharmacy inspected our facility for the Pharmacy Renewal and Outsourcing Permit. Several observations were noted, and the renewals were denied. Since we had ceased doing business in California at that time, we agreed to voluntarily surrender the permits effective April 3, 2019. Please note during the 2017 Inspection, Florida simultaneously conducted a full inspection. There was no discipline taken and all observations were corrected years ago. In addition, the FDA conducted a five-day inspection three months after the California inspection. None of the California Inspection observations were noted by the FDA



791 Park of Commerce Blvd.
Suite 600
Boca Raton, FL 33487
888.242.7996
www.gbtbio.com

Colorado: On April 3, 2018, Colorado temporarily suspended our permit. There were two findings: 1) we dispensed drugs ordered by individuals not licensed to prescribe and 2) we distributed compounds to an animal hospital. Neither of these findings were true. Once we submitted supporting documents, the suspension was vacated.

Oklahoma: On October 25, 2018, Oklahoma denied our renewal for an Outsourcing Permit. They stated this is due to the "Board's inability to monitor non-resident facility corrective actions".

Arkansas: On May 22, 2019, Arkansas denied our application for a Wholesale Distributor Permit. The denial was based on matters mentioned above.

Virginia: On January 22, 2020, Virginia suspended our Pharmacy permit based on the California matter above.

Colorado: On February 6, 2020, Colorado suspended our Pharmacy permit based on the California matter above.

These matters did not involve controlled substances or drugs of concern. We have never had any action taken in our home state of Florida from these matters or any other matter. If you need any additional information, please let me know.

Sincerely,

Scott Stanislaw, R.Ph.
561-430-2360
pharmacy@krsbio.com

Corporate Officers & Directors

Charles P. Richardson, M.D., M.B.A.
Chief Executive Officer
Director

Elsa Kerpi
President
Chief Operating Officer
Secretary
Registered Agent

James Roberts, M.D.
Chairman of the Board
Treasurer
Director

Kevin Hall, M.D.
Director

Haemoon Oh, Ph.D.
Director

Viviana Rodriguez
Director of Finance

KRS Global Biotechnology, Inc. (FEIN 65-1099340) is owned 100% by
Cleveland Diabetes Care, Inc. (FEIN 20-8735962).

KRS Officer's Address

791 Park of Commerce Blvd.
Boca Raton, FL 33487

Cleveland Diabetes Care, Inc.

10752 Deerwood Park Blvd. South
Jacksonville, FL 32256

State of Florida

Department of State

I certify from the records of this office that KRS GLOBAL BIOTECHNOLOGY, INC. is a corporation organized under the laws of the State of Florida, filed on April 12, 2001.

The document number of this corporation is P01000038423.

I further certify that said corporation has paid all fees due this office through December 31, 2019, that its most recent annual report/uniform business report was filed on March 26, 2019, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Twentieth day of February,
2020*



Randy Be
Secretary of State

Tracking Number: 5333393304CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>

ORGANIZED UNDER THE LAWS OF
THE STATE OF FLORIDA



AMERICAN
No. 4

AMERICAN
100

See Reverse for
Certain Definitions

KRS GLOBAL BIOTECHNOLOGY, INC.
Common Stock, \$1.00 par value

This is to certify that _____ is the owner of _____ fully paid and non-assessable shares of the above Corporation transferable only on the books of the Corporation by the holder thereof, in person, or by a duly authorized Attorney upon surrender of this Certificate properly endorsed.

CLEVELAND DIABETES CARE, INC.

ONE HUNDRED (100)

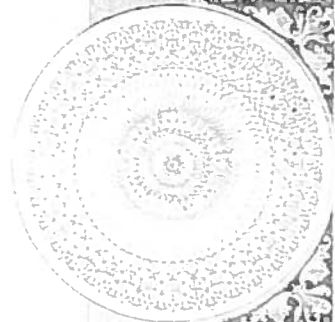
Witness, the seal of the Corporation and the signatures of its duly authorized officers.

November 8, 2019

Dated

Charles Richardson
Charles Richardson, CEO

Elsa Kerpi
Elsa Kerpi, CFO



DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

1857

DATE	LICENSE NO.	CONTROL NO.
11/06/2018	PH 23506	103784

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2024**

KRS GLOBAL BIOTECHNOLOGY, INC
791 PARK OF COMMERCE BLVD
BOCA RATON, FL 33487

QUALIFICATION(S):
SPECIAL P/E



Rick Scott
GOVERNOR



Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW



Department of Health

**License Number: PH23506***Data As Of 5/5/2020*

Profession	Pharmacy
License	PH23506
License Status	CLEAR/
Qualifications	Special P/E
License Expiration Date	2/28/2021
License Original Issue Date	07/24/2008
Address of Record	791 PARK OF COMMERCE BLVD BOCA RATON, FL 33487
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.



U.S. Food and Drug Administration
Protecting and Promoting Your Health

Compounding Quality Act Billing

FY 2020 Compounding Quality Act Invoice	Invoice Date	18-DEC-2019	Invoice Number	CQA207000610
	Due Date	02-JAN-2020	Invoice Amount	\$18,288.00
KRS Global Biotechnology, Inc. Attention: Charles Richardson, MD 791 Park of Commerce Blvd., Suite 600 Boca Raton, FL 33487 US				

Type of Fee	Fiscal Year to which this payment applies	Total
Annual Establishment Fee	2020	\$18,288.00
Total Fee:		\$18,288.00

Payment Information

Online payments:

The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card.

Make an online payment at <https://userfees.fda.gov/pay>.

Alternative Payment Options

Checks:

Mail payment and copy of your invoice to:
 Food and Drug Administration
 P.O. Box 979033
 St. Louis, MO 63195-6733

For overnight courier use only:

U.S. Bank
 ATTN: Government Lockbox 979033
 1005 Convention Plaza
 St. Louis, MO 63101

If a phone number is also required for courier delivery, use 314-418-4013.

Wire Transfers:

U.S. Department of the Treasury
 TREAS NYC
 33 Liberty Street
 New York, NY 10045

FDA Deposit Account Number: 75060099
 Routing/Transit Number: 021030004
 SWIFT Number: FRNYUS33

Reference - Invoice # CQA207000610

Payments should include the invoice number with the payment.
 All fees assessed by your financial institution for wire transfers should be added to your payment to ensure that the full invoice amount is received.

Payment must be received by the U.S. Food and Drug Administration by the due date. Any check or bank draft should be drawn on or payable through U.S. financial institutions located in the United States. Payments made by wire transfer must include the invoice number with the payment. **Bank fees assessed for wire transfers or currency exchange are the responsibility of the firm and should not be deducted from the payment amount.**

If full payment is not received by 02-JAN-2020, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

This invoice will not be considered paid until full payment has been cleared and the amount is received by the U.S. Food and Drug Administration.

For further information concerning this invoice, please contact the Office of Management Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov or by phone (301) 796-7900.



STATE OF FLORIDA DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE – ISU

503b Outsourcing Inspection Form



1860

CORPORATE NAME KRS GLOBAL BIOTECHNOLOGY, INC.	INSPECTION NUMBER 167345	TYPE OF PERMIT OUTSOURCING FACILITY	DATE OF INSPECTION 7/30-8/2, 8/5,8/6, 8/14/2019
DOING BUSINESS AS	FILE NUMBER 15916	LICENSE # PH23506	
STREET ADDRESS 791 PARK OF COMMERCE BLVD		TELEPHONE #	EXT #
CITY BOCA RATON	COUNTY PALM BEACH	STATE/ZIP FL/33487	

QUALITY 21CFR part 211 subpart B: Responsibilities of Quality Unit

Remark

Out of Specifications (OOS) investigations that include environmental excursions, sterility failures, and production equipment issues are deficient. Many investigations are closed without root cause analysis and assessing impact on batches that may or may not have been released.

Observation

- Investigation, impact of additional batches, preventative and corrective actions into environmental monitoring excursions in critical sterile compounding areas is not done.
- Surface sampling collected on 3/19/2019 in hood #313 located in cleanroom 4 resulted in mold growth. Batches produced in this hood include, and that were distributed include, L-Carnitine 170mg/ml (Lot 03192019@2) and Methylcobalamin 1mg/ml (Lot 03192019@8).
- Dynamic weekly surface sampling conducted in ISO 7 cleanroom 5 on 3/20/2019 resulted in TNTC (Too Numerous to Count) CFU's on syringe bin. Lot 03202019@12 (METHIONINE/INOSITOL/CHOLINE/CYANO-B12 25/50/50/1MG/ML, 30ML VIAL) and 03202019@3 (NICOTINAMIDE ADENINE DINUCLEOTIDE 500 MG/VIAL (PF) LYOPHILIZED, COMPOUNDED) were compounded in this room and distributed without determining root cause of growth.
- Quality failed to determine cause of EM OOS from 7/16/2018 through 5/22/2019 (OOS reports 1908, 1911, 1919, 1920, 1937, 1938, 1942, 1945, 1949, 1955, 1960, 1963, 1965, 1966, 1968, 1969, 1972, 1979, 1985, 1986, 1989, 1990, 1995, 2003, 2005, 2006, 2007, 2008, 2014, 2015, 2019, 2032, 2033, 2057, 2059, 2075). There was no assessment on possible batches that may have been affected and no documentation of preventative and corrective actions.

Observation

- Sterility failures were not investigated.
 - The following batches were released from OOS 1910 L-Asparaginase 10,1000 IU lyophilized (lot 0702218@1 Norepinephrine 8mg/ 250ml IV (lot 03122019@10).
 - There was no root cause determined for sterility failures found during sterility testing from 7/2/2018 through 5/13/2019 (OOS 1910, 1917, 1933, 1936, 1950, 1957, 1961, 1996, 1998, 1999, 2012, 2014, 2022, 2023, 2024, 2025, 2035, 2037, 2044, 2052, 2056, 2077).

Observation

- BI failure in de-pyrogenation oven that ensures glassware used in production (beakers / cylinders) and final product (vials 5ml, 10ml, 30ml, 50ml) is free from endotoxin.
 - OOS 1980, 2011, 2036, and 2049 indicates BI failure was due to technician error without identifying organism. Vials from two lots (11052018@4 and 11052018@20) were released.

Observation

- Quality Unit failed to monitor, review and remediate alerts for CIMScan monitoring of cleanrooms and PEC's for particle counts, temperature and cleanroom differential pressures.
 - On 8/13/2018, 8/22/2018, 8/24/2018, 8/28/2018, 9/19/2018 and 10/17/2018 non-viable particle counts were out of range in ISO 5 cleanroom 4. Excursions were not investigated and eight batches made on these days were released for distribution.

Observation

- Cleanroom and device certification reports are not reviewed and signed by Quality.
 - Internal cleanroom certification reports dated 6/4/2019 indicate primary and secondary engineering controls (PEC's and SEC's) were not reviewed by Quality.
 - Internal certification report dated 6/4/2019 indicates HEPA filters in hoods #301 and #610 were within conformance, however on 7/1/2019 third-party vendor failed both PEC's due to HEPA filter leaks. There was no investigation on impact of lots that were produced in the affected PEC's.

Observation

- Evoqua water system validation for WFI was not reviewed and approved by Quality and lacks substantiated data to support that the unit is within conformance as intended by manufacturer.
 - Non-sterile WFI from system is used in production of sterile product and for dilution of sterile cleaning agents used to clean PEC's and compounding production equipment.

- Quality failed to investigate cause of TNTC (Too Numerous to Count) micro contamination from water sampling. Reports show elevated micro-contamination collected from Port 3 of Evoqua water system on 4/25/2019. The WFI was used in seven sterile batches that were released for distribution.

Observations

- Quality failed to perform investigation that resulted in Out-of-Tolerance for Total Organic Carbon (TOC) meter during calibration on 7/26/2016 and 5/28/2018.

FACILITIES 21CFR part 211 subpart C: Design and Construction Features

Remark

The control of air pressure, dust, humidity and temperature is inadequate for the manufacturing, processing, and storage of drug products and containers.

Observation

- Records indicate recording of continuous particle counts inside ISO 5 and ISO 7 compounding rooms exceeded particle limits.
- Particle counts in ISO 5 cleanroom 4 were not continuously monitored from 7/1/2018 through 7/25/2019.
- ISO 7 cleanrooms 6 and 7 were not monitored from 7/1/2018 through 7/25/2019.
- ISO 7 cleanroom 8 was not monitored from 7/1/2018 through 8/1/2019.
- Non-viable particle counts are not monitored during production in any ISO 5 PEC or production equipment.
- Cleanroom certification report (7/12/2019) indicates non-viable particle counts were collected during "at-rest" conditions without production equipment on or components (vials, syringes, IV bags) inside PEC's.
- Policy P-OPS-009.11.7 requires triple clean when there are particle count excursions, but this is not documented.

Observation

- Air pressure differentials are not continuously monitored and do not demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding.
- Differential pressure logs dated 6/1/2019 through 7/31/2019 indicate cleanrooms 1, 2, 4, 5, 6, 7, and 8 were not in a state of control in that a cascading pressure differential was maintained throughout the compounding rooms.

Observation

- Smoke studies do not demonstrate sweeping action of HEPA filtered air over drug product.

- HEPA filters in PEC's, automated production equipment (Dara cleanroom 1; Colanar cleanroom 3; Cozzoli cleanroom 4) and ISO 5 path (from Cozzoli to lyophilizer) do not provide sufficient velocity to sweep particles over and away from product.
 - HEPA filtered air does not show laminar air over partially stoppered vials from the Cozzoli to the lyophilizer (ISO 5 cleanroom 4). Partially stoppered vials are placed on a work table under a non-HEPA filtered ceiling tile prior to transporting.
- Design and placement of Colanar fill line blocks vertical HEPA filtered air. During filling, arm rotates over vials inside a vertical laminar flow hood.
 - ISO 5 cleanrooms 3 and 4 that contain fill equipment lack laminar airflow.
 - Smoke studies show they were conducted without components (IV bags, syringes, vials) and repeater pumps inside PEC's.

Remark

The layout and organization of the facility is not designed in a way to prevent contamination.

Observation

- HEPA filter located in BSC hood #568 is dirty/rusted.

Observation

- Inadequate pressure and design of ISO 8 prep room 3 where in-process de-pyrogenated glassware (beakers, cylinders) and end-product containers (5ml, 10ml, 30ml, 50ml vials) are stored.
- Return vents in prep room 3 are in the ceiling which prevents top to down diluted HEPA filtered air.

Remark

Primary engineering controls are not re-certified whenever the unit is relocated.

Observation

- The following PEC's were not-recertified after moving: hood 903 was transferred from cleanroom 5 to cleanroom 7 on 7/12/2019; hood 568 was transferred from cleanroom 5 to cleanroom 2 on 7/12/ 2019; hood 303 was transferred from cleanroom 2 to cleanroom 3 on 8/3/2018.

ENVIRONMENTAL MONITORING 21CFR part211

Remark

Adverse changes in the environment are investigated and promptly remediated.

Observation

- Firm uses CIMScan system to monitor pressure, temperature and particles of cleanrooms.

- Records indicate there are numerous temperature, particle counts and pressure excursions that were not addressed.
- Alerts from CIMScan system were not monitored prior to June 2019.
- Alerts that were identified on monitoring system were not addressed and there was no corrective action.

Observation

- OOS 1990 Environmental monitoring logs indicate mold contamination in ISO 5 hoods, cleanrooms and ISO 7 airlock. No root cause or corrective actions documented in investigation.
 - EM conducted on 11/29/2018; All lots produced on this day were rejected.
 - Air settling plates: Mold - hoods 310, 305, 312, 313.
 - Surface sampling: Mold - hoods 313, 306, 301, 302, 302, 303, 308, 310, 315.
 - Surface sampling: Mold - cleanrooms 1, 2, 3, 4, 5, 6, 7, 8 and ISO 7 airlock.

Remark

Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment.

Observation

- Environmental re-testing of CFU excursions are not collected in affected areas.
 - OOS 2075 (5/22/2019) indicates dynamic surface sampling of syringe bins in cleanrooms 1 and 7 exceeded limits for ISO 7 environment. A level 3 remediation cleaning was performed (5/29/2019) and static surface sampling logs indicate syringe bins were not re-sampled.

Equipment 21CFR part 211 subpart D: Equipment design, construction, cleaning and maintenance, Filters

Remark

Cleaning and disinfecting of aseptic equipment is not done in a way to prevent possible contamination of sterile product.

Observation

- Firm does not have cleaning effective studies for critical compounding equipment.
- Surfaces inside LAFW's, BSC's and production equipment (Dara, Colanar, Cozzoli, Cozzoli crimper, Baxter repeater pumps) are cleaned with cleaning agents (LPH and Vesphene) that are diluted with non-sterile WFI or deionized water that are contained in non-sterile spray bottles.

Observation

- CIMScan non-viable count excursions are not remediated with level three cleanings per your SOP P-Prod-009 Sterile Compounding Area Cleaning and Disinfecting.
- Evoqua water system that produces DI used to dilute cleaning agents used to clean ISO 5 hoods and production equipment is not validated.

LABORATORY 21 CFR part 211 subpart I: Laboratory Controls**Remark**

Sterile formulations lack supportive evidence to support assigned Beyond Use Dates.

Observation

- Container closure studies have not been done for all CSP formulations to determine if there are impurities or degradants are contained in final product as a result of aging.
- Final drug containers for formulations are vials, syringes and IV bags.
- Stability studies of the following formulations are currently in process:
 - Glycopyrrolate (PF) 0.2mg/ml (90-day BUD)
 - Ketamine HCL (PF) 10 mg/ml (90-day BUD)
 - Moxifloxacin (PF) 1mg/ml ophthalmic syringe (90-day BUD)
 - Neostigmine Methyl sulfate (PF) 1mg/ml (90-day BUD)
 - Rocuronium Bromide (PF) 10mg/ml (45-day BUD)

21CFR210.1(b) "The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action".

Additional Remarks

Prior to this inspection, firm has responded to deficiencies via email based on June 20, 2019 inspection conducted by DOH.

Some observations documented from June 2019 inspection are in process for compliance.

This cGMP inspection was co-conducted with FDA Investigator Jennifer Huntington. Adam Malhoit QA Manager and Despina Menon VP Quality and Regulatory Affairs were present during inspection.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Riccardo D. Roscetti, Owner and President

PRINT NAME OF RECIPIENT_____

ID _____

_____	_____	_____
Institutional Representative	Date	Investigator/Sr. Pharmacist Signature

15D

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☒ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: NEPHRON STERILE COMPOUNDING CENTER, LLC

Physical Address: 4500 12th Street Ext.

City: West Columbia

State: SC

Zip Code: 29172

Telephone: 800-443-4313

Fax: 803-926-9853

Toll Free Number: 800-443-4313

(Required per NAC 639.708)

E-mail: LICENSE@NEPHRONPHARM.COM

Website: https://www.nephronpharm.com/

Supervising Pharmacist: Stuart Tolman

Nevada License #: 10916 ✓

SERVICES PROVIDED

Yes/No

☒ ☐ Parenteral

☒ ☐ Sterile Compounding

☐ ☒ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding

☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only

Date Processed: 3-26-2020

Amount: 500.00



RECEIVED
3-9-2020

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY**Page 2**FEI Number (From FDA application): 3011158388Please provide the name of the facility as registered with the FDA and the registration number:
NEPHRON STERILE COMPOUNDING CENTER, LLCPlease provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
NEPHRON 503B OUTSOURCING FACILITY

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Stuart Tolman Nevada License Number: 10916A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/AThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

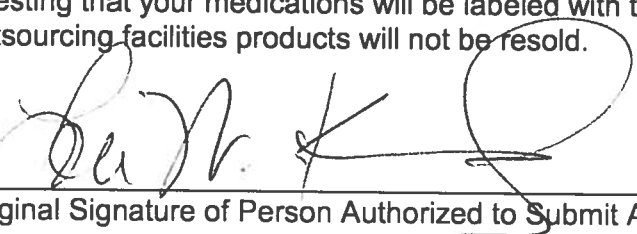
I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

X


Original Signature of Person Authorized to Submit Application, no copies or stamps

Lou w. Kennedy

Print Name of Authorized Person

Date

03/04/2020

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY**Page 5****OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**State of Incorporation: SOUTH CAROLINAParent Company if any: NEPHRON SC, INCAddress: 4500 12th Street Ext.City: West ColumbiaState: SCZip: 29172Telephone: 800-443-4313Fax: 803-926-9853Contact Person: LOU W. KENNEDY

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a)	<u>Lou W. Kennedy</u>	<u>4500 12th Street Ext. Columbia, SC 29172</u>
	Name	Address
b)	<u>William P. Kennedy</u>	<u>4500 12th Street Ext. Columbia, SC 29172</u>
	Name	Address
c)	<u>Ashley Kennedy Whitner</u>	<u>4500 12th Street Ext. Columbia, SC 29172</u>
	Name	Address
d)	<u>Courtney Kennedy McGowan</u>	<u>4500 12th Street Ext. Columbia, SC 29172</u>
	Name	Address

2) Provide the number of shares issued by the corporation. 10,0003) What was the price paid per share? No par value4) What date did the corporation actually receive the cash assets? 11/04/2011

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Business Entities Online

File, Search, and Retrieve Documents Electronically

NEPHRON STERILE COMPOUNDING CENTER LLC

Corporate Information

Entity Type: Limited Liability Company

Status: Good Standing

Domestic/Foreign: Domestic

Incorporated State: South Carolina

Important Dates

Effective Date: 03/12/2014

Expiration Date: N/A

Term End Date: N/A

Dissolved Date: N/A

Registered Agent

Agent: CT CORPORATION SYSTEM

Address: 2 OFFICE PARK COURT, SUITE 103
COLUMBIA, South Carolina 29223

Official Documents On File

Filing Type	Filing Date
Amendment	04/24/2014
Organization	03/12/2014

Former Names

Name	Filing Date
NEPHRON COMPOUNDING CENTER LLC	03/14/2014

Business Entities Online

1873

File, Search, and Retrieve Documents Electronically

NEPHRON STERILE COMPOUNDING CENTER LLC

Corporate Information

Entity Type: Limited Liability Company

Status: Good Standing

Domestic/Foreign: Domestic

Incorporated State: South Carolina

Important Dates

Effective Date: 03/12/2014

Expiration Date: N/A

Term End Date: N/A

Dissolved Date: N/A

Registered Agent

Agent: CT CORPORATION SYSTEM

Address: 2 OFFICE PARK COURT, SUITE 103
COLUMBIA, South Carolina 29223

Official Documents On File

Filing Type	Filing Date
Amendment	04/24/2014
Organization	03/12/2014

Former Names

Name	Filing Date
NEPHRON COMPOUNDING CENTER LLC	03/14/2014

PERMIT NO. 16464
DATE ISSUED 05/20/2019

PRC1035984

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy Outsourcing Facility Permit

2019-2020

Expires 06/30/2020

NEPHRON STERILE COMPOUNDING CENTER, LLC**Permit Holder: WILLIAM P. KENNEDY**

4500 12th ST EXT

WEST COLUMBIA SC 29172



Spencer A. Morris, Chairman



Eric Strauss, Vice Chairman

U.S. Food & Drug Administration | Home | About | Contact | Privacy Policy | Accessibility | Site Map

U.S. FOOD & DRUG ADMINISTRATION

Home | About | Contact | Privacy Policy | Accessibility | Site Map

Registered Outsourcing Facilities

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated 8/1/2019 12:00 PM

- Information Concerning Outsourcing Facility Registration
- Outsourcing Facility Product Reporting Information

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data link. Facilities that are newly updated to the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility	Date of Most Recent Registration as an Outsourcing Facility	End Date of Last FDA Inspection Related to Compounding	Has a Form FDA Inspection?	Other Allotment or Any Based on Last Inspection?	Intends to Compound Sterile Drugs from Bulk Drug Substances?
---------------	-------------------------------	---	---	--	----------------------------	--	--

WARNING: This table contains information that is not to be released to the public. It is for internal use only. Do not disseminate this information to the public.



Online reporting of disciplinary action is currently being updated. For current information on disciplinary actions taken against licensees please contact Board Staff at shunting@pharmacy.nv.gov or (775) 850-1440.

VERIFY LICENSE

Last Name	First Name	License#	City	State	Country	Discipline	Action
Tolman	Stuart	10916	TROUTMAN	NC	United States	None	

License Number : 10916

Name : Tolman, Stuart

License Type : Pharmacist

License Status : Active

License Date : 03/04/1992

Discipline :

Expiration Date : 10/31/2021



State of Incorporation: South Carolina
Corporate Address:
4500 12th Street Extension
Columbia, SC 29172
Parent Company: Nephron Inc.
FEIN: 37-175-2439

Nephron Sterile Compounding Center LLC Corporate Officers

Name	Title	Business Contact Information	Date of Birth
William Kennedy	Director (49%)	4500 12 th St. Ext. West Columbia, SC 29172	
Lou Kennedy	President, CEO, Owner (17%)	4500 12 th St. Ext. West Columbia, SC 29172	
Ashley Kennedy Whitner	Vice President Owner (17%)	4500 12 th St. Ext. West Columbia, SC 29172	
Courtney Kennedy McGowan	Vice President Owner (17%)	4500 12 th St. Ext. West Columbia, SC 29172	
Daniel Stoner	Secretary/ Treasurer	4500 12 th St. Ext. West Columbia, SC 29172	

NEPHRON SC, INC.

A South Carolina Corporation

STOCK TRANSFER LEDGER

Cert. No.	Date	No. of Shares	Issued To	Transfer			
				Date	To Cert. No.	To Whom Transferred	Shares
<u>Authorized Issuance:</u>							
<i>10,000 shares of Common Stock, of which 1,000 shares are Class A Voting Common Stock @ No Par Value and 9,000 shares are Class B Non-Voting Common Stock @ No Par Value</i>							
CLASS A VOTING COMMON STOCK							
1A	11/4/2011	340	Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT)				
2A	11/4/2011	170	Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP)				
3A	11/4/2011	490	William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002				
CLASS B NON-VOTING COMMON STOCK							
1B	11/4/2011	3,060	Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT)				
2B	11/4/2011	1,530	Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP)				
3B	11/4/2011	4,410	William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002				

NEPHRON SC, INC.

A South Carolina Corporation

RECORD OF SHAREHOLDERS

Name of Shareholder	Certificate No.	Date of Issuance	No. of Shares Issued (this certificate)	Total Cumulative Shares Issued	Ownership Percentage
CLASS A VOTING COMMON STOCK					
Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT) Special Trustee: Christopher E. Erblich	1A	11/4/2011	340	340	34%
Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP) Special Trustee: Christopher E. Erblich	2A	11/4/2011	170	170	17%
William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002 Special Trustee: Christopher E. Erblich	3A	11/4/2011	490	490	49%
TOTAL CLASS A VOTING:				1,000	100%
CLASS B NON-VOTING COMMON STOCK					
Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT) Special Trustee: Christopher E. Erblich	1B	11/4/2011	3,060	3,060	34%
Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP) Special Trustee: Christopher E. Erblich	2B	11/4/2011	1,530	1,530	17%
William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002 Special Trustee: Christopher E. Erblich	3B	11/4/2011	4,410	4,410	49%
TOTAL CLASS B NON-VOTING:				9,000	100%

RECAPITULATION OF VOTING AND NON-VOTING OWNERSHIP						
Shareholder	Voting		Non-Voting		Combined Voting & Non-Voting	
	Shares	% of Total Shares (10,000)	Shares	% of Total Shares (10,000)	Shares	% of Total Shares (10,000)
Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT)	340	3.4%	3,060	30.6%	3,400	34%
Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP)	170	1.7%	1,530	15.3%	1,700	17%
William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002	490	4.9%	4,410	44.1%	4,900	49%
TOTALS:	1,000	10%	9,000	90%	10,000	100%

15E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☒ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: OPS International Inc. dba Olympia Pharmacy

Physical Address: 6700 Conroy Rd, Ste 155

City: Orlando State: FL Zip Code: 32835

Telephone: 407-673-2222 Fax: 407-673-1234

Toll Free Number: 1-833-684-0495 (Required per NAC 639.708)

E-mail: confidence@olympiapharmacy.com Website: www.olympiapharmacy.com

Supervising Pharmacist: Brittney Baker Nevada License #: 20400

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral

☒ ☐ Sterile Compounding

☒ ☐ Non Sterile Compounding

☒ ☐ Mail Service Sterile Compounding

☐ ☐ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only

Date Processed: 5.12.2020

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

Page 2

FEI Number (From FDA application): 3009724085

Please provide the name of the facility as registered with the FDA and the registration number:

OPS International Inc. dba Olympia Pharmacy; 017674368

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.

Olympia Pharmacy

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Britney Baker Nevada License Number: 20400A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/AThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

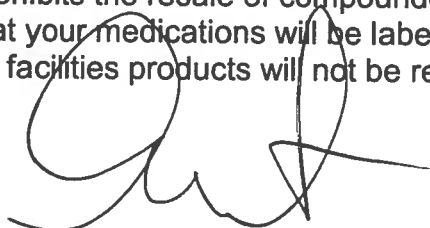
I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Marco Loleit

Print Name of Authorized Person

5-4-2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 7

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Marco Lolait (100% of business owned)

Business Name: OPS International Incorporated

Current Business Address: 6700 Carroy Rd, Ste 155

City: Orlando State: FL Zip Code: 32835

Telephone: 407-673-2222 Fax: 407-673-1234

List any physician shareholders and percentage of ownership.

Name: ~~NA~~ %: _____

Name: ~~N~~ %: _____

Name: ~~A~~ %: _____

Name: _____ %: _____



6700 Conroy Rd, Ste 155
Orlando, FL 32835
Phone (407) 673 2222

To Whom It May Concern:

I, Marco Loleit, is the sole 100% owner of OPS International Inc. DBA Olympia Pharmacy. Olympia Compounding Pharmacy is an FDA registered outsourcing facility; a full service pharmacy for the compounding (admixture) of sterile and non-sterile specialty medications for consumers.

The Pharmacy is open for operation AND call to its toll-free number at (888) 323-7788 **Monday through Friday, 9am to 6pm, Saturdays, 9am-1pm, closed on the Sundays.** Patients during these hours of operation have access to a Pharmacist who in turn has access to patient records in the McKesson pharmacy system.

Please do contact me at marco@olympiapharmacy.com for any further questions in this regard and for any future commitments.

Thank You,

Marco Loleit.



5 May 2020

To Whom It May Concern:

We wanted to inform since we are certain it is difficult to track these details, occurrences since our April 13th concluded FDA inspection. The inspection resulted in the attached FDA 483 notice, we initiated a response with corrective actions, the first and last of those responses are also attached.

Thereafter, we got a notice from the agency for a regulatory meeting in Dallas, Texas. The meeting was to discuss our corrective actions thus far and reconcile details with the agency since it had been a lot of paperwork back and forth. The outcome of the regulatory meeting held September 12th, 2019 was a Voluntary Action Indicated status. We continue to update the agency on quality improvements with the last of our updates to the agency in March of this year attached for your review as well.

Please feel free to contact me for any further clarification.

Thank You,

05 May 20




Confidence Ekeanyanwu
 Quality & Regulatory Manager
Olympia Compounding Pharmacy
 FDA Registered 503B Outsourcing Facility
 6700 Conroy Rd # 155 Orlando, FL 32835
Mobile: (407) 664-6608
Phone: (407) 673-2222
Fax: (407) 673-1234

"Knowledge is power. Information is liberating. Education is the premise of progress, in every society, in every family."

-Kofi Annan.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 4/6/2018-4/13/2018* FEI NUMBER 3009724085
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner		
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155	
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<p>A. Your procedure, Complaint Handling, P-219, Version 2, 28 July 16, fail to provide minimum requirements for an adequate investigation to be conducted in order to determine a root cause, customer complaint assessment requirements to assess for ADR reportability, and the documentation of such actions.</p> <p>B. Your quality unit failed to have conducted and documented an ADR assessment as part of the following received customer complaints where your firm was made aware of potential side effects for your firm's compounded sterile drug products.</p> <ol style="list-style-type: none"> 1. CC-2017-005, received 3/31/2017, RX # 4015834 for compounded sterile drug, 10 Testost CYP 200MG/ML *10 ML* Inj., Lot # A3218. 2. CC-2017-004, received 3/29/2017, RX # 4013414 for compounded sterile drug, 20 Testost CYP 200MG/ML *10 ML* Inj, Lot # 11725. 3. CC-2017-001, received 2/17/2017, RX # 6143784 for compounded sterile drug, 600 Polidocanol 0.35% MDV (30 ML). 4. CC-2017-013, received 8/31/2017, RX # 6185196 for compounded drug, 60 Estriol .1 MG/CLOBET .5% PETROL, Lot # H0016. <p>C. Your quality unit failed to adequately document and conduct an investigation into the following customer complaints to determine the root cause, and assign appropriate corrective action(s) the customer reported issues:</p> <ol style="list-style-type: none"> 1. CC-2018-05, received 3/28/2018, documents your firm shipping s Rx # 6248938, T-50 (PAP 8.8/PHE 0.29/AP 2.9) to the incorrect patient address. Your quality unit failed to adequately investigate to determine the root cause and document corrective actions to 		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	DATE ISSUED 4/13/2018
	Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 04-13-2018 19:13:08 X	
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 OF 9 PAGES		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 4/6/2018-4/13/2018* FBI NUMBER 3009724085
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner		
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155	
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>Protective apparel is not worn as necessary to protect drug products from contamination.</p> <p>Specifically,</p> <p>A. On 4/9/2018, your technician was observed in Buffer Room 2 (ISO 5 Classified) as having her neck exposed sporadically between the worn sterile hood and gown while aseptic manipulating a bag to bag sterile filtration transfer of drug product, PGE-2, Lot # D3009.</p> <p>B. On 4/9/2018, during EM sampling at shift end, your pharmacy technician was observed within your Non-Hazardous ISO 7, Prep Room 1 without being adequately gowned while collecting EM samples. Your technician failed to follow your firm's gowning clean room procedure, Hand Hygiene and Garbing, P-404, Version 3, by not wearing a sterile gown.</p>		
<p>OBSERVATION 2</p> <p>The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.</p> <p>Specifically,</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	DATE ISSUED 4/13/2018
	 Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 04-13-2018 19:13:08	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 4/6/2018-4/13/2018* FEI NUMBER 3009724085
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner		
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155	
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<p>prevent the recurrence.</p> <ol style="list-style-type: none"> 2. CC-2018-06, received 3/30/2018, documents your firm's failure to apply an auxiliary label on the finished drug product, RX # 6250411, TRIMIX (PA 15/PH .5/PG 5) Injection, which documents the sterile finished compounded drug storage conditions. 3. CC-2018-03, received 3/27/2018, documents your firm's shipping the incorrect finished compounded drug to a customer. Your firm incorrectly shipped HCG 10000, Lot # B18A12, BUD 2/19 instead of the correct sterile compounded sterile drug product HCG 5000, Lot # C18005, BUD 3/19. 4. CC-2017-011, received 8/28/17, documents your firm failure to document and have objective evidence in support of such corrective action. Complainant reported receiving Rx # 4019639 identified on the patient specific label incorrectly as 30 Testost 0.1% (1 MG/ML) Cream. The compounded drug should have been labeled as 30 Testosterone 1% (10MG/ML) CRM on the patient specific label. 		
OBSERVATION 3 Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. Specifically, D. Your procedure, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, P-304, Version 4 require the use of STERIS Spor-Klenz-Ready to Use (Sterliant/Sporicidal) with a contact time of 10 minutes, and PeridoxRTU Ready to Use (Disinfectant) with a contact time of 10 minutes for weekly and monthly clean room cleaning but fail to require the documentation of		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E. Moore -3 Date Signed: 04-13-2018 13:13:00	DATE ISSUED 4/13/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314		DATE(S) OF INSPECTION 4/6/2018-4/13/2018*	
		FEI NUMBER 3009724085	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner			
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy		STREET ADDRESS 6700 Conroy Rd Ste 155	
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515		TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<p>contact times as a form of verification for activity. Your documented contact time for STERIS Spor-Klenz-Ready to Use (Sterliant/Sporicidal) of 10 minutes failed to meet the manufacturers requirement of 30 minutes.</p> <p>E. Your firm fails to have scientific data and or performed any studies in support STERIS Alcare Plus Hand Sanitizer effectiveness as a disinfectant on sterile gloves used within your ISO 8, ISO 7, and ISO 5 classified clean room. The sanitizer is labeled as a hand disinfectant. STERIS Alcare Plus Hand Sanitizer labeling contains no information reporting it as being sterile and appropriate for use on gloves. STERIS Alcare Plus Hand Sanitizer has been used as a disinfectant on sterile gloves since 2015.</p>			
OBSERVATION 4 Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release. Specifically, no lyophilized sterile drug product reconstitution specification has been established to be used as part of the released criteria prior finished sterile drug product distribution. For example, your firm failed to establish a reconstitution specification for the release of the following drug products: <ul style="list-style-type: none"> • HCG • Sermorelin • Sermorelin GHRP 			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator		DATE ISSUED 4/13/2018
	Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 04-13-2018 19:13:05 X		
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 4 OF 9 PAGES			

**Detailed Response to
Form FDA-483
Dated 13APR18**



03MAY18



6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Thursday, May 3, 2018

Ms. Monica Maxwell
Program Division Director
United States Food and Drug Administration
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Good Day Ms. Maxwell,

We are writing in response to the FDA Form-483 observations issued on April 13, 2018 regarding the inspection of OPS International Incorporated DBA Olympia Pharmacy, located at 6700 Conroy Road, Suite 155, Orlando, FL 32835. Olympia takes FDA's observations very seriously and as such, we are continuing to make improvements to ensure compliance with all applicable laws and regulations. The goal is to protect patients with respect to sterility assurance and product quality which includes compliance with Title 21 CFR Parts 210 and 211.

Below is a detailed response to each observation issued, along with supporting documentation references and commitments. **Table 1** outlines the list of future commitments to the agency with respect to the observation items, while **Table 2** outlines the attachments corresponding to the detailed responses given.

We intend to provide at least one more response to the agency in 90-days specifying the status of the listed commitment action items toward the facility's quality improvement program and continue with reports every six-months thereafter until all commitments have been completed.

We appreciate the opportunity to continue working together with the FDA are fully committed to implementing the DQSA requirements in a way that preserves access to compounded drugs for patients who have a medical need for them, while protecting patients from poor quality or otherwise unsafe compounded drugs that could cause them serious harm.

For any questions or additional clarifications, please feel free to contact us at any time.


Sincerely,

A handwritten signature in blue ink, appearing to read "Marco Loleit", followed by the date "03 May 2018" written in a similar style.

Marco Loleit
Chief Executive Officer
Olympia Compounding Pharmacy
Mobile: 407-267-6468
Email: marco@olympiapharmacy.com

A handwritten signature in blue ink, appearing to read "Confidence Ekeanyanwu", followed by the date "03 May 2018" written in a similar style.

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 2 of 11
		Version Date: 03MAY18

NOTE:

- Form FDA-483 text is represented with Bold, Italic text.
- **Table 1** at the end of the document contains the Commitments to FDA outlined throughout this response letter and their due dates.
- **Table 2** contains the Attachment List.

OBSERVATION 1

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

- A. On 4/9/2018, your technician was observed in Buffer Room 2 (ISO 5 Classified) as having her neck exposed sporadically between the worn sterile hood and gown while aseptic manipulating a bag to bag sterile filtration transfer of drug product, PGE-2, Lot# D3009.*

OLYMPIA'S RESPONSE (1A):


In response to this observation, the Technician was immediately pulled from the cleanroom during the inspection. Deviation D-2018-05 was initiated to investigate this event. The completed and approved deviation can be found in **Attachment 1**. It was determined that the reason for the neck exposure was the Technician's hair in a bun, which caused the hood to bulge out in the back. The root cause of the event was due to the way the hair was tied creating a bulge within the garb hood. Gowning material used, and the general gowning process were found to be adequate and no changes are required. There is no impact to the product that was being filtered as all other environmental monitoring and personnel monitoring passed for the day, and PGE-2 lot # D3009 was ultimately discarded in response to Observation 6. As part of the deviation, the event was discussed with the Technician by the Quality Manager. No additional corrective actions were deemed necessary as this was determined to be a single incident due to the Technician's hair bun.

- B. On 4/9/2018, during EM sampling at shift end, your pharmacy technician was observed within your Non-Hazardous ISO 7, Prep Room 1 without being adequately gownned while collecting EM samples. Your technician failed to follow your firm's gowning clean room procedure, Hand Hygiene and Garbing, P-404, Version 3, by not wearing a sterile gown.*

OLYMPIA'S RESPONSE (1B):

We have undertaken a comprehensive and on-going corrective action identifying several changes to the control systems in place governing the aseptic technique and garbing protocol. Deviation D-2018-06 and CAPA 2018-02 were initiated to investigate and correct this event during the inspection. The deviation and CAPA documents were shown in draft form to the Inspector in immediate action for the observation to investigate the event. Completion of the investigation for D-2018-06 and execution of CAPA 2018-02 can be found as **Commitment 1 in Table 1**.

CONFIDENTIAL

 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 3 of 11
		Version Date: 03MAY18

OBSERVATION 2

The responsible procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

- A. Your procedure, Complaint Handling, P-219, Version 2, 28 July 16, fail to provide minimum requirements for an adequate investigation to be conducted in order to determine a root cause, customer complaint assessment requirements to assess for ADR reportability, and the documentation of such actions.*

OLYMPIA'S RESPONSE (2A):

During the inspection the inspector was briefed on changes that were in the process of being implemented for the complaint system, specifically surrounding adverse events. This was a known deficiency within the complaint process, and Olympia was taking steps to correct it prior to the inspection. A draft copy of policy P-219, Drug Safety and Surveillance Program, which included new requirements for adverse event evaluation, investigation requirements, root causes analysis, FDA reporting, and documentation of these activities, was reviewed with the inspector. The revised procedure has since been approved and made effective on 27APR18 and can be found in Attachment 2.


- B. Your quality unit failed to have conducted and documented an ADR assessment as part of the following received customer complaints where your firm was made aware of potential side effects for your firm's compounded sterile drug products.*

- 1. CC-2017-005, received 3/31/2017, RX# 4015834 for compounded sterile drug, 10 Testost CYP 200MG/ML *10 ML* Inj., Lot# A3218.*
- 2. CC-2017-004, received 3/29/2017, RX# 4013414 for compounded sterile drug, 20 Testost CYP 200MG/ML * 10 ML* Inj, Lot# 11725.*
- 3. CC-2017-001, received 2/17/2017, RX# 6143784 for compounded sterile drug, 600 Polidocanol 0.35% MDV (30 ML).*
- 4. CC-2017-013, received 8/31/2017, RX# 6185196 for compounded drug, 60 Estriol 0.1 MG/CLOBET 0.5% PETROL, Lot# H0016.*

OLYMPIA'S RESPONSE (2B):

After the revised P-219 was made effective as part of the response to Observation 2A, the complaints listed above will be re-evaluated under the new complaint and adverse event process. This includes an adverse event evaluation, investigation, root cause analysis, and CAPA requirements to be determined and documented in F-219. Completion of this re-evaluation of the above complaints can be found as **Commitment 2** in **Table 1**. As part of the initial investigations for these complaints, it was determined that no adverse event reporting to FDA was required for these events. The summary evaluation conducted as a start to registering the observed complaints

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 OLYMPIA COMPOUNDING PHARMACY <small>FOA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 4 of 11 Version Date: 03MAY18
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in the revised complaint system can be found as **Attachment 3**.

C. Your quality unit failed to adequately document and conduct an investigation into the following customer complaints to determine the root cause, and assign appropriate corrective action(s) the customer reported issues:

1. CC-2018-05, received 3/28/2018, documents your firm shipping s Rx# 6248938, T-50 (PAP 8.8/PHE 0.29/AP 2.9) to the incorrect patient address. Your quality unit failed to adequately investigate to determine the root cause and document corrective actions to prevent the recurrence.
2. CC-2018-06, received 3/30/2018, documents your firm's failure to apply an auxiliary label on the finished drug product, RX# 6250411, TRIMIX (PA 15/PH .5/PG 5) Injection, which documents the sterile finished compounded drug storage conditions.
3. CC-2018-03, received 3/27/2018, documents your finn's shipping the incorrect finished compounded drug to a customer. Your firm incorrectly shipped HCG 10000, Lot# B18A12, BUD 2/19 instead of the correct sterile compounded sterile drug product HCG 5000, Lot# CI 8005, BUD 3/19.
4. CC-2017-011, received 8/28/17, documents your firm failure to document and have objective evidence in support of such corrective action. Complainant reported receiving Rx# 4019639 identified on the patient specific label incorrectly as 30 Testost 0.1 % (I MG/ML) Cream. The compounded drug should have been labeled as 30 Testosterone 1 % (IOMG/ML) CRM on the patient specific label.

OLYMPIA'S RESPONSE (2C):

See Olympia's Response for Observation 2B.


OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- A. Your procedure, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, P-304, Version 4 require the use of STERIS Spor-Klenz-Ready to Use (Sterilant/Sporicidal) with a contact time of 10 minutes, and PeridoxRTU Ready to Use (Disinfectant) with a contact time of 10 minutes for weekly and monthly clean room cleaning but fail to require the documentation of contact times as a form of verification for activity. Your documented contact time for S'TERIS Spor-Klenz-Ready to Use (Sterilant/Sporicidal) of 10 minutes failed to meet the manufacturers requirement of 30 minutes.**

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 <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 5 of 11 Version Date: 03MAY18
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OLYMPIA'S RESPONSE (3A):

We have revised P-304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, to include hard coded locations on the cleaning forms to record contact time start time and end times in response to this observation. The revision also included clarification of the contact times for Steris Spor-Klenz-Ready to Use and PeridoxRTU. The manufacturer's specification for contact time for Steris Spor-Klenz-Ready to Use for use as a sterilant is 10 minutes, and for use as a sporicidal agent is 30 minutes. We have included both options in the procedure as Steris Spor-Klen-Ready to Use will be part of the rotation of cleaning agents for both sterilant and sporicidal use. The revised P-304 can be found in **Attachment 4**.

B. Your firm fails to have scientific data and or performed any studies in support S'TERIS Alcare Plus Hand Sanitizer effectiveness as a disinfectant on sterile gloves used within your ISO 8, ISO 7, and ISO 5 classified clean room. The sanitizer is labeled as a hand disinfectant. S'TERIS Alcare Plus Hand Sanitizer labeling contains no information reporting it as being sterile and appropriate for use on gloves. S'TERIS Alcare Plus Hand Sanitizer has been used as a disinfectant on sterile gloves since 2015.

OLYMPIA'S RESPONSE (3B):

CAPA 2018-03 was initiated and completed during the inspection in response to this observation, which can be found as **Attachment 5**. The CAPA states that the Alcare Plus Hand Sanitizer was removed from the cleanrooms. The revised P-304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility found in **Attachment 4** includes the change to remove the Alcare Plus Hand Sanitizer from use. Sterile 70% IPA shall be used in the cleanrooms for disinfecting the hands during compounding.

OBSERVATION 4


Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release. Specifically, no lyophilized sterile drug product reconstitution specification has been established to be used as part of the released criteria prior finished sterile drug product distribution. For example, your firm failed to establish a reconstitution specification for the release of the following drug products:

- HCG
- Sermorelin
- Sermorelin GHRP

OLYMPIA'S RESPONSE (4):

We have created **Commitment 3** in **Table 1** for performing a study for determining the time for dissolution from solid to liquid state for lyophilized products. This study is in addition to the already completed reconstituted product hold time study supporting a 45-day BUD under 2-8°C refrigerated storage condition. After this study is performed, P-217, Sterile Drug Product

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Specifications at Olympia Pharmacy, will be revised to include dissolution time testing as part of the release criteria for lyophilized products, and the dissolution time will be added to the Instructions for Use for these drugs that is provided with each prescription dispensed. In addition to the results for a potency, endotoxin, and sterility report for the finished compound, the dissolution time for the specific batch shall also be reported.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, on 4/9/2018, your pharmacy technician was observed touching door between Ante Room I (ISO 8 Classified) and Prep Room I (ISO 7 Classified) during the entry and exiting of the two rooms at the time of batch compounding mixing the drug product, PGE-2, Lot# D3009 without re-sanitizing sterile gloved hands with 70/30 % IP A while transferring components in preparation for compound batch mixing.

OLYMPIA'S RESPONSE (5):

The Technician noted in this observation has been re-trained on appropriate aseptic technique. There is no impact to the product that was being filtered as all other environmental monitoring and personnel monitoring passed for the day, and PGE-2 lot # D3009 was ultimately discarded in response to Observation 6. The training documentation can be found in **Attachment 6**.

OBSERVATION 6


Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your procedure, Policy on the Environmental and Personnel Monitoring Program, P-211, Version 7 reports the daily recording of differential pressure shall be performed for all room. Your differential pressures are recorded once per day and visually observe throughout the course of the day. On 4/9/2018, your firm was observed compounding the sterile drug product, PGE-2, Lot# D3009 which you began compounding at 2 :20 pm and finished undergoing your auto fill process at 5: 13 pm. Your recorded differential pressure for the non-hazardous clean room occurred at 7:00 am. No recorded differential pressure readings are available for the time in which the sterile drug PGE-2 was mixed, compounded, and filled to show no excursions in differential pressure occurred.

OLYMPIA'S RESPONSE (6):

We have requested and received a quote from Primex for the installation of a continuous monitoring system for differential pressure for the cleanroom facilities. This quote can be found in **Attachment 7**. We are currently evaluating the quote as well as awaiting additional quotes to determine the appropriate system to be installed for our cleanrooms. Installation of a system for

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continuous monitoring of differential pressures can be found as **Commitment 4** in **Table 1**. Additionally, P-211, Policy on the Environmental and Personnel Monitoring Program, and P-212, Environmental Monitoring, will be revised after installation of the continuous monitoring system to reflect the change. The revision of these documents can be found as **Commitment 5** in **Table 1**. In the interim until the installation is completed, the compounding formulation sheets have been revised to include a section to record the differential pressure for prior to and at the completion of production activity specific to each compounded product. A sample of this is shown as **Attachment 8** for a Lidocaine 1% Compounding formulation worksheet.

OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during a review of your 2017 smoke study for your Colanar Automated Modular Vial Filling System located in your non-hazardous sterile clean room, Buffer Room 3, failed to adequately assess the most complicate filling configuration to ensure equipment appropriately designed and unidirectional air flow in the prevention of contamination that would alter the safety, identity, strength, quality, or purity of the sterile finished drug product. The firm's smoke study only assessed the filling for 12 of 64 10 mL clear vials in a tray.

OLYMPIA'S RESPONSE (7):

In response to this observation, we initiated a work order to perform an additional smoke study for Buffer Room 3 to include dynamic operation of the Colanar Automated Modular Vial Filling System. This smoke study was completed by Micro Filtration on 26APR18. A copy of the work order and the new smoke study video can be found as **Attachment 9**.


OBSERVATION 8

Product Reporting:

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B (b)(2)(A). The following are examples of products that were compounded and not identified on your December 2017 product report:

- a. Alprostadil (PGE) 250 mcg/mL
- b. 300 mcg/mL and 350 mcg/mL injection
- c. anastrozole 0.5 mg and 0.75 mg capsule
- d. ascorbic acid 250 mg/mL and 500 mg/mL MDV
- e. avanafil 200 mg and 300 mg troche
- f. bacteriostatic water
- g. estradiol cypionate/testosterone cypionate 2 mg/50 mg/mL
- h. estradiol cypionate 2 mg/mL and 5 mg/mL injection

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 OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY	Detailed Response to Form FDA-483 Dated 13APR18	Page 8 of 11
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- i. *L-carnitine 500 mg/mL MDV*
- j. *Lysine 62.5 mg/arginine 50 mg cream*
- k. *papaverine 30 mg/mL injection MDV*
- l. *phenylephrine 1 mg/mL injection*
- m. *sildenafil citrate 110 mg and 150 mg troch*
- n. *tadalafil 20 mg, 25 mg, 40 mg, and 75 mg troche*
- o. *terbutaline 3 mg capsule*
- p. *varденаfil 40 mg and 75 mg troche*
- q. *Vitocin (oxytocin) spray 401U/spray*
- r. *zinc chloride 10 mg/mL MDV.*

This is not an all-inclusive list.

OLYMPIA'S RESPONSE (8):

With the initial use of the SPL reporting system for reporting away from the excel sheet method, several technical difficulties were encountered as far as finding the drug actives and the form of entry. We communicated with Mr. Troy Cu, a CDER Technical Information Specialist, to address these issues. We entered what was able to be entered into the system at the time, but due to the technical issues, we were unable to add all drugs. The omissions were not intentional, but due to a technical issue from the transition to the new SPL reporting system. As part of the response to this observation, we attempted to edit the 2017 report to include the missing drugs but encountered the same technical issue. We have another request for help from Mr. Troy Cu. Therefore, we have created a commitment to revise the 2017 report, as well as perform a comparison of the report to the drugs compounded to what was submitted ensure all drugs are included. This activity can be found as **Commitment 6** in **Table 1**.


OBSERVATION 9

Product Labeling:

The labels of some of your outsourcing facility's drug products do not include information required by section 503B(a)(1)(A). Specifically,

- A. ***The exact date the drug was compounded. Examples of product labels that do not contain this information include:***
 - *NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)*
- B. ***The expiration date. Examples of product labels that do not contain this information include:***
 - *NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)*
- C. ***Lot or batch number. Examples of product labels that do not contain this information include:***
 - *NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)*
- D. ***A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of product labels that do not contain this information include:***

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- **NB-343** (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)
- **QM4** (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 300 mcg/ml; atropine 0.2 mg/ml)

OLYMPIA'S RESPONSE (9):

We have reviewed the labels provided to the inspector and would like to clarify parts A-C of this observation, as all three of these requirements were included on the label provided. There may have been some confusion during review due to the labels being presented within the batch record and which label is on the units themselves. Both labels presented on the batch record can be used as the final unit label. The NB-343 labels provided to the Inspector can be found in **Attachment 10**. The date of compounding (printed as "CPD 03 14 18" or "CPD 14 MAR 18" on the labels), the expiration date (printed as "BUD 03/19" on the labels), and the lot number (printed as "Lot C18014" on the labels) can be found on the black strip portion of the label. We recognize that the single inactive ingredient "Sterile Water" is only included on one of the two labels for both NB-343 and QM-4. We have revised the labels to include "Sterile Water." A copy of the label proof for NB-343 and QM-4 can be found in **Attachment 11**. The use of these labels was made effective on 30APR18.

OBSERVATION 10

The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10) (B).

Specifically,

A. The phone number, 1-800- FDA-1088, to facilitate adverse event reporting. Examples of product labels that do not contain this information include:

- **NB-343** (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)
Polidocanol 2% injection
- **Sodium bicarbonate 8.4% injection**
- **Testosterone cypionate 200 mg/ml injection**
- **HCG 10,000IU (lyophilized powder)**

OLYMPIA'S RESPONSE (10):

We have created an auxiliary label that will be affixed on the outer product container for the product unit that includes FDA's phone number for the adverse reporting line. As this auxiliary label was already part of the labeling process and procedure, no additional revisions are required. Please note that the current labels include the adverse reporting website. A sample of this revised label can be found in **Attachment 12**.

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 LYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 10 of 11
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Table 1: Future Commitments to FDA

No.	Description of Action Required	Due on or Before	Status	Related FDA Observation	Attachment No.
1	Completion of D-2018-06 and execution of CAPA 2018-02.	08JUL18	In-Progress	1B	N/A
2	Complete re-evaluation of complaints for observation under the revised Drug Safety and Surveillance system.	31MAY18	In-Progress	2B & 2C	N/A
3	Perform study for time for dissolution from solid to liquid state for lyophilized drugs. Revise P-217 and IFUs once times are determined.	31JUL18	In-Progress	4	N/A
4	Installation of Continuous Differential Pressure monitoring system.	31JUL18	Quote	6	7
5	Revised P-211 and P-212 to include the Differential Pressure continuous monitoring system.	31JUL18	Not Started	6	N/A
6	Revise 2017 drug report and perform a comparison of the updated drug report to drugs compounded to ensure all drugs from reporting period are included.	31MAY18	In-progress	8	N/A

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 GLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 11 of 11
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Table 2: Attachments

No.	Document No. Reference	Attachment Description	Related Observation Number	Approval Date
1	D-2018-05	Deviation Record for gowning neck exposure	1A	16APR18
2	P-219, Version 3	Drug Surveillance and Safety Program	2A	27APR18
3	N/A	Complaint Summary	2B	N/A
4	P-304, Version 5	Cleaning-Sterilizing and Disinfecting of the Compounding Facility	3A, 3B	30APR18
5	CAPA-2018-03	CAPA Record for removal of Alcare Plus Hand Sanitizer	3B	30APR18
6	N/A	Aseptic Training and Qualifier for Technician	5	N/A
7	N/A	Quotation from Primex for Differential Pressure System	6	N/A
8	N/A	Sample Compounding Formula Worksheet for Differential Pressure Data	6	N/A
9	N/A	Copy of Work Order and Revised Smoke Study	7	N/A
10	N/A	Labels provided from inspection - NB343 & QM-4	9	14MAR18
11	N/A	Label Proof for NB-343 and QM-4	9	30APR18
12	N/A	Revised auxiliary label	10	30APR18

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6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Wednesday, August 22, 2018

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II
FDA/Office of Regulatory Affairs
John.diehl@fda.hhs.gov
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Good Day Mr. Diehl,

We are writing to update the agency on the status of the commitments we made in our initial response to the FDA Form-483 observations issued on April 13, 2018 regarding the inspection of OPS International Incorporated DBA Olympia Pharmacy, located at 6700 Conroy Road, Suite 155, Orlando, FL 32835. As described in our detailed response below, Commitments 1, 2, 4, 5, and 6 are complete. Commitment 3 is currently in progress.


It is imperative to mention that Olympia is committed to continuously improve our systems and processes. We strive to make improvements and uphold integrity in all aspects of service that we provide for quality and safety in patient care.

For any questions or additional clarifications, please feel free to contact us at any time. We appreciate the opportunity to continue working together with the FDA and are fully committed to implementing the DQSA requirements in a way that preserves access to compounded drugs for patients in need.

Sincerely,

A handwritten signature in black ink, appearing to read "Confidence Ekeanyanwu", written over a horizontal line.

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

 GLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 2 of 4
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NOTE:

- **Table 1** contains the Commitments to FDA outlined in the initial response letter and their due dates.
- **Table 2** contains the Attachment List for this response.

Table 1: Commitments to FDA

No.	Description of Action Required	Due on or Before	Status	Related FDA Observation	Related Attachment No.
1	Completion of D-2018-06 and execution of CAPA 2018-02.	08JUL18	Complete	1B	1 & 2
2	Complete re-evaluation of complaints for observation under the revised Drug Safety and Surveillance system.	31MAY18	Complete	2B & 2C	3 & 4
3	Perform study for time for dissolution from solid to liquid state for lyophilized drugs. Revise P-217 and IFUs once times are determined.	31JUL18 31OCT18	In-Progress	4	5
4	Installation of Continuous Differential Pressure monitoring system.	31JUL18	Complete	6	6
5	Revised P-225 and P-212 to include the Differential Pressure continuous monitoring system.	31JUL18	Complete	6	7
6	Revise 2017 drug report and perform a comparison of the updated drug report to drugs compounded to ensure all drugs from reporting period are included.	31MAY18	Complete	8	8

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 <small>FDA REGISTERED 303B OUTSOURCING FACILITY</small>	Detailed Response to Form FDA-483 Dated 13APR18	Page 3 of 4
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COMMITMENT 1:

The approved deviation for D-2018-06 is can be found in **Attachment 1**. The associated approved CAPA. CAPA-2018-02, can be found in **Attachment 2**. This commitment is complete.

COMMITMENT 2:

The complaints specified by the agency in the issued FDA Form-483 has been evaluated for adverse drug event reporting and there were no qualifiers. The initial response to this observation listed corrective actions that were executed with emphasis on the retraining and training of Pharmacy personnel for Drug Safety and Surveillance. The Pharmacists have been adequately trained on MEDDRA Coding. A Watchlist and trend reporting program are in place to assess the frequency of allergic reactions and ADR reports. The revised policy and procedure for complaint handling, P-219, version 3, can be found in **Attachment 3**. The pharmacy personnel training record can be found in Attachment 4 of this response. This commitment is complete.

COMMITMENT 3:

Attachment 5 to this response is the Reconstitution Study Quotation from Analytical Research Laboratories (ARL) for the study to determine the total amount of time required for dissolution for various lyophilized preparations. A study protocol shall be written by ARL to be approved by ARL and the Olympia. It is imperative to note that the study shall be for just the HCG combination products that the pharmacy offers, excluding Sermorelin and GHRP mentioned in the Form-483 observation. This is due to Olympia's Compliance letter to the agency issued, Wednesday, July 18th, 2018 to cease use of bulk drug substances in compounding (including Sermorelin, GHRP-2, and GHRP-6). This commitment is in progress still due for protocol execution, report, release testing criteria revision, and the instructions for use revision. The due date has been updated in **Table 1** to reflect the status of this commitment.

COMMITMENT 4:

In the initial response, the quote from Primex was attached for the proposed work. The differential pressure monitoring system was installed on 06AUG18. The completed work order for the installation and installation documentation from Primex can be found in **Attachment 6**. This commitment is complete.

COMMITMENT 5:

As part of the installation of the differential pressure monitoring system for Commitment 4, P-225 and P-212 for environmental monitoring required revision. These revisions are approved and effective as of 20AUG18. The document change request forms for these revisions can be found in **Attachment 7**. This commitment is complete.

COMMITMENT 6:

Revised Drug Product Reporting record for December 2017 pursuant to FDA Form-483 Observation #8 is noted as **Attachment 8** to this response. This commitment is complete.

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 GLYMPLA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY	Detailed Response to Form FDA-483 Dated 13APR18	Page 4 of 4
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Table 2: Attachments

No.	Document No. Reference	Attachment Description	Related Observation Number	Approval Date
1	D-2018-06	Deviation Record for Gowning	1B	09MAY18
2	CAPA-2018-02	CAPA Record D-2018-06-Gowning	1B	09MAY18
3	P-219, Version 3	Drug Safety and Surveillance	2B & 2C	27APR18
4	N/A	Training for P-219.3	2B & 2C	27APR18
5	N/A	Dissolution Study Quote	4	N/A
6	WO-18-015	Installation Documentation and Certificates for the Primex System for Differential Pressure continuous Monitoring	6	08AUG18
7	F-215.a	Document Control for P-225 and P-212	6	06AUG18
8	N/A	Revised Drug Reporting for December 2017	8	N/A

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October 31, 2018

VIA Electronic Mail

Marco Loleit, CEO and Owner
OPS International Inc. dba Olympia Pharmacy
6700 Conroy Road, Suite 155
Orlando, Florida 32835
marco@olympiapharmacy.com

Reference: CMS WA 213460 and FEI 3009724085

Mr. Loleit:

We completed our review of the Establishment Inspection Report (EIR) for the inspection conducted by an FDA investigator at your facility in Orlando, Florida, from April 6, 2018, to April 13, 2018. A Form FDA 483 was issued to your firm at the conclusion of the inspection.

We have also reviewed your firm's responses dated May 3, 2018, July 18, 2018, August 22, 2018, and September 27, 2018, including the supportive documentation attached. However, additional information is required to fully evaluate whether you have adequately addressed the inspectional observations. Within five working days of receipt of this letter, submit the following so that we may complete our evaluation of your facility inspection and Form FDA 483 response.

1. Your response to Observation 3A included a copy of your revised procedure, P-304, *Cleaning-Sterilizing and Disinfecting of the Compounding Facility*, which was updated "to include hard coded locations on the cleaning forms to record contact time start time and end times". Provide copies of completed logs for the previous three months to demonstrate that appropriate contact times are being adhered to for sporicidal agents. Please clarify whether Spor-Klenz is reapplied to keep the surface wet and ensure a full 30-minute contact time as specified in your procedure.
2. Provide any updates to your response to Observation 4 since your September 27, 2018, response, including revision of release testing criteria and documentation of the additional testing on drug product batches, if completed. Additionally, the ARL "Reconstitution Study for HCG Formulations Final Report" provided via email on 09/27/2018 appears to be missing page 7; provide a complete copy of this report.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

3. Provide copies of your firm's revised procedures, P-225, *Continuous Monitoring Systems*, and P-212, *Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia*, referenced in your response to Observation 6.
4. Describe your storage conditions for depyrogenated vials. Note that if you store vials in an unclassified area for an extended period of time, they may become contaminated.
5. A smoke study labeled "Micro Filtrations, Inc.", "Olympia Compounding Pharmacy USP 797 Smoke Video", "Buffer Room Vial Transfer" was provided during the inspection. This video does not support that vials are protected by unidirectional air flow during transfer to the lyophilizer. Provide any additional videos or documentation to support the protection of these vials during transfer from the laminar flow hood to the lyophilizer. If your firm no longer lyophilizes drug products in this room, please state such, and any plans to resume.
6. The document titled "Batch Record for Process 1 Aseptic Process Simulation", provided during the inspection, includes the production of four intermediates which are stored "at the appropriate temperature for no less than 3 days". Provide the following information regarding this process:
 - a. Provide a list of products produced by your firm which use intermediates, as well as a recent executed batch record for each product.
 - b. Clarify whether intermediates are sterilized prior to storage.
 - c. Provide information on the integrity of the container closures used to store the intermediates and describe under what conditions (temperature and location) intermediates are stored.

If the requested information cannot be submitted within five working days, state the reason for the delay and the time frame within which you will submit the information. Your written response should be electronically submitted to Dayna I. Martinez at dayna.martinez@fda.hhs.gov and ORAPHARM2_RESPONSES@fda.hhs.gov.

If you have any questions about this letter, please contact Ms. Martinez, Compliance Officer, via (787) 729-8608 or dayna.martinez@fda.hhs.gov.

Sincerely,

John W. Diehl - S

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II



6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

November 8, 2018

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II
FDA/Office of Regulatory Affairs
john.diehl@fda.hhs.gov
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Reference: CMS WA 213460 and FEI 3009724085

Good Day Mr. Diehl,


We are writing in response to the additional information requested to fully evaluate whether we have adequately addressed the inspectional observations from FDA-Form 483 dated 13APR18. Below is a detailed response to each of the inquiry made by the agency. **Table 1** represents the attachment list of documents and supplemental information for this response.

Olympia is committed to continuously improve our systems and processes for the services that we provide with respect to safety in patient care. For any questions or additional clarifications, please feel free to contact us at any time.

Sincerely,

A handwritten signature in black ink, appearing to be "Confidence Ekeanyanwu", with the date "08NOV18" written next to it.

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com


 <p>OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY</p>	Reference: CMS WA 213460 and FEI 3009724085 Dated 08NOV18	Page 2 of 5
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1. ***Your response to Observation 3A included a copy of your revised procedure, P- 304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, which was updated "to include hard coded locations on the cleaning forms to record contact time start time and end times". Provide copies of completed logs for the previous three months to demonstrate that appropriate contact times are being adhered to for sporicidal agents. Please clarify whether Spor-Klenz is reapplied to keep the surface wet and ensure a full 30-minute contact time as specified in your procedure.***
 - a. Attachment 1 of this response represents Olympia's cleaning logs for the past three months in reflection of the revised procedure, P-304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility.
 - b. Spor-Klenz utilized as a sporicidal agent in our facility is applied in enough volume to completely immerse the hard, non-porous surfaces for a full wet 30-minutes contact time (**Olympia SOP-P-304.6, Section 7.1.1.1.1**). No reapplication of the cold sterilant is performed to keep the surface wet for the time duration specified.

2. ***Provide any updates to your response to Observation 4 since your September 27, 2018, response, including revision of release testing criteria and documentation of the additional testing on drug product batches, if completed. Additionally, the ARL "Reconstitution Study for HCG Formulations Final Report" provided via email on 09/27/2018 appears to be missing page 7; provide a complete copy of this report.***
 - a. The purpose of the study was to outline the procedure for the reconstitution of various lyophilized formulations at Olympia. The study was executed as cGMP work comprised on three (3) separate vials of each formulation reconstituted with bacteriostatic water for injection at a specified volume.
 - b. Reconstitution instructions for dispensing of these compounds have been revised accordingly. The revised instructions are represented as **attachment 2** of this response.
 - c. The complete and revised ARL reconstitution study final report is reattached as **attachment 3**.

3. ***Provide copies of your firm's revised procedures, P-225, Continuous Monitoring Systems, and P-212, Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia, referenced in your response to Observation 6.***
 - a. Attachment 4 represents P-225, continuous Monitoring Systems, and **attachment 5**, P-212, Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia.

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4. Describe your storage conditions for depyrogenated vials. Note that if you store vials in an unclassified area for an extended period of time, they may become contaminated.

- a. Depyrogenated vials are stored in a controlled cleanroom space at the Pharmacy; the controlled room space is at a minimum, ISO 8 certified. The depyrogenated vials are prepared for sterilization wrapped thrice for a procedure of removing each layer of foil according to each cleanroom air exposure. **Attachment 6** for this response is Olympia's operating procedure for the Sterilization of Components and Utensils used for compounding.


5. A smoke study labeled "Micro Filtrations, Inc.," "Olympia Compounding Pharmacy USP 797 Smoke Video," "Buffer Room Vial Transfer" was provided during the inspection. This video does not support that vials are protected by unidirectional air flow during transfer to the lyophilizer. Provide any additional videos or documentation to support the protection of these vials during transfer from the laminar flow hood to the lyophilizer. If your firm no longer lyophilizes drug products in this room, please state such, and any plans to resume.

- a. **Attachment 7** is an additional smoke study video to support the protection of vial transfer from the laminar flow hood to the lyophilizer by unidirectional air in the ISO 5 cleanroom. Micro Filtrations, the cleanroom certification vendor to further clarify the tests performed in the cleanrooms, has also provided a letter of notice to this effect. This letter is **attachment 8** for this response.
- b. Secondly, the compounding technicians are trained on conduct in controlled areas and aseptic technique for handling and manipulation of drug products to purport sterile drug compounds. Education is specific to critical sites, Contact surfaces, First Air, Direct Compounding Area, and movement in the cleanroom. Refer to **attachment 9** for this response.

6. The document titled "Batch Record for Process 1 Aseptic Process Simulation", provided during the inspection, includes the production of four intermediates which are stored "at the appropriate temperature for no less than 3 days". Provide the following information regarding this process:

- a. **Provide a list of products produced by your firm which use intermediates, as well as a recent executed batch record for each product.**
 - i. **Attachment 10** is listing of products compounded at Olympia by Process 1 Aseptic Process Simulation. **Attachment 11** represents a batch record organized in the numerical listing of attachment 10.
 - ii. **Attachment 12** of this response is a Labeling Memo for clarification.

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 <p>OLYMPIA COMPOUNDING PHARMACY FOA REGISTERED 503B OUTSOURCING FACILITY</p>	<p>Reference: CMS WA 213460 and FEI 3009724085 Dated 08NOV18</p>	<p>Page 4 of 5</p> <p>Version Date: 08NOV18</p>
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b. Clarify whether intermediates are sterilized prior to storage.

- i. Intermediates are not sterilized prior to storage. They are utilized in production within three (3) days for the finished drug product. An intermediate is one step in the preparation of a finished sterilized drug product. The intermediates are combined in the appropriate volumes for a bulk solution, filtered for sterilization, and filled into vials. This is the overall process of producing sterile injectables at Olympia by Process 1 Aseptic Process Simulation. This is further represented by the batch records in attachment 11.

c. Provide information on the integrity of the container closures used to store the intermediates and describe under what conditions (temperature and location) intermediates are stored.

- i. For the hold time of these Intermediates prior to their combination into a bulk solution, the intermediates are either held in a 1000-ML, 3000-ML, or 5000-ML sterile flexible bag. These are gamma irradiated sterilized bags with verified certificate of analysis for each batch received.
- ii. If an intermediate is prepared in a volume less than 100-ML, it is held in a glass vial. These vials obtained from Wheaton Vials are precleaned/washed and sterilized by method of depyrogenation prior to use.
- iii. The certificate of analysis for the bags and vial from the manufacturer is **attachment 12** for this response to validate the integrity of these containers for intermediates.
- iv. The intermediates are held in a validated controlled environment according to the intermediate drug's specification, i.e. controlled room temperature or refrigeration.

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 OLYMPIA COMPOUNDING PHARMACY <small>FOA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: CMS WA 213460 and FEI 3009724085 Dated 08NOV18	Page 5 of 5
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Table 1: Attachments

No.	Document No. Reference	Attachment Description
1	F-304.b/F-304.d	Cleaning Logs
2	N/A	Revised reconstitution instructions for dispensing of lyophilized drug products.
3	N/A	Reconstitution study final report- ARL Biopharma
4	P-225	Continuous Monitoring Systems
5	P-212	Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia
6	P-601	Sterilization of Components and Utensils
7	N/A	Additional smoke video for Vial Transfer to Lyophilizer
8	N/A	Letter of Notice from Micro Filtration
9	P-412	Conduct of Personnel in Controlled Areas and Aseptic Technique Overview
10	N/A	Product Listing for which Intermediates are used for Process 1
11	N/A	Most recent executed batch records for the products listed
12	N/A	Labeling Memo
13	N/A	Sterile bags and Vial certificate of analysis.

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DATE 03/27/2019

CMS Case # 573273

Regulatory Meeting Request Letter

VIA UPS EXPRESS

Marco Loleit
Owner/CEO
OPS International, Inc. dba Olympia Pharmacy
6700 Conroy Road, Suite 155
Orlando, FL 32835

Dear Mr. Loleit:

We request that you and your management staff attend a regulatory meeting, with the FDA at the Office of Pharmaceutical Quality Operations, Division II, located at 4040 N. Central Expressway, Suite 300 Dallas, Texas 75204. Please contact Dayna Martinez Division Compliance Officer, at 787-729-8608, to schedule a date and time to meet with us.

The purpose of the meeting is to discuss the compliance status of OPS International, Inc. dba Olympia Pharmacy, including your efforts to bring your operations, facilities, and procedures into compliance with requirements of the Federal Food, Drug, and Cosmetic Act. Enclosed as an attachment is a request for information relating to our concerns.

Please respond with the requested information and documentation, via email, by 15 business days from letter issuance date to Dayna Martinez, Division Compliance Officer, at Dayna.Martinez@fda.hhs.gov. In addition, please submit a signed copy of your response to ORAPHARM2_RESPONSES@fda.hhs.gov. Please include in your response your confirmed attendee list with titles, a contact name and number, and any materials that you plan to present to FDA during the meeting. Please confirm receipt of this letter. If you have any questions regarding the contents of this letter you may contact Ms. Martinez by email, or by phone at 787-729-8608.

Sincerely,

Tamala P. Magee -S

Tamala Magee
Acting Program Division Director
Office of Pharmaceutical Quality Operations
Division II

Digitally signed by Tamala P. Magee -S
DN: cn=US, ou=U.S. Government, ou=HHS, ou=FDA,
ou=People, o=U.S. 2342 1920309 1001 1=1300118538
cn=Tamala P. Magee -S
Date: 2019.03.27 16:36:39 -0500

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

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OPS International, Inc. dba Olympia Pharmacy
03/27/2019

Enclosure:
FDA Comments and/or Request for Information

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OPS International, Inc. dba Olympia Pharmacy
03/27/2019

ATTACHMENT
FDA Questions and Requests for Information

1. Dissolution Time Testing

Your firm's May 3, 2018, response stated, "P-217, Sterile Drug Product Specifications at Olympia Pharmacy, will be revised to include dissolution time testing as part of the release criteria for lyophilized products" ... "In addition to the results for a potency, endotoxin, and sterility report for the finished compound, the dissolution time for the specific batch shall also be reported." Provide your revised procedure P-217, as well as documentation to show that dissolution time testing is performed on lyophilized drug product batches as part of batch release and when such testing began.

2. Depyrogenation of Components

SOP P-601, Sterilization of Components and Utensils, provided in your firm's November 8, 2018, response letter, states that depyrogenated vials are wrapped in three layers of foil and stored in a controlled room space (ISO 8 minimum). Provide scientific justification to support that these storage conditions are adequate to protect against contamination and ensure the sterility of depyrogenated vials for the assigned expiry period of one month.

3. Lyophilization

Regarding the non-hazardous cleanroom smoke study video provided in your firm's November 8, 2018, response letter:

- a. What lyophilized products are currently produced at your facility? What are your plans for future production within the non-hazardous cleanroom?
- b. How does your firm decontaminate and/or sterilize the lyophilizer prior to production?
- c. Provide documentation showing the air velocity in the critical area where lyophilized drug products are transferred within the non-hazardous cleanroom, and justification that this velocity is adequate to protect vials during the transfer process.

4. Sporocidal Disinfection

Regarding the use of Spor-Klenz as described in your firm's November 8, 2018, response letter, how does your firm ensure that a surface, being exposed to multiple air changes, remains wet for the entire 30-minute contact time without reapplication?

5. Production Intermediates

Regarding the use of intermediates as described in your firm's November 8, 2018, response letter, the Agency is concerned with the prolonged storage of non-sterile intermediates. While the product will be filter sterilized at a later step, there is the potential for bioburden to proliferate during storage. Endotoxin will not be removed by filter sterilization. While endotoxin testing can be performed as a release test on the finished drug product, this process represents a poor practice.

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OPS International, Inc. dba Olympia Pharmacy
03/27/2019

6. Product Labeling

Regarding your corrective actions to your firm's drug product labels as described in your firm's November 8, 2018, response letter, we note that most of the labeling deficiencies appear to be adequately addressed. However, it appears that your corrective action with respect to the list of inactive and active ingredients and the quantity or proportion of each ingredient is not adequate. Section 503B(a)(10)(A)(iii)(X) requires a list of active and inactive ingredients, identified by established name and the *quantity or proportion of each ingredient*, to be listed on the label. If there is not space for such information on the label, per section 503B(a)(10)(B)(i), the container from which the individual units of the drug are removed for dispensing or for administration shall include such information. We request that you provide revised labels or container labels to address this deficiency.

7. Dynamic Medical Solutions (DMS)

We understand that you have partnered with Dynamic Medical Solutions (DMS), a company that seeks to meet the needs of healthcare providers by offering sterile and non-sterile products from your facility. We have the following questions regarding your partnership with DMS:

- a. Describe your business relationship with Dynamic Medical Solutions (DMS)? Do you have a contract with DMS? If so, please provide a copy of the contract.
- b. How does your firm receive orders for these drug products? What is the quantity that is ordered? Please provide any documents related to the ordering process.
- c. Describe the process from prescribing to receipt of the medications (who is doing what, and where is the product throughout the process).
- d. Are products distributed with DMS labels on them? Do products ship with DMS branding affixed to the products? If so, who provides the DMS labels? Please provide labels if available.
- e. Does DMS provide the product specifications to your firm?
- f. What products are manufactured/stored/distributed by your firm when DMS is used as an intermediary?
- g. Does your firm receive any complaints or adverse event reports regarding these drug products? Do you have a procedure for investigating the reports? Do you communicate complaints or adverse events to DMS?

8. Ineligible Bulk Substances

On July 18, 2018, your firm submitted a written response to FDA stating, "as a corrective action, effective May 1, 2018, Olympia Pharmacy ceased use of bulk drug substances in compounding (including Sermorelin, GHRP-2, and GHRP-6)." However, during a recent FDA inspection of a 503A facility we observed that Sermorelin, GHRP-2 and GHRP-6 were produced and distributed to the facility from your firm subsequent to your

Page 5 – Mr. Loleit, Owner/CEO
OPS International, Inc. dba Olympia Pharmacy
03/27/2019

commitment to cease production with these bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities. Additionally, we note that your December 2018 product report (covering the period of June 1, 2018, through November 30, 2018) shows that you have produced thousands of vials of drug product containing these ineligible bulk drug substances during this reporting period. Please provide your rationale as to why your firm committed to cease the production and distribution of drug products using ineligible bulk drug substances but has continued this practice. Do you intend to continue to produce and distribute drug products using bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities?



6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Monday, May 6, 2019

LCDR John W. Diehl, M.S.
Director, Compliance Branch
C/O: Dayna Martinez
Division Compliance Officer
Office of Pharmaceutical Quality Operations, Division II
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Reference: CMS Case # 573273

Good Day Mr. Diehl,

We are writing in response to the regulatory meeting request letter issued March 27th, 2019 by the FDA to discuss the compliance status of OPS International, Inc. dba Olympia Pharmacy ("Olympia"), located at 6700 Conroy Road, Suite 155, Orlando, FL 32835. This letter details the specific information requested by FDA prior to the regulatory meeting. **Table 1** represents Olympia's quality improvement commitments to the FDA. **Table 2** represents the list of attached documents and supplemental information for this response. Please note that Olympia received an extension until May 6, 2019, to respond to the regulatory meeting request letter.

The following will be in attendance for the proposed meeting date of **Thursday, August 8th, 2019**:


- Ms. Confidence Ekeanyanwu, Olympia Quality Manager and the designated contact for all correspondences – contact information is listed below
- Ms. Naomi Loomis RPh., Olympia Director of Operations – (407) 673-2222
- Ms. Rachael Pontikes, Partner, Reed Smith LLP, the firm's legal counsel – (312) 207-2857
- A representative from Kymanox, the firm's CGMP Consultant – (919) 246-4896

Olympia is committed to continuously improving our systems and processes in alignment with FDA's expectations. For any questions or additional clarifications, please feel free to contact us at any time.

Sincerely,

Confidence Ekeanyanwu
Digitally signed by
Confidence Ekeanyanwu
Date: 2019.05.06
17:13:11 -04'00'

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

 OLYMPIA COMPOUNDING PHARMACY <small>FOA REGISTERED 303B OUTSOURCING FACILITY</small>	Reference: CMS Case #573273 Dated 27MAR19	Page 2 of 13
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1. Dissolution Time Testing

Your firm's May 3, 2018, response stated, "P-217, Sterile Drug Product Specifications at Olympia Pharmacy, will be revised to include dissolution time testing as part of the release criteria for lyophilized products" ... " In addition to the results for a potency, endotoxin, and sterility report for the finished compound, the dissolution time for the specific batch shall also be reported." Provide your revised procedure P-217, as well as documentation to show that dissolution time testing is performed on lyophilized drug product batches as part of batch release and when such testing began.

Response:

Olympia concluded reconstitution dissolution time studies on all lyophilized drug products on 20MAR19. The signed final reports can be referenced in **Attachment 1**. Following completion of the studies, Olympia's Standard Operating Procedure (SOP) P-217, Sterile Drug Product Specification at Olympia Pharmacy, was revised to include dissolution time testing as part of release requirements. This revision was made effective on 01APR19 and can also be referenced in **Attachment 1**. Dissolution time testing was included as part of batch release criteria for all lyophilized drug products as of 01APR19, in conjunction with the effective date of the associated P-217 revision. Refer to **Attachment 2** for an example Certificate of Analysis (COA) for reconstitution dissolution time of a recent batch of lyophilized drug product that is now required for batch release. Refer to **Attachment 3** for the newly revised patient advisory for reconstituting lyophilized products compounded by Olympia.


2. Depyrogenation of Components

SOP P-601, Sterilization of Components and Utensils, provided in your firm's November 8, 2018, response letter, states that depyrogenated vials are wrapped in three layers of foil and stored in a controlled room space (ISO 8 minimum). Provide scientific justification to support that these storage conditions are adequate to protect against contamination and ensure the sterility of depyrogenated vials for the assigned expiry period of one month.

Response:

The established process for depyrogenation and storage (assigned expiry period of one month) of glass vials at Olympia involves the use of a dry heat oven that resides immediately outside of the controlled environment in a non-classified area. To mitigate the potential exposure of the vials to particulates for depyrogenation preparation and storage, prior to use in aseptic filling, the vials are transferred into the controlled environment, specifically the ISO 7 cleanroom, to be triple-wrapped in aluminum foil. Each layer of foil contains a chemical indicator affixed on the surface of the pack. The wrapped vials are then transferred out of the controlled classified environment and placed in a validated dry heat oven for depyrogenation, with biological indicators for each shelving space that a pack of vials is placed into. The dry heat oven is re-assessed annually to ensure it remains in an appropriate validated state. After depyrogenation, the vials are transferred back into the controlled environment and stored in the ISO 8 cleanroom until needed for aseptic filling.

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 <small>OLYMPIA</small> <small>COMPOUNDING PHARMACY</small> <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: CMS Case #573273 Dated 27MAR19	Page 3 of 13
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When needed for aseptic filling, the triple-wrapped vials follow a controlled process for transfer into the aseptic filling environment. From storage in the ISO 8 cleanroom, the first and outermost layer is removed as the vials transition into the ISO 7 cleanroom. The second layer is then removed as the vials transition into the ISO 5 cleanroom. The third and innermost foil layer is unwrapped within the Laminar Airflow Workbench (LAFW) as the vials transition into the ISO 5 LAFW prior to filling. The wrapped vials are visually checked during removal of each layer of foil and prior to filling to ensure that the packaging and vials have not been compromised during storage or transit. All rooms and LAFWs noted during this transfer process are cleaned, certified by an external party semi-annually, and monitored through the environmental monitoring program per internal procedures. Additionally, to date, airborne particulate levels within the affected cleanrooms have been in a state of control as shown during routine certification and air monitoring testing. Refer to **Attachment 4** for a trend on particulate testing and cleanroom certification for the last year for the storage cleanroom space.

To further validate this process for the assigned expiry period of one month, Olympia is performing a sterility and endotoxin challenge study for depyrogenated glass vials. The study protocol can be referenced in **Attachment 5**. The final report of this study shall be reported to the FDA in a follow-up response, which is represented as **Commitment 1** in this response letter.

Olympia is evaluating a change to using pre-sterilized glass vials in place of the current process described above. While we feel the current process provides an adequate level of microbiological and particulate control based on all available data, we understand there may be benefits to using pre-sterilized vials that are adequately protected and ready-to-use upon receipt. However, a change of this nature requires re-validation of our aseptic process and so the potential benefit may be outweighed by the risks and complexity of implementing the change. Therefore, we will inform FDA of our evaluation once complete, which is represented as **Commitment 2** in this response letter.

3. Lyophilization

Regarding the non-hazardous cleanroom smoke study video provided in your firm's November 8, 2018, response letter:


- a) *What lyophilized products are currently produced at your facility? What are your plans for future production within the non-hazardous cleanroom?*

Response:

The following lyophilized products are compounded at Olympia's facility currently:

- HCG 2000IU Injection per vial
- HCG 5000IU Injection per vial
- HCG 10,000IU Injection per vial
- HCG 5000IU/Hydroxocobalamin 5mg Injection per vial
- HCG 10,000IU/Hydroxocobalamin 5mg Injection per vial
- Sermorelin Acetate 3mg Injection per vial

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 <p>GLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY</p>	<p>Reference: CMS Case #573273 Dated 27MAR19</p>	<p>Page 4 of 13 Version Date: 06MAY19</p>
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- Sermorelin Acetate 9mg Injection per vial
- NAD+ 500mg/vial
- Sincalide 5mcg/vial

Presently, Olympia houses two Virtis Ultra Lyophilizer Units attached to their respective cleanrooms for the separate compounding of hazardous and non-hazardous drugs. The future for production within the non-hazardous cleanroom consists of compounding lyophilized the drug products Sincalide and Methylcobalamin. No other lyophilized products are planned at this time in the non-hazardous cleanroom.

b) How does your firm decontaminate and/or sterilize the lyophilizer prior to production?

Response:

The lyophilizers are manually disinfected daily using a disinfecting agent (Iradexon Bleach) followed by a residue removal with sterile water for injection, and finally a secondary disinfection using 70% sterile isopropyl alcohol. A manual sporicidal disinfection is carried out weekly using one of two sporicidal agents (Spor-Klenz and Peridox) on a rotating basis, followed by a secondary disinfection using 70% sterile isopropyl alcohol.

The most recent cleaning and disinfecting log for each of the lyophilizers at Olympia can be referenced in **Attachment 6**.

c) Provide documentation showing the air velocity in the critical area where lyophilized drug products are transferred within the non-hazardous cleanroom, and justification that this velocity is adequate to protect vials during the transfer process.

Response:


Olympia has carried out air velocity mapping of the critical area where lyophilized drug products are transferred within the non-hazardous cleanroom. Refer to **Attachment 7** for the report provided by an external party that performed the mapping. The data collected testing the air velocity in this critical area had a range of 41 feet per minute (FPM) and a high of 150 FPM within the sampled area, with an average airflow of 82 FPM. This meets the requirement of a minimum of 40 FPM to provide protection to the partially stoppered vials.

4. Sporicidal Disinfection

Regarding the use of Spor-Klenz as described in your firm's November 8, 2018, response letter, how does your firm ensure that a surface, being exposed to multiple air changes, remains wet for the entire 30-minute contact time without reapplication?

Response:

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 <p>OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY</p>	<p>Reference: CMS Case #573273 Dated 27MAR19</p>	<p>Page 5 of 13</p>
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Olympia has not historically performed a re-application of Spor-Klenz to ensure the surfaces remain wet for the entire 30-minute contact time, as the environmental monitoring data for the facility have not indicated any undesirable trends with respect to spores since the facility has been in operation. Olympia agrees that it is important to follow the manufacturer's recommended wet contact time unless objective evidence can be provided to support alternative approaches. To that end, Olympia has decided to perform a disinfecting process validation study with an external party, represented as **Commitment 3** in this response letter. Revision of P-304 to align with results of this study is represented as **Commitment 4** in this response letter.

Analytical Research Laboratories (ARL) has been contracted for the validation study of all decontamination and cleaning agents used at the facility to confirm the manufacturer's claims regarding the efficacy of the agents at the concentrations of use and to establish minimum wet contact times on simulated facility surfaces. Through this evaluation and based on historical environmental monitoring data, Olympia hopes to validate the current disinfecting process used and potentially achieve shorter wet contact times than what the manufacturer recommends in their labeling. The pass/fail criteria for the study shall be based on log reduction values from the inoculation population. Refer to **Attachment 8** for the study protocols.

5. *Production Intermediates*


Regarding the use of intermediates as described in your firm's November 8, 2018, response letter, the Agency is concerned with the prolonged storage of non-sterile intermediates. While the product will be filter sterilized at a later step, there is the potential for bioburden to proliferate during storage. Endotoxin will not be removed by filter sterilization. While endotoxin testing can be performed as a release test on the finished drug product, this process represents a poor practice.

Response:

Olympia would like to clarify that the duration of the hold times during Aseptic Process Simulation (APS) are not the routine hold times used during compounding. The hold times during APS (3 days for intermediate bulks, 24 hours for sterilized final bulk) represented the "worst case" scenario for hold times that might be encountered if an unexpected delay in processing occurred during operations. In routine operations, the hold times are typically <24 hours for intermediate bulks and <6 hours for sterilized final bulks.

Although the APS batches to-date have not resulted in any failures or concerns regarding hold times, Olympia is committed to continued quality improvement in this area. As such, we intend to revise the current aseptic process to include an additional sterile filtration of the intermediate bulk materials prior to the hold time, which will help to further mitigate the risk of microbiological growth in our product formulations. We will also shorten the hold times during APS to 24 hours for the intermediate bulks and 12 hours for the sterilized final bulks, which still allows for operational flexibility but is well beyond our typical hold time duration.

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 <p>OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY</p>	<p>Reference: CMS Case #573273 Dated 27MAR19</p>	Page 6 of 13
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These changes will require a re-validation of the APS process by three consecutive passing trials, which will be executed in place of the July semi-annual re-qualification. This is represented as **Commitment 5** in the response letter.

6. **Product Labeling**

*Regarding your corrective actions to your firm's drug product labels as described in your firm's November 8, 2018, response letter, we note that most of the labeling deficiencies appear to be adequately addressed. However, it appears that your corrective action with respect to the list of inactive and active ingredients and the quantity or proportion of each ingredient is not adequate. Section 503B(a) (10) (A)(iii)(X) requires a list of active and inactive ingredients, identified by established name and the **quantity or proportion of each ingredient**, to be listed on the label. If there is not space for such information on the label, per section 503B(a)(10) (B)(i), the container from which the individual units of the drug are removed for dispensing or for administration shall include such information. We request that you provide revised labels or container labels to address this deficiency.*

Response:

Refer to **Attachment 9** for samples of newly revised label proofs for product labeling of the Bimix, Trimix, and QuadMix products produced by Olympia. These proofs are consistent with the firm's November 8th, 2018 response letter for products that utilize production intermediates for finished product compounding.

7. **Dynamic Medical Solutions (DMS)**


We understand that you have partnered with Dynamic Medical Solutions (DMS), a company that seeks to meet the needs of healthcare providers by offering sterile and non-sterile products from your facility. We have the following questions regarding your partnership with DMS:

- a) Describe your business relationship with Dynamic Medical Solutions (DMS)? Do you have a contract with DMS? If so, please provide a copy of the contract.*

Response:

Dynamic Medical Solutions (DMS) is a Value-Added Reseller (VAR), also known as an independent sales representative with Olympia, with no exclusivity to Olympia. As a VAR, DMS builds relationships with physicians who use compounded medications to treat patients. DMS becomes a liaison between Olympia and the physician to facilitate the ordering process only. DMS does not stock or directly distribute any medications that Olympia compounds. DMS sets up the physician/pharmacy relationship using an account set-up form, which collects all necessary and applicable information about the physician's office. Refer to **Attachment 10** for the account set-up forms utilized by DMS, which are provided by Olympia. There is a reseller contract in place between Olympia and DMS for the relationship just described. Refer to **Attachment 11** for the contract.

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 <p>OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY</p>	<p>Reference: CMS Case #573273 Dated 27MAR19</p>	<p>Page 7 of 13</p>
		<p>Version Date: 06MAY19</p>

- b) *How does your firm receive orders for these drug products? What is the quantity that is ordered? Please provide any documents related to the ordering process.*

Response:

Olympia receives the orders by fax at 877-622-3232 and by email to a designated email account, orders@olympiapharmacy.com. The email order is sent by the ordering physician to a DMS representative who serves as the liaison between the physician's office and Olympia, ensuring that the order is received, fulfilled and shipped. The quantity ordered is determined by the physician and varies with each order; it is included on the order form at the time an order is placed. Refer to **Attachment 13** for mocked DMS order forms as would be received by Olympia for fulfillment.

- c) *Describe the process from prescribing to receipt of the medications (who is doing what, and where is the product throughout the process).*

Response:

The physician sends the completed and signed order form to DMS. DMS verifies availability with Olympia, BUD, and turnaround time. DMS then transmits the order via email or fax to Olympia Pharmacy. Once the order is received by Olympia pharmacy, it is handled in the same manner as any other order. It is received and entered the pharmacy's McKesson software by a licensed pharmacy technician, the licensed pharmacist does a pre-verification/clinical review for appropriateness of order and physician credentials are verified. If there is an issue with the order the physician is contacted directly by the pharmacist for clarification or correction. The order is fulfilled by a licensed pharmacy technician and a final check for accuracy of the medication is done by a licensed pharmacist. After which the completed order is transferred to the shipping department where it is shipped directly to the physician's office.

- d) *Are products distributed with DMS labels on them? Do products ship with DMS branding affixed to the products? If so, who provides the DMS labels? Please provide labels if available.*


Response:

No, the compounded products distributed have Olympia labels affixed on the unit vials and prescriptions labels for designated physician's office on the outer container. No DMS branding is affixed to the products. Olympia only labels products according to its policy on labeling. No vendor labels are used.

- e) *Does DMS provide the product specifications to your firm?*

Response:

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 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: CMS Case #573273 Dated 27MAR19	Page 8 of 13
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No, Olympia compounds products pursuant to the CGMP requirements and internal policies and procedures for drug product specifications. DMS does not provide any product specifications to Olympia Pharmacy.

- f) *What products are manufactured/stored/distributed by your firm when DMS is used as an intermediary?*

Response:

Olympia does not compound any products specifically for DMS; rather, our product offering menu is the same for all physicians and patients. Refer to **Attachment 12** for mock order forms used by DMS for compounded products offered by Olympia.

- g) *Does your firm receive any complaints or adverse event reports regarding these drug products? Do you have a procedure for investigating the reports? Do you communicate complaints or adverse events to DMS?*


Response:

No complaints or adverse event reports have been made to Olympia from DMS for any compounded drug product compounded by Olympia. The physician's office also has the FDA and Olympia's direct contact information, provided on the vial labels, should they wish to report an adverse event directly to the FDA or Olympia. Olympia has a procedure for investigating any such reports if we receive them. Refer to **Attachment 13** for the SOP on complaint handling, P-219, Drug Safety and Surveillance. Olympia will communicate complaints and or adverse events to DMS for all applicable circumstances.

8. Ineligible Bulk Substances

On July 18, 2018, your firm submitted a written response to FDA stating, "as a corrective action, effective May 1, 2018, Olympia Pharmacy ceased use of bulk substances in compounding (including Sermorelin, GHRP-2, and GHRP-6)." However, during a recent FDA inspection of a 503A facility we observed that Sermorelin, GHRP-2, and GHRP-6 were produced and distributed to the facility from your firm subsequent to your commitment to cease production with these bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities. Additionally, we note that your December 2018 product report (covering the period of June 1, 2018, through November 30, 2018) shows that you have produced thousands of vials of drug product containing these ineligible drug substances during this reporting period. Please provide your rationale as to why your firm committed to cease the production and distribution of drug products using ineligible bulk drug substances but has continued this practice. Do you intend to continue to produce and distribute drugs using bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities?

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 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: CMS Case #573273 Dated 27MAR19	Page 9 of 13
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Olympia's Response:

Olympia appreciates and acknowledges the importance of compounding with eligible bulk drug substances and meeting the FDA's current expectations. Toward that end, Olympia would like to take this opportunity to provide further insight into its rationale for its compounding with bulk substances Sermorelin Acetate, GHRP-2, and GHRP-6, as well as provide our proposed strategy for compounding with bulk substances moving forward.

Olympia's Use of Bulk Substances Sermorelin Acetate, GHRP-2, and GHRP-6


Although Olympia represented to the FDA that it would cease compounding Sermorelin Acetate, GHRP-2, and GHRP-6, Olympia continued to compound with these bulk substances to balance the FDA's evolving expectations with Olympia's commitment to continuity of care to its patients. Sermorelin Acetate, GHRP-2, and GHRP-6 are not components of any commercially available drug products, and, therefore, Olympia can only prepare compounded medication containing these drugs if it uses bulk substances. As such, Olympia was concerned that an abrupt and immediate cease in compounding using these bulk substances would cause medical harm to the thousands of patients that rely on these compounded medications. Olympia felt it had a commitment to avoid any interruption in care, and, accordingly, continued to compound with bulk Sermorelin Acetate, GHRP-2, and GHRP-6 to keep these compounded medications available for patient care.

Effective June 1st, 2019 Olympia will cease compounding with bulk GHRP-2 and GHRP-6, as it understands these substances are currently not eligible for the exemptions provided by section 503A or 503B, are not the subject of an applicable USP or NF monograph, and are not components of an FDA approved human drug and do not appear on the 503A or 503B bulks list. As noted above, this makes these compounds unavailable for patient care as they cannot be prepared from any commercially available drug; however, in deference to the FDA, Olympia will cease to prepare these compounds and will inform its physicians and patients that compounding pharmacies can no longer offer this treatment.

Regarding compounding from bulk Sermorelin Acetate, Olympia believes the FDA should exercise enforcement discretion over the compounding with nominated bulk substances until the FDA has completed its review of the nominated bulk substance. Based on Olympia's longstanding involvement in the industry and as a member of the Outsourcing Facilities Association ("OFA"), Olympia understands the FDA's position on compounding bulk drug substances by an outsourcing facility to be as follows: If a bulk drug substance is nominated and does not appear in Category 1, 2, or 3, then FDA will exercise enforcement discretion over the compounding with that particular bulk substance until FDA makes a determination on the categorization of the bulk substance. As such, because Sermorelin Acetate was nominated by OFA for the FDA's consideration, Olympia expects that the FDA will exercise enforcement discretion as to compounding with bulk Sermorelin Acetate until a determination has been made on the categorization of this bulk substance. Refer to **Attachment 14** for the Sermorelin Acetate Nomination. Olympia will immediately cease compounding Sermorelin Acetate if FDA does not place this substance in Category 1 and/or on the final 503B Bulks List.

As indicated above, Sermorelin Acetate is also not a component of any commercially available drug, and therefore, if bulk Sermorelin Acetate cannot be used to compound, these compounded medications will not be available to patients. Sermorelin Acetate, however, was a component of the commercially available drug product called GEREf, which has been discontinued by the

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 OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY	Reference: CMS Case #573273 Dated 27MAR19	Page 10 of 13
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manufacturer, but was not withdrawn from sale for reasons of safety or effectiveness. Refer to **Attachment 15** for the Federal Register Notice Regarding Withdrawal of GEREf. Thus, the only way for patients to currently receive this treatment is through compounding this bulk substance.

Olympia's Proposed Strategy for Compounding from Bulk Substances

To provide a complete and comprehensive response to FDA's request regarding Olympia's use of bulk drug substances in compounding, Olympia would like to take this opportunity to explain its current business model and the plans it has underway for transitioning the patient-specific portion of its practice to a traditional compounding pharmacy.


Currently, Olympia compounds on both a patient-specific and non-patient-specific basis in its outsourcing facility. Given that Olympia is registered as a 503B outsourcing facility, and, as is required by the statute, all the medications we prepare are compounded pursuant to CGMP standards. However, when Olympia conducted an analysis of the needs of its patients and physicians that require the patient-specific medications, it revealed that these needs would be best served by a traditional pharmacy compounding under Section 503A. Toward that end, Olympia is in the process of establishing a 503A compounding pharmacy so that it can transfer its patient-specific compounding to that facility. This facility will be located at 4600 LB McLeod Rd, Orlando, FL (the "McLeod Location"). Olympia has already leased this space and has ordered a modular pre-fabricated cleanroom for the opening of the compounding pharmacy. Refer to Cleanroom Invoice, McLeod Location Architectural Agreement, McLeod Location Floor Design Drawing, and the McLeod Lease Agreement as **Attachment 16**. As soon as the McLeod Location is fully compliant with Florida regulations and Section 503A standards, all patient-specific compounding practices will be separated from Olympia's current 503B outsourcing facility and transferred to the McLeod Location. The anticipated date of completion for this business segregation is early 2020.

In the interim, Olympia is asking for the opportunity to be able to transition its patient-specific practice to the McLeod Location. Specifically, Olympia is requesting that FDA exercise enforcement discretion during this transition period to allow Olympia to prepare patient-specific compounds with bulk substances that meet the requirements of Section 503A; that is, the bulk substances are compounded according to a USP or NF monograph, are components of a commercially available drug product, or appear on Category 1 of FDA's Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. All these patient-specific compounds will continue to be prepared under CGMP requirements at Olympia's current facility until they are transitioned to the traditional compounding pharmacy at the McLeod Location. Olympia will only use bulk substances that appear on Category 1 or under FDA consideration pursuant to a nomination for any compounds prepared without a patient-specific prescription.

In summary, going forward and to address the FDA's concerns, Olympia has proposed the following strategy:

- (1) Olympia will continue to compound Sermorelin Acetate with the understanding that FDA will exercise enforcement discretion over nominated bulk drug substances until a determination is made on the substance's categorization. If Sermorelin Acetate is not placed in 503B Bulks Category 1, Olympia will cease compounding with this bulk substance unless and until it is placed in 503B Bulks Category 1 and/or on the finalized 503B Bulks List;

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 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: CMS Case #573273 Dated 27MAR19	Page 11 of 13
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- (2) Olympia will cease compounding GHRP-2 and GHRP-6 by June 1, 2019, unless and until these substances are placed in 503B Bulks Category 1 and/or on the finalized 503B Bulks List (**Commitment 6**); and
- (3) Olympia will fully separate its 503A and 503B compounding operations into two separate locations and anticipates completion of this separation by early 2020 (**Commitment 7**).

Olympia looks forward to discussing its proposed strategy and continuing this constructive dialogue with the FDA at the proposed regulatory meeting.

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 GLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY	Reference: CMS Case #573273 Dated 27MAR19	Page 12 of 13
		Version Date: 06MAY19

Table 1: Commitments to FDA

No.	Description of Action Required	Due on or Before	Status	Related Inquiry
1	Sterility and Endotoxin Challenge for Depyrogenated Vials	31JUL19	In-Progress	2
2	Evaluation of pre-sterilized vials under change control	30NOV19	In-Progress	2
3	Sterilant and Disinfectant Challenge Study Completion	31JUL19	In-Progress	4
4	Revise P-304, Cleaning- Sterilizing and Disinfecting of the Compounding Facility, to align with study results	31JUL19	Not-Started	4
5	Revision of APS protocols and re-execution of APS with revised hold times	31JUL19	In-progress	5
6	Cease compounding of GHRP-2 and GHRP-6 unless and until these substances are in Category 1 of the 503B Bulks List	01JUN19	N/A	8
7	Separation of 503A and 503B facilities	Early 2020	In-progress	8

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 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: CMS Case #573273 Dated 27MAR19	Page 13 of 13
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Table 2: List of Attachments

No.	Document No. Reference	Attachment Description
1	P-217	Sterile Drug Product Specification at Olympia Pharmacy and Reconstitution Final Reports
2	N/A	Sample Reconstitution Dissolution Release Testing Report
3	N/A	Revised Patient Reconstitution Instructions for Dispensing of Lyophilized Drug Products.
4	N/A	Particulate testing trend report and cleanroom certification for the last year for the ISO 8 cleanroom space for storage of depyrogenated vials.
5	N/A	Sterility and Endotoxin Challenge Study Protocol for Depyrogenated Glass Vials
6	F-304	Most Recent Lyophilizer Cleaning and Disinfecting Log
7	N/A	Micro Filtration Report on Air Velocity Mapping for Lyophilization Vial Transfer
8	N/A	Sterilant and Disinfectant Challenge Study Protocols and Use Dilution Report.
9	N/A	Revised Label Proofs
10	N/A	DMS Account Set-Up Form
11	N/A	DMS Contractual Agreement with Olympia Pharmacy as a VAR
12	N/A	DMS Sample Order forms as received by Olympia Pharmacy
13	P-219	Drug Safety and Surveillance
14	N/A	GEREF Federal Register Notice
15	N/A	Bulks Substance Nomination
16	N/A	Bulks List Compliance Exhibits

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From: [Diehl, John](#)
To: [Confidence Ekeanyanwu](#)
Cc: [Martinez, Dayna](#); [ORA PHARM2 Responses](#)
Subject: RE: OPS International Inc. DBA Olympia Pharmacy- Building UPDATE
Date: Wednesday, October 23, 2019 10:59:42 AM
Attachments: [image001.png](#)

Good Morning Ms. Ekeanyanwu – thank you for the update and good luck with the new building.

CDR John W. Diehl, M.S.
 Director, Compliance Branch
 Office of Pharmaceutical Quality Operations, Division II
 FDA/Office of Regulatory Affairs
 O: (214) 253-5288
 C: (972) 971-7912
John.diehl@fda.hhs.gov

From: Confidence Ekeanyanwu <confidence@olympiapharmacy.com>
Sent: Tuesday, October 22, 2019 3:29 PM
To: Diehl, John <John.Diehl@fda.hhs.gov>
Cc: Martinez, Dayna <Dayna.Martinez@fda.hhs.gov>; [ORA PHARM2 Responses](#)
 <ORAPHARM2_RESPONSES@fda.hhs.gov>
Subject: OPS International Inc. DBA Olympia Pharmacy- Building UPDATE

Good Day Mr. Diehl,

During a Regulatory Meeting held Thursday, September 12th, 2019, OPS dba Olympia Pharmacy informed the agency of the firm's **project**, the 'Separation of 503A and 503B Operations with a separate 503A Facility' intended toward a compliance path on the subject of bulk substances as applicable to the compounding sector. To reiterate our plan, the first phase of the project involved site and facility development and installation of modular cleanrooms. We had submitted our application for a building permit to the City of Orlando but were waiting for approval.

While building permits are rate limiting, today, we are happy to update you and the agency that the building permit for **4600 LB McLeod Road, Orlando, FL 32811** has been approved by the City of Orlando. The building permit approval is attached (**Building Permit-BLD2019**) for your review and for our file as we continue to update the agency on our progress with compliance commitments made under the VAI status. To further express our commitment to this project, we have made additional payments to Precision Building Construction, LLC. Attached are paid invoices 190049 & 190051 for the LB McLeod build out progress and fire alarm design revisions required by the City of Orlando. This sum of \$188,810.73 secures the construction labor critical for the progression of the project.

Olympia is committed to continuously improving its systems and processes in alignment with FDA's expectations to ensure patient and public safety. This email correspondence supplements the regulatory meeting response submitted **October 3rd, 2019** to the agency. For any questions or

additional clarification, please feel free to contact me at any time.

Thank You,



Confidence Ekeanyanwu

Quality Manager

Olympia Compounding Pharmacy

FDA Registered 503B Outsourcing Facility

6700 Conroy Rd # 155 Orlando, FL 32835

📞 (781) 686-0640 📠 (407) 673-1234

"Knowledge is power. Information is liberating. Education is the premise of progress, in every society, in every family."

-Kofi Annan.



6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Wednesday, March 11, 2020

LCDR John W. Diehl, M.S.
Director, Compliance Branch
C/O: Dayna Martinez
Division Compliance Officer
Office of Pharmaceutical Quality Operations, Division II
Food and Drug Administration
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Good Day Mr. Diehl,

We are writing to update the agency on the status of our bulk substances commitment with respect to separating our pharmacy operations into separate 503A and 503B facilities. This response will also update the agency on air velocity concerns for current compounding operations in our classified cleanroom space. This is specific to the transfer of drug products to the lyophilizer. For this project at our current facility, a completion response shall be due to the agency on or before **15MAY20**.

These updates are in accordance to the Voluntary Action Indicated (VAI) status discussed and agreed upon at the Regulatory meeting held September 12th, 2019.

For the purpose of this update, **Table 1** shall represent the commitment listing and **Table 2** shall represent the listing of attached supporting documents related to the commitments in **Table 1**.

Olympia is committed to continuously improving its systems and processes in alignment with FDA's expectations to ensure patient and public safety. For any questions or additional clarifications, please feel free to contact me at any time.

Sincerely,

Confidence C. Ekeanyanwu


Confidence C. Ekeanyanwu

Quality Manager

Olympia Compounding Pharmacy

Mobile: 781-686-0640

Email: confidence@olympiapharmacy.com

 OLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: Regulatory Meeting Dated 12SEP19	Page 2 of 4
		Version Date: 10MAR20

NOTE:

- The Agency's meeting conclusion comments are represented with *Bold, Italic* text.
- **Table 1** at the end of the document contains the commitments to the agency and their due dates.
- **Table 2** contains the Attachment List.


1. *In relation to the "Air Velocity Study" included in your May 6, 2019 response, provide justification to support that air velocity and airflow patterns in your non-hazardous cleanroom are adequate to ensure the protection of partially stoppered vials during transfer to the lyophilizer.*

UPDATE:

The previous update informed the agency of the proposed and signed labor contract for a Germfree constructed laminar airflow workstation. The LAF will contain the auto-filling machine for the filling and partial stoppering of vials for lyophilization. As stated, the LAF will maintain a downward, vertical unidirectional barrier of HEPA filtered air during operation to protect the product from contamination and assure product sterility. The LAF will provide an ISO Grade 5 (EU Grade A) environment for all operations that expose components to the environment including Tyvek lid removal, Nest Transport (to and from Olympia's Virtis Ultra 35 XL), Filling, Closing and Capping as well as transfer of materials from Olympia's Virtis Ultra 35 XL.

The project timeline and working engineering drawing for the unit is reflected as **attachment 1** of this response document. The unit is in the fabrication shop now and according to the work schedule provided by Germfree, the unit is set to be completed on 18MAR2020. An initial quality check would be done before preparation for the weld shop, then assembly, testing, and a final quality check. They currently show a ship date of 20APR20. Upon delivery to Olympia, a workstation and cleanroom certification shall be completed, and smoke study done. These documents and videos will be submitted to the agency demonstrating laminar air flow during the transfer of vials to the lyophilizer.

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 OLYMPIA COMPOUNDING PHARMACY FDA REGISTERED 503B OUTSOURCING FACILITY	Reference: Regulatory Meeting Dated 12SEP19	Page 3 of 4
		Version Date: 10MAR20

2. Provide updates on the new facility as it regards to progression completion.

UPDATE:

Attachment 2 is a project completion notice from PBC Inc. for the **first phase** of the bulk drug substances' commitment. This phase was the building development and construction stage as the timeline below outlines. The **video clip** showing construction completion and constructed facility with the installed modular cleanrooms for hazardous and non-hazardous drug compounding is **attachment 3** of this response.

The **second phase** of the separation project begins with the qualification/validation plan for the cleanrooms, personnel, and equipment for sterile processing. We have also begun the permitting process which kicked off with the community pharmacy permit application to the Florida Board of Pharmacy. The application and facility are approved after an initial inspection by the board. The permit issuance notice and inspection report are shown as **attachment 4** of this update. The sterile processing application for Florida has since been submitted (**attachment 5**), awaiting the cleanroom initial qualification and certification for a sterile facility inspection by the Florida DOH for permitting.

The DEA application is pending (application submission shown as **attachment 6**) and the National Practitioner Identifier (**NPI**) and **NCPDP** Provider Identification number, formerly known as the NABP number for the pharmacy has been obtained. This is shown as **attachment 7** of the update response. Non-Resident Pharmacy permit applications are underway, and we hope to obtain licensure in all 49 states on or before DEC20.

Bulk Drug Substances

- Separation of 503A and 503B Operations with a New 503A Facility
- Capital Budget - \$3 million USD
- **First Phase – Site/Facility- COMPLETE**
 - Building permits from the City of Orlando is complete.
 - Construction labor is secured, and site development is underway.
- **Second Phase – Qualification/Registration- Start Date- 04MAR20.**
 - Will need to qualify facility, equipment, and personnel per Validation Master Plan.
 - Obtain licensure in each of the 49 states on a rolling basis.

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 GLYMPIA COMPOUNDING PHARMACY <small>FDA REGISTERED 503B OUTSOURCING FACILITY</small>	Reference: Regulatory Meeting Dated 12SEP19	Page 4 of 4
		Version Date: 10MAR20

Table 1: Commitments to FDA

No.	Description of Action Required	Due on or Before	Status
1	Lyophilization compounding process Quality Improvement project	31MAR20 15MAY20	In-Progress
2	Separation of 503A and 503B facilities	DEC 20	In-progress

Table 2: List of Attachments

No.	Document No. Reference	Attachment Description
1	N/A	Project timeline and engineering drawing
2	N/A	PBC Inc. construction completion notice.
3	N/A	Constructed facility video clip.
4	N/A	FL permit issue and Inspection report- Community Pharmacy.
5	N/A	Submitted Sterile Processing application.
6	N/A	DEA application submission
7	N/A	NPI and NCPDB notices.

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1/31/2020

Establishment Registration



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Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form required fields.

Header Details

Document Type: **ESTABLISHMENT REGISTRATION**

Set ID: * 0b76b8c9-d894-0eb9-e054-00144ff8d46c
 Root ID: * 9c326b6f-3caa-40b8-e053-2995a90aed8b

Version Number: 9

Effective Date: * 01-15-2020

Registrant Details

Registrant Name: **OPS INTERNATIONAL INC. DBA OLYMPIA COMPOUNDING PHARMACY**

Registrant DUNS: **017674368**

Registrant Contact Details

Contact Name: * **CONFIDENCE EKEANYANWU**
 Contact Email: * **confidence@olympiapharmacy.com**
 Contact Phone: * **781-686-0640**
 Phone Extension:

Registrant Contact Address

Country: * **United States**
 Street Address: **6700 Conroy Windermere Rd Ste 155**
 City: * **ORLANDO**
 State: * **Florida**
 Postal Code: * **32835**

Establishments

row(s) 1 - 1 of 1

ESTABLISHMENT DUNSE	ESTABLISHMENT FEI	ESTABLISHMENT NAME
017674368	3011158365	OLYMPIA COMPOUNDING PHARMACY

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4/24/2020

FL DOH MQA Search Portal |



Department of Health

License Number: PH27414

Data As Of 4/24/2020

Profession	Pharmacy
License	PH27414
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2021
License Original Issue Date	01/24/2014
Address of Record	6700 CONROY ROAD STE 155 ORLANDO, FL 32835 UNITED STATES
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.



Department of Health

License Number: PH27363

Data As Of 4/24/2020

Profession	Pharmacy
License	PH27363
License Status	CLEAR/
Qualifications	Community PharmacySchedule II & III
License Expiration Date	2/28/2021
License Original Issue Date	01/09/2014
Address of Record	6700 CONROY ROAD STE 155 ORLANDO, FL 32835
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

AC#8679438

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/05/2018	PH 27363	105539

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**


OPS INTERNATIONAL INCORPORATED

Olympia Pharmacy
6700 CONROY ROAD
STE 155
ORLANDO, FL 32835

QUALIFICATION(S):

**COMMUNITY PHARMACY
SCHEDULE II & III**

3:1 PHARMACY TECHNICIAN RATIO APPROVED



Rick Scott
GOVERNOR



Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

AC#8679437

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/05/2018	PH 27414	105541

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

OPS INTERNATIONAL INCORPORATED

Olympia Pharmacy
6700 CONROY ROAD
STE 155
ORLANDO, FL 32835

QUALIFICATION(S):

SPECIAL STERILE COMPOUNDING

3:1 PHARMACY TECHNICIAN RATIO APPROVED



Rick Scott
GOVERNOR



Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

State of Florida

Department of State

I certify from the records of this office that OPS INTERNATIONAL INCORPORATED is a corporation organized under the laws of the State of Florida, filed on October 3, 2013, effective October 2, 2013.

The document number of this corporation is P13000081512.

I further certify that said corporation has paid all fees due this office through December 31, 2019, that its most recent annual report/uniform business report was filed on April 6, 2019, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

*Given under my hand and the
Great Seal of the State of Florida
at Tallahassee, the Capital, this
the Twelfth day of February, 2020*



Randy Be
Secretary of State

Tracking Number: 9107518418CU

To authenticate this certificate, visit the following site, enter this number, and then follow the instructions displayed.

<https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication>

15F

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☒ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: QuVa Pharma, Inc.

Physical Address: 1075 West Park One Drive Suite 100

City: Sugar Land State: Texas Zip Code: 77478

Telephone: 888 339 0874 Fax: _____

Toll Free Number: 888 339 0874 (Required per NAC 639.708)

E-mail: michelle.kostroun@quvapharma.com Website: www.quvapharma.com

Supervising Pharmacist: Varsha Gaitonde Nevada License #: 20064

OK
exp
10/31/21

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral

☒ ☐ Sterile Compounding

☒ ☐ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding

☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 4/20/2020 Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY**Page 2**FEI Number (From FDA application): 3012053582Please provide the name of the facility as registered with the FDA and the registration number:
QuVa Pharma, Inc.Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Varsha Gaitonde Nevada License Number: 20064A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/AThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

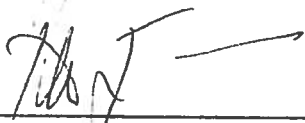
I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Peter Jenkins

Print Name of Authorized Person

4/10/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: QuVa Pharma Holdings, Inc.Address: 3 Sugar Creek Center Blvd. Ste. 250City: Sugar Land State: TX Zip: 77478Telephone: 888-339-0874

Fax: _____

Contact Person: Michelle Kostroun

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) 100% of the shares are owned by QuVa Pharma Holdings

Name

Address

b) _____

Name

Address

c) _____

Name

Address

d) _____

Name

Address

2) Provide the number of shares issued by the corporation. 10003) What was the price paid per share? No Par value4) What date did the corporation actually receive the cash assets? N/A5) Provide a copy of the corporation's stock register evidencing the above information N/A**Include with the application for a non publicly traded corporation**

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors - see attached

per conversation will forward
Once received mk 04.13.2020

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: QuVa Pharma, Inc.

Address: 5920 South General Bruce Drive

City: Temple State: TX Zip: 76502

I hereby authorize the The Texas Department of Health and Human Services to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Michelle Kothmann

**THIS FORM MUST BE FORWARDED TO THE HOME STATE
LICENSING AGENCY FOR COMPLETION. DO NOT WRITE BELOW THIS LINE**

License Number	License Status	Date License Issued	Date License Expires
<u>1001828</u>	<u>Current</u>	<u>10.23.2019</u>	<u>11.2.2021</u>

Has this license been encumbered in any way?
☐ Yes ☒ No

Type of Encumbrance: (if any)
☐ Revoked ☐ Surrendered ☐ Limited
☐ Suspended ☐ Restricted ☐ Probation
 Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has applicant met all licensing requirements of your state? (If no, please explain)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Signature of State Official	Title	State	Date	State Seal
<u>[Signature]</u>	<u>Chief Pharmacist</u>	<u>TX</u>	<u>4.21.2020</u>	

State of Delaware
 Secretary of State
 Division of Corporations
 Delivered 05:35 PM 05/28/2015
 FILED 04:34 PM 05/28/2015
 SRV 150811868 - 5755668 FILE

CERTIFICATE OF INCORPORATION

OF

QUVA, INC.

The undersigned, in order to form a corporation under and pursuant to the provisions of the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the corporation is Quva, Inc. (the "Corporation").

SECOND: The address of the Corporation's registered office in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, New Castle County 19808. The name of its registered agent at such address is Corporation Service Company.

THIRD: The purposes for which the Corporation is formed are to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware (the "DGCL") and to possess and exercise all of the powers and privileges granted by such law and any other law of Delaware.

FOURTH: The total number of shares of stock which the Corporation shall have authority to issue is One Thousand (1,000) shares of Common Stock each without par value.

FIFTH: The name and mailing address of the Incorporator are as follows:

<u>Name</u>	<u>Address</u>
Peter Jenkins	135 Central Park West New York, NY 10023

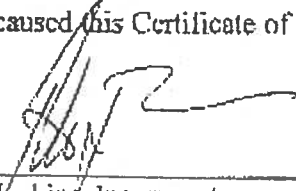
SIXTH: In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized and empowered to make, alter or repeal the bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any bylaw made by the board of directors.

SEVENTH: The Corporation reserves the right at any time and from time to time to amend, alter, change or repeal any provisions contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article.

EIGHTH: The election of directors need not be by written ballot, unless the bylaws of the Corporation shall so provide.

NINTH: To the fullest extent permitted by the DGCL as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that this Article shall not eliminate or limit the liability of a director for (i) any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Incorporation to be executed this 28th day of May, 2015.



Peter Jenkins, Incorporator

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:05 PM 07/13/2015
FILED 05:06 PM 07/13/2015
SRV 151042713 - 5755668 FILE

CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
QUVA, INC.

It is hereby certified that:

1. The name of the corporation (hereinafter called the "Corporation") is QuVa, Inc.
2. The Certificate of Incorporation of the Corporation is hereby amended by striking out Article FIRST thereof and by substituting in lieu of said Article FIRST the following new Article FIRST:

"FIRST: The name of the corporation is QuVa Pharma, Inc. (the "Corporation").

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to the Certificate of Incorporation of QuVa, Inc. to be executed as of this 10th day of July, 2015.

QUVA, INC.

By: 

Name: Peter Jenkins

Title: Chief Development Officer, Treasurer and
Secretary

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "QUVA PHARMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF APRIL, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "QUVA PHARMA, INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF MAY, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.



5755668 8300

SR# 20202775186

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature of Jeffrey W. Bullock in black ink, written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 202759509

Date: 04-13-20

- ★ Please contact this office immediately if any information on this license is incorrect.
- ★ This license must be displayed at the address licensed.
- ★ The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a \$100.00 delinquency fee for each location and must be remitted before the license will be issued.
- ★ A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at www.dshs.state.tx.us/fdlicense.
- ★ If you have any questions or desire additional information concerning the application process or this license, please contact the Food and Drug Licensing Group at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: <https://reglicensing.questionpro.com>. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

OUVA PHARMA INC
1075 W PARK ONE DR STE 100
SUGAR LAND TX 77478



TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT



QUVA PHARMA INC
1075 W PARK ONE DR STE 100
SUGAR LAND, TX 77478

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

PRESCRIPTION DRUG MANUFACTURER

License # 1001747
Expires: August 12, 2021

NON-TRANSFERABLE

Commissioner

512042

NABP ACCREDITED

DRUG DISTRIBUTOR

QuVa Pharma, Inc

located at

1075 West Park One Dr, Ste 100, Sugar Land, TX 77478

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.


Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary



06/08/2018 - 06/07/2021

Period of Accreditation

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Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisks indicate required fields.

HEADER DETAILS

Document Type: ☒ ESTABLISHMENT REGISTRATION

Set ID: 1a239c5e-a74f-4edd-e054-001447b646c

Version Number: 9

Root ID: 969d21df-219e-478f-e053-2a95a50ac26f

Effective Date: 11-05-2019

REGISTRANT DETAILS

Registrant Name: QuVa Pharma, Inc.

Registrant DUNS: 079937015

REGISTRANT CONTACT DETAILS

Contact Name: Travis McGrady

Contact Email: Travis.McGrady@quvapharma.com

Contact Phone: 832-500-7113

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: United States

Street Address: 1075 West Park One Drive, Suite 100

City: Sugar Land

State: Texas

Postal Code: 77478

ESTABLISHMENTS

row(s) 1 - 2 of 2

ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
079937015	3012953542	QuVa Pharma, Inc.
090084259	390246908	QuVa Pharma, Inc.

Sugar Land Registration

ESTABLISHMENT DETAILS

Establishment Name: * Quva Pharma, Inc
Establishment DUNS: * 079937015
Establishment FEI: 3012053582

ESTABLISHMENT ADDRESS

Country: * United States
Street Address: * 1075 West Park One Drive, Suite 100
City: * Sugar Land
State: * Texas
Postal Code: * 77478

ESTABLISHMENT CONTACT DETAILS

Contact Name: * Travis McGrady
Contact Email: * Travis McGrady@QuVaPharma.com
Contact Phone: * 832-500-7113
Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: * United States
Street Address: * 1075 West Park One Drive, Suite 100
City: * Sugar Land
State: * Texas
Postal Code: * 77478

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

BUSINESS OPERATION(S)

BUSINESS OPERATION		QUALIFIER	row(s) 1 - 2 of 2
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY		INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS	
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY		NOT COMPOUNDING FROM BULK II: GREDIENT	



Corporate Officers for QuVa Pharma, Inc.

Stuart Hinchon - CEO

Home address:

Dunstan Road Apt
Houston Tx

Business address/Corporate address:

3 Sugar Creek Center
Sugar Land, TX 77478

Business phone no: 832-500-7360

Peter Jenkins - Chief Development Officer/Secretary/Treasurer

Home Address:

Dunstan Road
Houston, Texas

Business address/Corporate address:

3 Sugar Creek Center
Sugar Land, Texas 77478

Business phone no: 832-500-7020

15G

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

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☐ Partnership - Pages 1-3 & 6

☒ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: QuVa Pharma, Inc.

Physical Address: 5920 South General Bruce Drive

City: Temple State: Texas Zip Code: 76502

Telephone: 888 339 0874 Fax: _____

Toll Free Number: 888 339 0874 (Required per NAC 639.708)

E-mail: michelle.kostroun@quvapharma.com Website: www.quvapharma.com

Supervising Pharmacist: Travis Leeah Nevada License #: 20307

OK
exp
10/31/2

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral

☒ ☐ Sterile Compounding

☒ ☐ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding

☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 4/20/2020

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

Page 2

FEI Number (From FDA application): 3002468086

Please provide the name of the facility as registered with the FDA and the registration number:
QuVa Pharma, Inc.

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Travis Leeah Nevada License Number: 20307

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

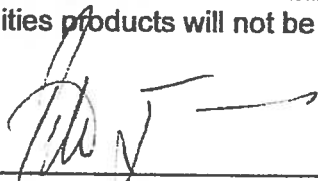
I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Peter Jenkins

Print Name of Authorized Person

4/10/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATIONState of Incorporation: DelawareParent Company if any: QuVa Pharma Holdings, Inc.Address: 3 Sugar Creek Center Blvd. Ste. 250City: Sugar Land State: TX Zip: 77478Telephone: 888-339-0874

Fax: _____

Contact Person: Michelle Kostroun

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) 100% of the shares are owned by QuVa Pharma Holdings

Name

Address

b) _____

Name

Address

c) _____

Name

Address

d) _____

Name

Address

2) Provide the number of shares issued by the corporation. 10003) What was the price paid per share? No Par value4) What date did the corporation actually receive the cash assets? N/A5) Provide a copy of the corporation's stock register evidencing the above information N/AInclude with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. - Ordered Will send per our conversation as soon as received. mk 04-13-2020

List of officers and directors - attached

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: QuVa Pharma, Inc.

Address: 5920 South General Bruce Drive

City: Temple

State: TX

Zip: 76502

I hereby authorize the The Texas Department of Health and Human Services to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant

Michelle Kottmann

THIS FORM MUST BE FORWARDED TO THE HOME STATE
LICENSING AGENCY FOR COMPLETION. DO NOT WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
<u>1001829</u>	<u>Current</u>	<u>10.23.2019</u>	<u>11.2.2021</u>

Has this license been
encumbered in any way?

☐ Yes ☒ No

Type of Encumbrance: (if any)

☐ Revoked ☐ Surrendered ☐ Limited
☐ Suspended ☐ Restricted ☐ Probation

Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has applicant met all licensing requirements of your state? (If no, please explain)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Signature of State Official	Title	State	Date	State Seal
<u>[Signature]</u>	<u>Chief Pharmacist</u>	<u>TX</u>	<u>9.21.2020</u>	

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Notes: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required fields.

HEADER DETAILSDocument Type: **ESTABLISHMENT REGISTRATION**

Set ID: 1e239c5e-a74f-4c0d-e054-00144f8d6c

Version Number: 9

Root ID: 96921d1-219e-478f-e053-2d95a90ac28f

Effective Date: 11-05-2019

REGISTRANT DETAILS

Registrant Name: CuVa Pharma, Inc.

Registrant DUNS: 079837015

REGISTRANT CONTACT DETAILS

Contact Name: Travis McGrady

Contact Email: Travis.McGrady@cuva-pharma.com

Contact Phone: 832-500-7113

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: United States

Street Address: 1075 West Park One Drive, Suite 100

City: Sugar Land

State: Texas

Postal Code: 77478

ESTABLISHMENTS

		row(s) 1 - 2 of 2	
ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME	
079837015	3012053582	CuVa Pharma, Inc.	
080064250	3002466056	CuVa Pharma, Inc.	

Temple registratoin

ESTABLISHMENT DETAILS

Establishment Name: *

QuVa Pharma, Inc.

Establishment DUNS: *

080064259

Establishment FEI:

3002468086

ESTABLISHMENT ADDRESS

Country: *

United States

Street Address: *

5920 S General Bruce Drive, Suite 100

City: *

Temple

State: *

Texas

Postal Code: *

76502

ESTABLISHMENT CONTACT DETAILS

Contact Name: *

Travis Leeah

Contact Email: *

travis.leeah@quvapharma.com

Contact Phone: *

1-254-9334429

Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: *

United States

Street Address: *

5920 S General Bruce Drive, Suite 100

City: *

Temple

State: *

Texas

Postal Code: *

76502

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

BUSINESS OPERATION(S)

row(s) 1 - 3 of 3

BUSINESS OPERATION	QUALIFIER
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	COMPOUNDING FROM BULK INGREDIENT
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	COMPOUNDING STERILE PRODUCTS

NABP ACCREDITED

DRUG DISTRIBUTOR

QuVa Pharma, Inc

located at

5920 South General Bruce Dr, Temple, TX 76502

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.



Carmen A. Catzone, MS, RPh, DPh
Executive Director/Secretary



06/08/2018 - 06/07/2021
Period of Accreditation



Corporate Officers for QuVa Pharma, Inc.

Stuart Hinchon - CEO

Home address:

Dunstan Road Apt 1
Houston Tx

Business address/Corporate address:

Sugar Creek Center
Sugar Land, TX 77478

Business phone no: 832-500-7360

Peter Jenkins - Chief Development Officer/Secretary/Treasurer

Home Address:

Dunstan Road Ap
Houston, Texas 77005

Business address/Corporate address:

3 Sugar Creek Center
Sugar Land, Texas 77478

Business phone no: 832-500-7020



**DEPARTMENT OF STATE HEALTH
SERVICES
P.O. Box 149347
Austin, Texas 78714-9347**

No. 07-1307

Date: 01/31/19

Firm Name QuVa Pharma, Inc.

Classification Prescription Drug
Manufacturer/503B Outsourcing
Facility

Person Contacted Mr. Travis Leeah

Title Vice President of Clinical Development

City Temple

Address 5920 S General Bruce Dr.

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

1. Corrective and preventive action (CAPA) activities are not performed as specified by the firm's written operating procedures. Specifically, the firm's CAPA extension request EXT-00131 for CAPA-0004 was submitted two days after the CAPA due date.

Signature of Firm Representative

State Food and Drug Inspector
Elizabeth Richter

VP Clinical Development, PIC
Title

Sample No. N/A

(If collected)



February 11, 2019

To:

Elizabeth Richter
Texas Department of State Health Services
P.O. Box 149347
Austin, TX 78714-9347

Subject: Observation Response - to Texas Department of State Health Services Inspection Report issued January 31, 2019.

Dear Elizabeth Richter,

QuVa Pharma remains committed to our continued work with Texas Department of State Health Services in a cooperative and responsible manner to ensure that effective system enhancements are accomplished to support sustainable cGMP compliance at the Temple manufacturing facility.

Observation 1 in form E-14, No 07-1307 issued January 31, 2019, stated "Corrective and preventive action (CAPA) activities are not performed as specified by the firm's written operating procedures. Specifically, the firm's CAPA extension request EXT-00131 for CAPA-0004 was submitted two days after the CAPA due date.

Demonstrating our level of commitment to cGMP compliance, QuVa Temple has initiated and approved CR-3713, "DCR-TEM-SOP-QS-0004 CAPA Management". This document has been updated to provide clarity of the timely extension request submittals and processing and will be effective February 25, 2019.

If any clarification is required on the information presented in this letter and/or the attached follow-ups, please feel free to contact me as provided below.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Travis Leah".

Travis Leah, RPh
Vice President, Clinical Development
Travis.Leah@quvapharma.com
phone: (254) 933-4429

A handwritten signature in black ink, appearing to read "Michael Tuggle".

Michael Tuggle
Site Head of Quality
Michael.Tuggle@quvapharm.com
Phone: (603) 261-0672

State of Delaware
 Secretary of State
 Division of Corporations
 Delivered 05:35 PM 05/28/2015
 FILED 04:34 PM 05/28/2015
 SRV 150811868 - 5755668 FILE

CERTIFICATE OF INCORPORATION

OF

QUVA, INC.

The undersigned, in order to form a corporation under and pursuant to the provisions of the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the corporation is Quva, Inc. (the "Corporation").

SECOND: The address of the Corporation's registered office in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, New Castle County 19808. The name of its registered agent at such address is Corporation Service Company.

THIRD: The purposes for which the Corporation is formed are to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware (the "DGCL") and to possess and exercise all of the powers and privileges granted by such law and any other law of Delaware.

FOURTH: The total number of shares of stock which the Corporation shall have authority to issue is One Thousand (1,000) shares of Common Stock each without par value.

FIFTH: The name and mailing address of the Incorporator are as follows:

<u>Name</u>	<u>Address</u>
Peter Jenkins	135 Central Park West New York, NY 10023

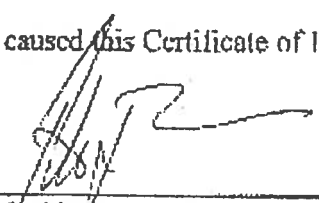
SIXTH: In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized and empowered to make, alter or repeal the bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any bylaw made by the board of directors.

SEVENTH: The Corporation reserves the right at any time and from time to time to amend, alter, change or repeal any provisions contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article.

EIGHTH: The election of directors need not be by written ballot, unless the bylaws of the Corporation shall so provide.

NINTH: To the fullest extent permitted by the DGCL as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that this Article shall not eliminate or limit the liability of a director for (i) any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Incorporation to be executed this 28th day of May, 2015.



Peter Jenkins, Incorporator

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:05 PM 07/13/2015
FILED 05:06 PM 07/13/2015
SRV 151042713 - 5755668 FILE

CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
QUVA, INC.

It is hereby certified that:

1. The name of the corporation (hereinafter called the "Corporation") is QuVa, Inc.
2. The Certificate of Incorporation of the Corporation is hereby amended by striking out Article FIRST thereof and by substituting in lieu of said Article FIRST the following new Article FIRST:

"FIRST: The name of the corporation is QuVa Pharma, Inc. (the "Corporation").

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to the Certificate of Incorporation of QuVa, Inc. to be executed as of this 10th day of July, 2015.

QUVA, INC.

By: 

Name: Peter Jenkins

Title: Chief Development Officer, Treasurer and
Secretary

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "QUVA PHARMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF APRIL, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "QUVA PHARMA, INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF MAY, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.



5755668 8300

SR# 20202775186

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature of Jeffrey W. Bullock in black ink, written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 202759509

Date: 04-13-20

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

4040 N. Central Expressway, #300
Dallas, TX 75204
214-253-5200

DATE(S) OF INSPECTION

02/26-28/19, 03/01, 4-8, & 14/19

FEI NUMBER

3002468086

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Alicia L. Ashford, Director of Manufacturing Operations*

FIRM NAME

QuVa Pharma, Inc.

STREET ADDRESS

5920 S. General Bruce Drive

CITY, STATE AND ZIP CODE

Temple, TX 76502

TYPE OF ESTABLISHMENT INSPECTED

Outsourcing Facility

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Written procedures are lacking which describe in sufficient detail the receipt, identification, approval, and rejection of components.

Specifically, your firm is using non-pharmaceutical grade components in the formulation of sterile drug products. For example,

- a) Your firm uses Sodium Hydroxide 10% (w/v) for adjusting the pH of sterile drug products. The Sodium Hydroxide is labeled "NOT FOR DRUG, FOOD, OR HOUSEHOLD USE".
- b) Your firm uses Hydrochloric Acid ACS – Reagent Grade for adjusting the pH of sterile drug products.

OBSERVATION 2

There are no established written methods of cleaning or methods of processing to remove pyrogenic properties.

Specifically, your firm has not validated the depyrogenation process for the glass vessels/carboys used in compounding sterile drug products. Your firm has not demonstrated that the washing process you have implemented is adequate for endotoxin removal.

Add Continuation Page

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Margaret M. Annes
[Signature]

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Margaret M. Annes, CSO
Aqualia L. Nelson, CSO

DATE ISSUED

3/14/19

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

4040 N. Central Expressway, #300
Dallas, TX 75204
214-253-5200

DATE(S) OF INSPECTION

02/26-28/19, 03/01, 4-8, & 14/19

FEI NUMBER

3002468086

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Alicia L. Ashford, Director of Manufacturing Operations*

FIRM NAME

QuVa Pharma, Inc.

STREET ADDRESS

5920 S. General Bruce Drive

CITY, STATE AND ZIP CODE

Temple, TX 76502

TYPE OF ESTABLISHMENT INSPECTED

Outsourcing Facility

Your firm had a confirmed endotoxin failure in January 2019 (Finished product lot #10019623 of Heparin PF 0.25 U/mL 48 mL 0.5 NS – Bulk lot # TTX000000003663).

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) In January 2019, your firm removed the pass thrus in all three (3) ISO 7 Cleanrooms that were between the unclassified hallway and the ISO 7 Cleanroom. As part of the change control, your firm did not perform an assessment to justify how you are bringing the materials into the cleanroom or if any changes were needed to the environmental monitoring program as a result of the change.

b) Your firm is not sampling sites that are frequently touched during production such as the surface of the Baxter Repeater Pump and the door handle from the ISO 7 Cleanroom into the ISO 8 Gowning/Ante Room.

OBSERVATION 4


The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, rust and residue could be seen on the metal hinges of the totes used to hold and bring items into and out of the ISO 7 Cleanrooms and/or the ISO 8 Gowning/Ante Rooms, including empty sterile bags used for filling the sterilized product into; packages containing sterile tubing, filters, and environmental monitoring plates; and bags with the unfiltered and filtered drug product. Rust was also noted on the wheels of the trash cart in the ISO 7 Cleanroom 3 and the inside of the lid on the trash can in the ISO 8 Gowning/Ante Room for Cleanroom 3.

Add Continuation Page

SEE
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PAGE

EMPLOYEE(S) SIGNATURE

Margaret M. Annes


EMPLOYEE(S) NAME AND TITLE (Print or Type)

Margaret M. Annes, CSO
Aqualia L. Nelson, CSO

DATE ISSUED

3/14/19

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

4040 N. Central Expressway, #300
Dallas, TX 75204
214-253-5200

DATE(S) OF INSPECTION

02/26-28/19, 03/01, 4-8, & 14/19

FEI NUMBER

3002468086

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Alicia L. Ashford, Director of Manufacturing Operations*

FIRM NAME

QuVa Pharma, Inc.

STREET ADDRESS

5920 S. General Bruce Drive

CITY, STATE AND ZIP CODE

Temple, TX 76502

TYPE OF ESTABLISHMENT INSPECTED

Outsourcing Facility

OBSERVATION 5

Production personnel were not practicing good sanitation and health habits.

Specifically, your firm does not have handwashing facilities near the gowning areas for entry into compounding areas, including entry into ISO 7 Cleanrooms/ISO 5 Glove Box. In addition, your written procedures regarding gowning do not require hand washing.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not validated the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates. Your firm is incubating the plates at 20-25 degrees C first and then 30-35 degrees C.


OBSERVATION 7

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Add Continuation Page

SEE
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OF THIS
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EMPLOYEE(S) SIGNATURE

Margaret M. Annes


EMPLOYEE(S) NAME AND TITLE (Print or Type)

Margaret M. Annes, CSO
Aqualia L. Nelson, CSO

DATE ISSUED

3/14/19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

4040 N. Central Expressway, #300
Dallas, TX 75204
214-253-5200

DATE(S) OF INSPECTION

02/26-28/19, 03/01, 4-8, & 14/19

FEI NUMBER

3002468086

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Alicia L. Ashford, Director of Manufacturing Operations*

FIRM NAME

QuVa Pharma, Inc.

STREET ADDRESS

5920 S. General Bruce Drive

CITY, STATE AND ZIP CODE

Temple, TX 76502

TYPE OF ESTABLISHMENT INSPECTED

Outsourcing Facility

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- Neostigmine methylsulfate 1mg/1ml
- Glycopyrrolate 0.2mg/ml
- Midazolam PF 1mg/ml

OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10) (A). Specifically, the following information is not found on your drug product labels:

- The statement "This is a compounded drug";
- ~~The name, address, and phone number of the outsourcing facility;~~ *mMA 3/14/19*
- ~~The dosage form and strength;~~ *mMA 3/14/19*
- ~~The quantity or volume;~~ *mMA 3/14/19*
- The National Drug Code number, if available;
- The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only";
- ~~A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.~~ *mMA 3/14/19*

Add Continuation Page

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OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Margaret M. Annes
[Signature]

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Margaret M. Annes, CSO
Aqualia L. Nelson, CSO

DATE ISSUED

3/14/19

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

4040 N. Central Expressway, #300
Dallas, TX 75204
214-253-5200

DATE(S) OF INSPECTION

02/26-28/19, 03/01, 4-8, & 14/19

FEI NUMBER

3002468086

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Alicia L. Ashford, Director of Manufacturing Operations*

FIRM NAME

QuVa Pharma, Inc.

STREET ADDRESS

5920 S. General Bruce Drive

CITY, STATE AND ZIP CODE

Temple, TX 76502

TYPE OF ESTABLISHMENT INSPECTED

Outsourcing Facility

Examples of your drug product labels that do not contain this information include:

- Fentanyl 10mcg/mL Preservative Free (PF) 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

OBSERVATION 9

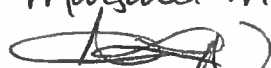
The containers of your outsourcing facility's drug products does not include information required by section 503B (a)(10)(B). Specifically, your containers do not include the following information:

- a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088;

Examples of your container labels that do not contain this information include:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	<i>Margaret M. Annes</i> 	Margaret M. Annes, CSO Aqualia L. Nelson, CSO	3/14/19

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: *Alicia L. Ashford, Director of Manufacturing Operations*

FIRM NAME

QuVa Pharma, Inc.

STREET ADDRESS

5920 S. General Bruce Drive

CITY, STATE AND ZIP CODE

Temple, TX 76502

TYPE OF ESTABLISHMENT INSPECTED

Outsourcing Facility

b) Route of administration.

Examples of drug product containers that do not contain this information:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

(Three large, empty, curved lines for additional examples)

Add Continuation Page

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Margaret M. Annes
(Signature)

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Margaret M. Annes, CSO
Aqualia L. Nelson, CSO

DATE ISSUED

3/14/19

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."



April 5, 2019

Monica Maxwell
U.S. Food and Drug Administration
4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214) 253-5200

April 5, 2019

Subject: Response to the Department of Health and Human Services Food and Drug Administration (FDA) Inspection Report (FEI 3002468086) issued March 14, 2019

Dear Ms. Monica Maxwell,

Attached please find the QuVa Pharma, Inc. response to the FDA 483 Inspection Observations Report Issued on March 14, 2019 by Investigators Margaret M. Annes and Aqualia L. Nelson at the completion of their inspection of the manufacturing facility located in Temple, Texas. The FDA inspection took place on February 26th, 27th, 28th, March 1st, 4th, 5th, 6th, 7th, and 8th. QuVa Pharma is registered as a 503B outsourcing facility manufacturing Compounded Sterile Products.

We would like to acknowledge and thank the FDA investigators who performed the inspection for their professionalism and thoroughness. Please be assured that the entire management team at QuVa Pharma, Inc. is fully committed to ensuring that enhancements are appropriately made and implemented to further strengthen the Integrated Pharmaceutical Management System at the Temple, Texas site.

Details regarding the specific actions taken are included within our response to the FDA 483 Inspectional Observations Report. Timelines for the completion of remaining actions are included accordingly, and these commitments have been integrated into our site Quality Management System for continued tracking at the site.

QuVa Pharma remains committed in continuing to work with the Agency in a cooperative and responsible manner to ensure that effective system enhancements are accomplished to support sustainable cGMP compliance at the Temple facility.

A handwritten signature in blue ink, appearing to read "Darren Hassey", with a horizontal line underneath.

Darren Hassey
Senior Director, Quality
darren.hassey@quvapharma.com
phone: (281) 644-9655

A handwritten signature in blue ink, appearing to read "Alicia Ashford", with a horizontal line underneath.

Alicia Ashford
Director, Manufacturing Operations
alicia.ashford@quvapharma.com
phone: (248) 882-0335



April 5, 2019

OBSERVATION 2

There are no established written methods of cleaning or methods of processing to remove pyrogenic properties.

Specifically, your firm has not validated the depyrogenation process for the glass vessels/carboys used in compounding sterile drug products. Your firm has not demonstrated that the washing process you have implemented is adequate for endotoxin removal. Your firm had a confirmed endotoxin failure in January 2019 (Finished product lot #10019623 of Heparin PF 0.25 U/mL 48 mL 0.5 NS - Bulk lot# TTX000000003663).

RESPONSE 2

QuVa Pharma understands that Observation 2 is related to the lack of specific Log reduction validation for the carboy rinsing process' capability of removing endotoxin load. Post the inspection QuVa Pharma has collaborated with external industry subject matter experts, Charles River Laboratories, in designing a study protocol to best supplement the existing validation in a single discreet protocol. This protocol will be executed by 30 June 2019.

During the Inspection, QuVa Pharma presented the Investigator Engineering study, FR-ENG-2017-048, from 2017 which was performed to evaluate the DI water system and glassware cleaning process utilized by the QuVa Pharma Temple, TX Facility.

Additionally, QuVa Pharma performed a retrospective review of Historical data to determine the occurrence of the confirmed Heparin Endotoxin OOS result. Based upon the information reviewed from the manufacturing process, DI water rinse process evaluation, routine DI water sampling program, and historical endotoxin data for products with a similar specification to that of Heparin there was no indication of a systematic trend related to endotoxin bioburden levels exceeding product specifications at the QuVa Pharma Temple Facility. This data confirms the current processes for Endotoxin control is sufficient and that there is no risk to our products. See attachment 2A.



April 5, 2019

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- a) In January 2019, your firm removed the pass thrus in all three (3) ISO 7 Cleanrooms that were between the unclassified hallway and the ISO 7 Cleanroom. As part of the change control, your firm did not perform an assessment to justify how you are bringing the materials into the cleanroom or if any changes were needed to the environmental monitoring program as a result of the change.*
- b) Your firm is not sampling sites that are frequently touched during production such as the surface of the Baxter Repeater Pump and the door handle from the ISO 7 Cleanroom into the ISO 8 Gowning/ Ante Room.*

RESPONSE 3

3A

Though QuVa Pharma completed an extensive Change Control and Training for the pass thru decommissioning and removal, it is acknowledged that the specific assessment mentioned in the observation did not occur. This assessment was completed during the audit, to confirm suitability of the current plan, see attachment 3A, and was verbally acknowledged as acceptable by the Investigator.

3B

QuVa Pharma acknowledges that not every site that are frequently touched are sampled. QuVa Pharma has performed an additional risk assessment for each of the ISO 8 Gowning rooms and ISO 7 cleanrooms to identify additional sites that are frequently touched and a report of such has been generated, TEM-RA-R-00003, see attachment 3B. Further to this, the sampling sites identified in the observation, plus two others (airlock handles and airlock purge buttons) will be incorporated into the environmental sampling program via Change Control CR-0437. The additional sites will be incorporated by 3 May 2019.

QuVa Pharma has a series of contamination controls designed to minimize risk of microbial contamination ingress into the aseptic manufacturing environment, (Contained ISO 5). The aseptic manufacturing process itself is contained within an ISO 5 Compounding Isolator found within the ISO 7 Clean Room. All



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materials are processed into each isolator using attached pass thru boxes that use a purge mechanism to clear the internal air prior to introducing into the interior area of the Isolator.

The ISO 7 cleanrooms (CR2, 3, and CSCR) are used as buffer areas that support aseptic manufacturing with an enclosed compounding isolator unit, which is used to establish the ISO 5 environment.

A review of the environmental monitoring data was performed and documented as "Risk Assessment of Current Environmental Monitoring sites for Classified Areas" during the Inspection, please refer attachment 3A. The review covered historical viable and non-viable environmental data for ISO 5 (Isolator), ISO 7 (Clean rooms), and ISO 8 (ante room) areas from 2017, 2018, and Q1 of 2019 and demonstrated that the current sampling plan provides suitable and robust data produced from monitoring the conditions of the ISO 7 cleanrooms and associated ISO 8 anterooms.

The design of the ISO 8 Gowning rooms, ISO 7 cleanrooms, and ISO 5 Isolators along with the robust aseptic gowning program QuVa Pharma has put into place provides the required environmental controls to prevent environmental contamination from aseptic manufacturing. The environmental program currently in place demonstrates that the environment is in control to produce sterile bulk product.



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OBSERVATION 4

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, rust and residue could be seen on the metal hinges of the totes used to hold and bring items into and out of the ISO 7 Cleanrooms and/or the ISO 8 Gowning/Ante Rooms, including empty sterile bags used for filling and sterilized product into; packages containing sterile tubing, filters, and environmental monitoring plates; and bags with the unfiltered and filtered drug product. Rust was also noted on the wheels of the trash cart in the ISO 7 Cleanroom 3 and the inside of the lid on the trash can in the ISO 8 Gowning /Ante Room for Cleanroom 3.

RESPONSE 4

QuVa Pharma understands Observation 4, that rust and residue was observed on the metal hinges of the totes used to transfer disinfected materials into the ISO 8 and ISO 7 cleanroom areas as well as waste receptacles in the ISO 8 and ISO 7 cleanroom areas.

During the inspection, immediate actions were taken to ensure full compliance:

- Work order FM000702 was generated on 1 March 2019 during the inspection to address the stainless-steel trash cart in the Ante Room and the stainless-steel trash cart in the cleanroom.
- The trash carts in the Ante Room were replaced on the day of observation, and the Cleanroom trash carts were evaluated on 4 March 2019, with removal of the wheel canisters from the trash carts completed on that same day.

The work order is provided, see attachment 4A. To further remediate the use of materials, with metal parts (affected by cleaning agents), QuVa has sourced plastic totes without metal hinges, and all prior totes have been removed. The totes selected, align with disinfectant efficacy study completed in March 2017, see attachment 4B.

To prevent reoccurrence, the work instructions governing the disinfection and preparation of materials for introduction into the cleanroom have been revised. TEM-WI-SA-0002, Preparation of Compounding and Cleanroom Supplies, has been revised to include the use of the newly selected totes for cleanroom processing. Also, TEM-WI-SA-0003 Cleanroom Cleaning and TEM-FM-SA-0001, Cleanroom Cleaning/Prep Chart, has been revised to include requirement to inspect equipment for damage, degradation; and cleaning residue; removal; replacement and repair. The form, TEM-FM-SA-0001, is completed in the



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cleanroom, prior to all compounding activities. This form enhancement allows operators to evaluate, report and escalate any equipment or material concerns. See attachments 4C, 4D and 4E.

As a continuous improvement opportunity, QuVa Pharma had an outside resource, and Industry Subject Matter Experts, Contec, Inc., to evaluate any opportunities for improvement of the current cleaning processes. On 25 March 2019, the technical representative from Contec, Inc. demonstrated proper cleaning techniques with our on-site trainers, Andrew Posey and Amanda Jarrett. Those techniques have been shared with the Temple site employees as an awareness training for proper cleaning techniques for disinfection and completeness of removal of disinfectants from equipment in the cleanroom. For evidence of training see attachment 4F and 4G.



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OBSERVATION 5

Production personnel were not practicing good sanitation and health habits.

Specifically, your firm does not have handwashing facilities near the gowning areas for entry into compounding areas, including entry into ISO 7 Cleanrooms/ISO 5 Glove Box. In addition, your written procedures regarding gowning do not require hand washing.

RESPONSE 5

To further enhance sanitization practices, QuVa Pharma will implement a specific hand wash area. As such CR-0443 has been initiated for this change. See attachment 5A for evidence of engagement in work. This is a significant Engineering project to plan and complete properly without impact to our current excellent state of control. We anticipate this will complete by 30 September 2019.

QuVa Pharma complies with CFR211.52 with regard to providing adequate sanitation and handwashing facilities within the site. QuVa Pharma has long believed that the provision of city water close to controlled manufacturing environments may in fact present an increased Microbiological risk. To these ends, QuVa Pharma implemented the use of hand sanitant, gloving, and qualified sterile gowning procedures to assure cleanliness of operator's hands and to ensure high levels of general sanitization. During the inspection, the hand sanitant qualification technical qualification documentation detailing a 3 Log reduction in microbial load following use was presented.



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OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not validated the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates. Your firm is incubating the plates at 20-25 degrees C first and then 30-35 degrees C.

RESPONSE 6

To ensure full validation of the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates, a new study, (COR-ENG-P-00002) has been initiated to perform a specific validation of QuVa Pharma's current incubation strategy. See attachment 6A for the protocol. This protocol will be complete by 3 May 2019.

Based upon the below information QuVa Pharma's current dual incubation strategy is proven effective. See Attachment 6B.

- QuVa Pharma Temple Feasibility Study (TEM-RPT-QC-0005), was provided and discussed during the audit, based upon the outcome of the study it was determined that both, the TSA media and the dual incubation strategy were satisfactory in supporting enumeration of bacterial organisms and met growth acceptance criteria.
- A review of the growth promotion testing requirements currently established for Environmental (EM) and Personnel Monitoring (PM) media was performed, which demonstrated 100% effectiveness.



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OBSERVATION 7

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- Neostigmine Methylsulfate 1mg/1ml
- Glycopyrrolate 0.2mg/ml
- Midazolam PF 1 mg/ml

RESPONSE 7

QuVa understands the FDA has concerns that finish product is not in compliance with the FDA 503B Guidance document for Essential Copies (*Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, January 2018).

QuVa's Pharmacy Services team and the hospital's DOP collaborated in evaluating the Neostigmine Methylsulfate 1mg/1ml, Glycopyrrolate 0.2mg/ml, and Midazolam PF 1mg/ml with respect to Essential Copy following the 503B guidance document. Following this collaborative discussion, QuVa Pharma has initiated a change control, (CR-0449) to convert those CSPs made by QuVa Pharma from the Glycopyrrolate bulk drug substance source to only be made from bulk drug substance if the commercially available drug product is on the FDA Drug Shortage list. This CR will be completed by 3 May 2019.

The CSP needed by the practitioner for Neostigmine Methylsulfate 1mg/ml and Midazolam PF 1mg/mL must be compounded by drug substance because of the difference in formulation with the commercially available drug product. Please see the attached, (attachment 7A and 7B) hospital's clinical need justification for Neostigmine Methylsulfate 1mg/ml and Midazolam PF 1mg/mL.



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The Glycopyrrolate 0.2mg/ml CSPs would be considered an Essential Copy if compounded from drug substance because there is not a difference in formulation that is needed by the practitioner. The practitioner does have a clinical need for the product to be in a syringe rather than the commercially available vial. Please see the attached (attachment 7C) clinical need justification for Glycopyrrolate 0.2mg/ml.



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OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10) (A). Specifically, the following information is not found on your drug product labels:

- a) The statement "This is a compounded drug";*
- ~~b) The name, address, and phone number of the outsourcing facility;~~*
- c) The dosage form and strength;*
- ~~d) The quantity of volume~~*
- e) The National Drug Code number, if available;*
- f) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only";*
- ~~g) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient~~*

**line out denotes items removed by investigator during close out meeting*

RESPONSE 8

For clarification, these items are an Intermediate Bulk solution that are not for commercial sale but are further processed into compounded sterile preparations (CSP) such as syringes, cassettes, or IV bags. QuVa Pharma transports the Bulk Intermediate from the Temple, TX facility to one of two QuVa Pharma 503B Outsourcing facilities for further processing into the finish CSP. QuVa Pharma understands the DQSA labeling requirements for a product leaving a 503B facility to include the additional detail in the above observation.

QuVa Pharma will make the following changes to our existing bulk intermediate label information:

1. Change "In-Process Bulk Bag" to "Intermediate In-Process Bulk Bag"
2. Add the statement "This is a compounded drug"
3. The dosage form will be added as "injection." We will add this statement; "Injection Solution-Not for Resale-Office Use Only"



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QuVa Pharma does not have bulk bags listed NDC numbers with the FDA. We use an 11-digit item code for internal tracking. As a result, we do not name the 11-digit item code as an NDC number on the label.

All bulk labels will be updated. This process has been initiated under CR-0446 and will complete by 30 June 2019.



April 5, 2019

OBSERVATION 9

The containers of your outsourcing facility's drug products does not include information required by section 503B (a)(IO)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088; Examples of your container labels that do not contain this information include:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

b) Route of administration.

Examples of drug product containers that do not contain this information:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

RESPONSE 9

9A

QuVa would like to clarify that the labels referenced in this observation are for intermediate bulk batches that are not for sale and will be further compounded into a CSP at a QuVa 503B outsourcing facility. To meet the DQSA labeling requirements, QuVa will add to our intermediate bulk bag labels the adverse event reporting statement: *To Report Suspected adverse reactions, contact QuVa Pharma at 877-296-0190 or FDA at www.fda.gov/medwatch and 1-800-FDA-1088.*



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9B

QuVa Pharma understands the DQSA labeling requirements for a product leaving a 503B facility to include the route of administration on the label. In the clinical setting, route of administration is used on a finished compounded sterile preparation (CSP) to instruct the practitioner on administration. The QuVa labels referenced in this observation are for intermediate bulk bags that are not for sale but will be further processed to a CSP at a QuVa 503B outsourcing facility. QuVa may use the same intermediate bulk batch to compound different CSPs. For example, one intermediate bulk batch may be used to compound one CSP for a local nerve block and another CSP for epidural use. To comply with the DQSA labeling requirements, we will add the potential CSP routes of administration on the intermediate bulk bag label, one example is shown below.

Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag "Not for direct Infusion, further processing required for epidural use"

All bulk labels will be updated. This process has been initiated under CR-0446 and will complete by 30 June 2019

15H

NEVADA STATE BOARD OF PHARMACY
 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Outsourcing Facility

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Publicly Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☐ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Sincerus Florida, LLC

Physical Address: 3265 W McNab Road

City: Pompano Beach State: FL Zip Code: 33069

Telephone: 954-228-6632 Fax: 954-256-5043

Toll Free Number: 800-604-5032 (Required per NAC 639.708)

E-mail: elicense@sincerususa.com Website: www.sincerususa.com

Supervising Pharmacist: Jenny Liu Nevada License #: Pending 20340 exp 10/31/21

SERVICES PROVIDED

Yes/No

☒ ☐ Parenteral

☒ ☐ Sterile Compounding

☒ ☐ Non Sterile Compounding

☒ ☐ Mail Service Sterile Compounding

☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

Page 2

FEI Number (From FDA application): 3012384835

Please provide the name of the facility as registered with the FDA and the registration number:
3012384835 - Sincerus Florida, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
 Name: Jenny Liu Nevada License Number: 20340

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Jonathan Fenster

Print Name of Authorized Person

May 5, 2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY**Page 5****OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**State of Incorporation: DelawareParent Company if any: Sincerus, LLCAddress: 3265 W McNab RoadCity: Pompano Beach State: FL Zip: 33069Telephone: 561-404-8885 Fax: 561-503-4131Contact Person: Maria Yeager

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Sincerus, LLC 3265 W. McNab Road, Pompano Beach, FL 33069

Name

Address

b)

Name

Address

c)

Name

Address

d)

Name

Address

2) Provide the number of shares issued by the corporation. 100 Membership Units3) What was the price paid per share? N/A4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Arizona Board of Pharmacy
Complaint No: 180170

Sincerus Florida, LLC (Sincerus) received a request for records from the Arizona Board of Pharmacy in connection with a consumer complaint. The complaint was the result of miscommunication between the consumer and the prescriber, the consumer's inaccurate research, and the prescriber's failure to properly label the dispensed medication. The complaint alleged that the practitioner's office orders ingredients from Sincerus to later compound in-office. This explanation was incorrect. Sincerus ships all compounded medications as final products and not as individual ingredients. The consumer also found a wholesaler license for Sincerus and assumed that Sincerus was shipping product into Arizona under that license. Sincerus is an FDA registered 503B Outsourcing Facility. The facility is licensed in Arizona as a Non-resident Manufacturer, as is required for any out-of-state 503B Outsourcing Facility doing business in Arizona. No further permits/licenses are required under Arizona law.

Please see the enclosed copy of the complaint and the response submitted on July 16, 2018, the matter was heard before the Arizona Board of Pharmacy on July 31, 2019 . Vice-President Snair moved for dismissal.

Nevada Board of Pharmacy
Case 17-011

Sincerus Florida, LLC (Sincerus) received an investigative Letter from the Nevada Board of Pharmacy based on misinformation received by the Board. Specifically, the Letter states that Sincerus "sells bulk and compounded products in conjunction with Prescriber's Choice (PC Operations, LLC) to physician groups in Nevada [that] are then re-compounded and/or repackaged for final sale to patients by the practitioner". As Sincerus response indicates, this is an inaccurate description of Sincerus' business. Sincerus submitted its response on June 2019, and an updated response on February 2020; the matter is pending.



Jonathan Feaster - COO

5-5-20

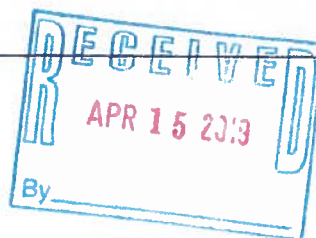
**Arizona State Board of Pharmacy**

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007

Mailing Address: P.O. Box 18520, Phoenix, AZ 85005

p) 602-771-2727 f) 602-771-2749

www.azpharmacy.gov



April 5, 2019

Sincerus Florida, LLC
3265 W. McNab Road
Pompano Beach, FL 33069

RE: Arizona Board of Pharmacy Complaint Number 18-0170

Dear Sir or Madam,

On April 4, 2019, the Board office sent a notice regarding the conference scheduled for Board Case No. 18-0170, which was set for May 9, 2019. That conference has been rescheduled. It is now scheduled for:

July 31, 2019**1:00 – 5:00 P.M.****Arizona State Board of Pharmacy Meeting****Arizona State Board of Pharmacy Office****1616 W. Adams, Suite #120 – Board Room****Phoenix, AZ 85007**

Please review the circumstances surrounding this complaint and come prepared to discuss the pertinent facts and answer questions from Board members.

Please be present by 1:00 P.M. Please remain in the audience until your name is called by the President to come forth to speak with the Board Members. Your case will be heard between 1:00-5:00 P.M.

Pursuant to A.R.S. § 32-1927.02(K) there are a number of options available to the Board after a conference, including but not limited to dismissing the matter, filing an advisory letter, mandating continuing education, or entering into a consent agreement that could include a letter of reprimand, a decree of censure, practice restrictions or referring the matter to a formal hearing for the revocation or suspension of the license.

If you have any questions regarding this matter, please contact this office.

Sincerely,

A handwritten signature in cursive script that appears to read "Elizabeth Dodge".

Elizabeth Dodge, PharmD

Deputy Director

edodge@AZPharmacy.gov

ED/jcm

C: Roger Morris, Esq.



Sandy Sutcliffe, RPh, JD
 Arizona Board of Pharmacy
 Compliance Officer
 1616 West Adams Street
 Suite 120
 Phoenix, Arizona 85007
ssutcliffe@azpharmacy.gov

RE: Complaint 180170


Dear Ms. Sutcliffe:

We are in receipt of the above-referenced complaint ("Complaint") and provide the attached documents in response. Sincerus Florida, LLC ("Outsourcing Facility") denies the allegations in the Complaint and offers the below as rebuttal.

- Outsourcing Facility is a Delaware limited liability company registered with the U.S. Food and Drug Administration ("FDA") as an "outsourcing facility" pursuant to Section 503B of the Food, Drug & Cosmetic Act. Outsourcing Facility is not registered, nor is required to be registered, with FDA as a repackager.
- As noted in your letter dated June 29, 2018, Outsourcing Facility currently holds in Arizona a non-resident manufacturer permit (#M0008206) based on its federal registration. Outsourcing Facility also holds in Arizona a non-resident, full-service wholesaler permit (#W002841). We were initially instructed by the AZ BOP that we required both licenses, but on review, it appears that our operations do not require a wholesaler permit. Unless we hear otherwise from you, we will prepare to relinquish it and maintain only the non-resident manufacturer permit in connection with our federal 503B registration.
- Outsourcing Facility compounds and ships medications ordered by physicians. All compounded medications are shipped as the final product and not as individual ingredients. The compounded medication that Outsourcing Facility ships are labeled properly in accordance with Federal law. We have attached a sample label for your convenience. Included on the label is the Beyond Use Date (BUD) appropriate for the product. For the product mentioned in the complaint, the appropriate BUD is 6-months. Physicians are expected to apply a state-specific label prior to dispensing.

Please let us know if you have any further questions.

Sincerely,


 Deirdre J. Boling-Lewis*
 General Counsel

Encl.

Sincerus Florida, LLC
 3265 W McNab Road, Pompano Beach FL 33069

* Licensed in CA, CT & DC
 Authorized Florida House Counsel – Not a Member of The Florida Bar



Sincerus

Sincerus Florida, LLC
3265 W McNab Road
Pompano Beach, FL 33069
(800)-604-5032

**081033 LIDOCAINE 2% /
MUPIROCIN 2% / TRANILAST 1%
OINTMENT**

QUANTITY: 400 ML

LOT:

MFG/CD:

BUD:

ACTIVE INGREDIENTS:

MUPIROCIN USP 2%

LIDOCAINE USP 2%

TRANILAST 1%

INACTIVE INGREDIENTS:

ALOE VERA 0.2%

PETROLATUM 94.8%

Directions for Use: As Directed by Physician

Route of Administration: Topical

Store at Controlled Room Temperature (20-25C)

This is a Compounded Drug

Office Use Only/Not for Resale

Wash Hands After Use

For External Use Only

RX Only

**To report suspected adverse reactions, contact
Sincerus Florida, LLC at 800-604-5032, or FDA at
www.FDA.gov/MedWatch or 1-800-FDA-1088.**

SAMPLE LABEL

MOTION PASSED.**25.e. 18-0170**

Compounded medication (503b) sold by a practitioner to a patient.

Compliance Officer Sutcliffe summarized for the Board that in May of 2018, the complainant's wife received a compounded medication from a dermatologist that did not contain a label with a beyond-use date. She presented photos of cartridges provided by Prescriber's Choice that are to be used in a device provided by Prescriber's Choice. She added that documentation was requested from the company including policies and procedures regarding removal of medication from the cartridge. Board staff discovered that the beyond-use date on the label did not match the log formula worksheet provided by the company, as the label indicated a beyond-use date of 60 days rather than the 30 days.

The CEO was present with Counsel, including Mr. Roger Morris. Mr. Morris explained that this is an outsourcing facility that is FDA approved and holds an Arizona manufacturing permit. He stated that the outsourced product that is sold to practices is then dispensed to patients pursuant to the law. The CEO explained that the cartridges displayed in the photos that were submitted within the complaint never made it production as the physicians lacked the technical knowledge from a pharmaceutical perspective to modify the medication in the office as originally planned. He stated that the device referenced in the complaint is a historical relic that is no longer used as the current process involves shipment to physicians in a final container without the need for compounding in the office.

Mr. Morris stated that the company used USP guidelines for the beyond-use dates that were clearly listed on the label. He stated that it was not the outsourcing facility's fault that the medication was dispensed after the beyond-use date expired as it was properly labeled, and that the physician should not have dispensed the medication. Ms. Walmsley noted that the Florida license is in good standing and has not had any compliance issues with respect to inspections, and that there have been no other formal investigations or discipline in any other state.

After hearing the process from start to finish from the company's CEO, the Board questioned Board staff as to the obligations of a prescriber to dispense the medication under Arizona law. Mr. Morris clarified that there was no compounding being performed by the physicians in the office as they were receiving a finished mixed product that they had the ability to portion out into a different container. Ms. Walmsley spoke in favor of dismissing the case and referring the matter to the Arizona Medical Board for review as physician prescribing practices are not under the jurisdiction of the Pharmacy Board.

Mr. Blaire stated that since the passage of DQSA, the Board has seen an enormous movement of compounding from pharmacies into physicians' offices. He stated that while compounding continues to evolve, the laws that regulate compounding were developed when there were very few people engaging in such practice. Mr. Blaire stated that the Board at some point will need to address or revisit their general opinion on the practice of compounding. He added that he was impressed with the model presented for the Board's review in this matter, and that while it may conform to the letter of the law, he was not sure that it was the spirit of the law. He stated that the Board needs to bring the regulation of compounding into the current time. President Leyba stated that the interpretation of the law could be clarified by the FDA.

MOTION: Vice-President Snair moved for dismissal and for the matter to be referred to the Arizona Medical Board.

SECOND: Mr. Blaire



3265 W McNab Road
Pompano Beach, FL 33069
Phone: (561) 404-8885
Fax: (561) 503-4131

March 19, 2019

Monica R. Maxwell
Acting Program Division Director
U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations (OPQO), Division II
4040 N. Central Expressway, Suite 900
Dallas, TX 75204

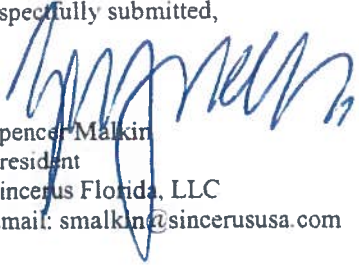
RE: Update to Sincerus Florida, LLC (Sincerus) Response to FDA Form 483 issued September 17, 2018

Dear Director Maxwell:

This letter is being sent to update you on the progress that Sincerus Florida has made since our response to the FDA form 483 observations made during the last FDA inspection of our facility at 3265 McNab Road, Pompano Beach, FL 33069. The inspection was conducted on August 30, 2018, August 31, 2018, and September 17, 2018. Our last response to your observations during that inspection was sent to you on October 9, 2018.

Sincerus Florida takes cGMP concerns very seriously and continues to make great strides in taking the necessary steps to comply with those regulations as well as the new 503B draft guidelines (Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Draft Guidance for Industry December 2018) to the best of our ability. We are also planning to modify our facility in 2019 to comply with the new USP <800> and USP <795> regulations. And while we are currently developing potency methods, due to the number of APIs at multiple strengths in our compounded drug formulations, we have additional work that must be completed. Our efforts to address all of these concerns are described in this update. Lastly, Sincerus Florida has recently decided that as soon as practical in 2019, our packaging will change from cartridges to final containers (i.e., airless pumps). This will help to maintain product stability and allow us to extend our compounds' BUDs. These changes have caused delays in our progress as we work through the processes needed to implement these beneficial changes. However, we truly believe that all these improvements are necessary to provide our customers with the best compounded products available. Our plan is to send you routine updates on our progress towards satisfying all of the observations noted during the inspection.

Respectfully submitted,


Spencer Malkin
President
Sincerus Florida, LLC
Email: smalkin@sincerususa.com


Joanne Hoefling
Director of Regulatory Compliance and Quality
Sincerus Florida, LLC
Email: jhoefling@sincerususa.com

Company Confidential

OBSERVATION 1

Each lot of components is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Your firm uses Distilled Water or Preserved Water (Parabens) Solution in the formulation of your nonsterile drug products. However, your firm did not provide any documentation supporting this component, which is not USP grade. Your firm does not conduct any microbial testing on any drug products that use D1 water or Preserved Water (Parabens).

RESPONSE 1:

In response, CAPA18-25 was issued. Sincerus recognizes that prior to the execution of CAPA18-25, Sincerus utilized commercially available purified water in the compounding of 42 non-sterile formulations. Sincerus now uses only USP grade purified water in the compounding of its non-sterile products. Forty-two (42) master formulation records have been updated to include this change. See attachment 1 for the list of the 42 affected formulations, COA for the USP grade purified water and an example of the change in the master formulation records.

Please see Attachment 1, CAPA18-25 with attachments, which was closed on 10/09/2018.

2019-Q1 UPDATE: CAPA18-25 was closed on 10/09/2018 and copy of closed CAPA18-25 was attached to Sincerus' 10/09/2018 response. No further action planned at this time.

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm has failed to perform release testing for potency on each batch of drug product produced at your facility. Examples include, but are not limited to the following:

- Product 031041- Fluocinolone Acetonide 0.01% / Minoxidil 5% / Tretinoin 0.025%, Lot 031041AIBFCABI@14, BUD 09/14/18
- Product 031089- Fluocinolone Acetonide 0.01% / Minoxidil 7% / Progesterone 0.1% / Tretinoin 0.025%, Lot 031089AFDBCABI@5, BUD 06/30/18
- Product 031070- Tacrolimus 0.1%, Lot 031070AIDACABI@14, BUD 09/29/18
- Product 031101- Ketoconazole 2% / Minoxidil 7% / Tretinoin 0.05%, Lot 031101AHBGCABI@14, BUD 08/15/18
- Product 041013- Betamethasone Dipropionate 0.05% / Menthol 2% / Pramoxine HCL 1% / Tranilast 0.5%, Lot 041013AICJCABI@14, BUD 09/27/18
- Product 141030- Hydroquinone 8%, Lot 141030AJAFCABI@14, BUD 10/05/18
- Product 201017- Lidocaine 23% / Prilocaine 5% (Oleabase), Lot 201017AIBGCABI@1, BUD 02/12/19

RESPONSE 2:

In response, CAPA18-26 was issued. Sincerus recognizes that it is only using pharmacist discretion according to Board of Pharmacy standards to release non-sterile drug products. Sincerus has a Quality Control lab that includes 4-HPLCs and employs 2 full-time method development chemists. Method development for potency testing in order to establish final specifications for the release of our non-sterile drug products according to GMP regulations was in-process prior to inspection. In order to expedite this process, Sincerus will take a two-phase approach. Phase One will entail developing sound potency methods and utilizing accelerated stability results to first assess our non-sterile products and then establishing potency specifications. There is a target date of 4-months to complete Phase One. Phase Two will be a fully compliant stability assessment including real-time studies. It is expected that Phase Two will require an additional 5-months to complete.

Please see Attachment 2, CAPA18-26. There is a 9 month target date for the completion of this project.

2019-Q1 UPDATE: Due to the number of APIs at multiple strengths in our compounded medication formulations, we have additional work before we can finalize reliable, sound methods to extract the actives from our compounds. We must accurately measure their content in our products which contain from one to seven active ingredients. This abundance of caution in providing the best possible outcome has caused some delays in our aggressive plan to complete Phase One during the 4 months period previously targeted. We are moving the original 4 month target date to 9 months for Phase 1. To date we have developed potency methods covering 38 of our non-sterile formulations which are currently being validated.

OBSERVATION 3

The in-process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Specifically, your firm failed to validate your current formulary procedures are in accordance with your reference procedures to ensure homogeneity and blend uniformity are obtained.

RESPONSE 3:

In response, CAPA18-27 was issued. Sincerus recognizes the need to examine the adequacy of mixing to ensure uniformity and homogeneity. Sincerus has a Quality Control lab that includes 4-HPLCs and employs 2 full-time method development chemists. Method development for potency testing in order to establish final specifications for the release of our non-sterile drug products according to GMP regulations was in-process prior to inspection. Once method development is complete the adequacy of compounding mixing processes will be assessed ASAP after potency specifications are approved.

Please see Attachment 3, CAPA18-27. There is a 12-month target date to complete this project for our current 210 non-sterile formulations.

2019-Q1 UPDATE: Due to the aforementioned work described in Observation 2 – 2019 Q1 Update above that is needed prior to the actions required to resolve this observation, it is necessary to move the 12 month target out 3 months for CAPA18-27 which addresses the adequacy of mixing to ensure uniformity and homogeneity. In addition, Sincerus has been evaluating several commercially available options for automating our mixing process. We engaged engineers at Schold Manufacturing, Chicago, IL to design a specialized bowtie type blade for their LMX mixer. It is a custom fit for our batch containers to help ensure thorough, even mixing of our non-sterile compounded drug products. See attached product information, blade diagram and PO.

Please see 2019-Q1 Attachment 1, Schould Products LMX Mixer Information, Blade Diagram and PO

OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm has not performed stability testing on any drug product to ensure the shelf-life of the drug products. Examples include, but are not limited to:

- Product 501010- Magnesium sulfate in 5% Dextrose, Lot 501010SAGBDCABI@1, BUD 06/22/18
- Product 141030- Hydroquinone 8%, Lot 141030AJAFCABI@14, BUD 10/05/18

RESPONSE 4:

In response, CAPA18-28 was issued. Sincerus recognizes that currently, there are no stability studies performed on our non-sterile compounded products and USP standards are being utilized for the BUD (Beyond Use Dates) assigned to our non-sterile products. Sincerus has a Quality Control lab that includes four HPLCs and two stability chambers and employs 2 full-time method development chemists, a senior quality chemist, and a lab technician. Method development for potency testing in order to establish final specifications for the release of our non-sterile drug products according to GMP regulations was in-process prior to inspection. In order to expedite this process, Sincerus will take a two-phase approach. Phase One will entail developing sound potency methods and utilizing accelerated stability results to first assess our non-sterile products and then establishing potency specifications. There is a target date of 4 months to complete Phase One. Phase Two will be a fully compliant stability assessment including real-time studies. It is expected that Phase Two will require an additional 5 months to complete.

Sincerus did perform stability studies on our sterile product, 2G Magnesium Sulfate in 5% Dextrose 50 ML Bag Injection. While the protocol called for a 28-day study, Sincerus only sells this sterile product with a 9-day BUD. Sincerus was able to confirm 14-days. An Addendum Report to the Original Process Validation has been issued and is attached. (Attachment 5)

Please see Attachment 4, CAPA18-28.

Please see Attachment 5, Addendum to Process Validation Report for the Compounding of Medium Risk Sterile Preparations (14 Day Stability Results) 2 GM Magnesium Sulfate in 5% Dextrose 50 ML Bag Injection.

2019-Q1 UPDATE: A 14-day stability study report for our sterile product, 2G Magnesium Sulfate in 5% Dextrose 50 ML Bag Injection, was attached to Sincerus' 10/09/2018 response. No further action planned at this time.

Due to the aforementioned work described in Observation 2- 2019 Q1 Update for developing reliable, sound potency methods to determine the level of actives in Sincerus' non-sterile products, it is necessary to move the 4 month target date for Phase 1 to 9 months in CAPA18-28 which addresses non-sterile compounded drug product stability studies.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, multiple complaint investigations into adverse events lacked a thorough investigation into the root cause for the complaint. Examples include, but are not limited to:

- Complaint 18-52- Five patients experienced redness during use of Product 201019-Lidocaine 23% / Tetracaine 7%, Lot 201019ABAECABI@6, BUD 05/09/18. There was no root cause or potential root cause identified.
- Complaint 18-84- Four patients experienced a rash after use of Product 011009- Niacinamide 4% / Tretinoin 0.05%, Lot 011009BBCBCABH@8, BUD 12/21/17. There was no root cause or potential root cause identified.
- Complaint 18-138- Multiple patients experienced redness, hives, itching, or swelling within five (5) minutes of applying Product 201016- Lidocaine 7% / Tetracaine 7%, Lot 201016ADCJCABI@2, BUD 09/25/18. There was no root cause or potential root cause identified.

RESPONSE 5:

In response, CAPA18-29 was issued. Although Sincerus performs a thorough investigation of customer complaints including, but not limited to, batch record reviews, review of similar prior complaints and checking our retains, Sincerus recognizes that we did not always request the return of consumers' products that were subject to a quality complaint and/or adverse reaction. Sincerus did not have designated sections in our complaint investigation report for "root cause" or "evaluation notes for returned product." SOP QA-10 Management of Customer Complaints and/or Adverse/Adverse Events has been updated to address these concerns.

Sincerus recognizes that the potency testing of returned products would provide better insight to the root cause of a legitimate quality complaint, including those involving adverse events. For non-sterile products, potency testing of returned products with legitimate quality and/or adverse events will commence once potency specifications have been established. For sterile products, Sincerus has not received any complaints. Although not previously documented in our SOPs, Sincerus' plan has always been to test sterile products returned for legitimate quality complaints and/or adverse reactions. SOP QA-10 Management of Customer Complaints and/or Adverse/Adverse Events has been revised to address these issues.

Please see Attachment 5, CAPA18-29 and Attachment 6, SOP QA-10 Management of Customer Complaints and/or Adverse/Adverse Events

2019-Q1 UPDATE: CAPA18-29 was closed on 12/21/2018 and copy of closed CAPA18-29 is attached to this update. No further action planned at this time. See Attachment 2.

Please see 2019-Q1 Attachment 2, CAPA18-29. No further action planned at this time.

OBSERVATION 6

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, hazardous drugs, hormones, and antibiotics were produced in your firm's non-sterile suite area without providing adequate cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. However, your firm does not have a cleaning procedure for these drug products to ensure cross-contamination does not occur. In addition, your firm places dedicated utensils in the dishwasher with non-dedicated utensils used in production. On 08/30/2018, we observed hazardous/antibiotics being produced under the same hood as non-hazardous drugs. We also observed powdered residue on your firm's Exakt Rolling Mill used in the production of cream and emollient drug products. According to your firm's Pharmacist-In-Charge, this equipment's status was clean.

RESPONSE 6:

In response, CAPA18-30 was issued. Sincerus recognizes that utensils and labware marked for use with antibiotics or hormones were comingled with general labware during washing. SOP NC-04, Operation of the Hobart LXeR Dishwasher has been updated to use separate wash cycles for antibiotics, hormones, and general labware.

NOTES:

- Train all compounding personnel on preventing cross-contamination and improved cleaning procedures

Sincerus recognizes the fact that while hormone containing products were compounded in a dedicated hood, products containing antibiotics were not. Sincerus is in the process of certifying a separate hood that will be dedicated to compounding products containing antibiotics. SOP NC-15, "General cleaning procedure - pharmacies - non-sterile areas" is currently being drafted to address the cleaning of non-sterile compounding areas and will include swab testing and cleaning non-sterile powder containment hood areas to the level used for hazard drugs. In the meantime, a cleaning log has been created to document the cleaning of non-sterile hood after the compounding of each lot. In addition, Sincerus has created usage and cleaning logs for the ointment mills used in the compounding of non-sterile drug products to capture the use, cleaning, and cleaning verification of ointment mills. All compounding personnel will be trained by a Pharmacist on preventing cross-contamination and improved cleaning procedures including blanketing all hood surfaces by spraying 70% IPA spray then wiping and wiping down all equipment with wipes saturated with 70% IPA.

Please see Attachment 8, CAPA18-30

Please see Attachment 9, SOP NC-04, Operation of the Hobart LXeR Dishwasher

Please see Attachment 10, Ointment Mill Use and Cleaning Log

Please see Attachment 11, Non-Sterile Powder Hood Cleaning Log

2019-Q1 UPDATE: SOP NC-04, Operation of the Hobart LXeR Dishwasher, the Ointment Mill Use and Cleaning Log, and the Non-Sterile Powder Hood Cleaning Log were addressed in Sincerus' 10/09/2018 response and are currently in use. See Attachments 3 and 4. A powder containment hood dedicated to compounding products containing antibiotics is now in use. See Attachment 5. SOP F-09, General Cleaning of Sincerus' Non-Sterile cGMP Areas has been drafted. See Attachment 6. An SOP is currently being drafted to address the operation, use and cleaning procedures for ointments mills.

Please see 2019-Q1 Attachment 3, Example of a Powder Containment Hood Use and Cleaning Log

Please see 2019-Q1 Attachment 4, Example of an Ointment Mill Use and Cleaning Log

Please see 2019-Q1 Attachment 5, Pictures of Hood Dedicated to Compounding Products Containing Antibiotics

Please see 2019-Q1 Attachment 6, SOP F-09, General Cleaning of Non-Sterile cGMP Areas DRAFT

Information of Organization

Sincerus Florida, LLC, Sole owner and operator of facility
EIN: 30-0891087

Mailing Address: 3265 W McNab Road, Pompano Beach FL 33069
Phone No: 561-404-8893
legal@sincerususa.com

Officers of Applicant:

Spencer Malkin, CEO of Sincerus Florida, LLC (0% direct ownership)
Jonathan Fenster, COO of Sincerus Florida, LLC (0% direct ownership)

AC# 8771491

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29976	111165

THE PHARMACY

named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

SINCERUS FLORIDA, LLC
Sincerus Florida, LLC
3265 W MCNAB ROAD
POMFANO BEACH, FL 33069



QUALIFICATION(S):
SPECIAL STERILE COMPOUNDING

Ron DeSantis
GOVERNOR

DISPLAY IF REQUIRED BY LAW

EXPIRATION DATE: FEBRUARY 28, 2021

Your license number is PH 29976. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

Medical Quality Assurance has a new and improved Online Services Portal. In the new system, you have the ability to renew your license, update your mailing and practice location addresses, request a name change, request a duplicate license and update your profile information all from the convenience of your online account.

1. Go to www.FLHealthSource.gov.
2. Click on "Provider Services" and select "Manage Your License."
3. Select your profession and license type and click "Submit."
4. The question "Have you Renewed or Applied Online Since 2015?" will display.
 - a. Click on "No" if you have not registered for an account in the new system and follow the instructions provided for new user registration.
 - b. Click on "Yes" if you are a returning user. Enter the user ID and password you selected during the registration process, then select "Sign In" to access your MDA Online Services Portal account.

IMPORTANT ANNOUNCEMENTS

Are You Renewal Ready?

Grounds for Discipline

QUALIFICATION(S):
Special Sterile Compounding

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29976	111165

The PHARMACY
named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: FEBRUARY 28, 2021

SINCERUS FLORIDA, LLC

LICENSEE SIGNATURE

AC#8771490

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29905	111156

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: FEBRUARY 28, 2021

SINCERUS FLORIDA, LLC
3265 W MCNAB ROAD
POMPANO BEACH, FL 33069



QUALIFICATION(S):
COMMUNITY PHARMACY
3:1 PHARMACY TECHNICIAN RATIO APPROVED

Ron DeSantis
GOVERNOR

DISPLAY IF REQUIRED BY LAW

EXPIRATION DATE: FEBRUARY 28, 2021

Your license number is PH 29905. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

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QUALIFICATION(S):
Community Pharmacy
3:1 Pharmacy Technician Ratio Approved

STATE OF FLORIDA AC# 8771490
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29905	111156

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: FEBRUARY 28, 2021

SINCERUS FLORIDA, LLC

LICENSEE SIGNATURE



Department of Health

License Number: PH29976

Data As Of 5/5/2020

Profession	Pharmacy
License	PH29976
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2021
License Original Issue Date	03/23/2016
Address of Record	3265 W MCNAB ROAD POMPANO BEACH, FL 33069 UNITED STATES
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Official license certifications have been ordered from FL BOP, they will be forwarded to your office immediately upon receipt.
Please accept this on-line verification in the interim



Department of Health

License Number: PH29905

Data As Of 5/5/2020

Profession	Pharmacy
License	PH29905
License Status	CLEAR/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2021
License Original Issue Date	02/19/2016
Address of Record	3265 W MCNAB ROAD POMPANO BEACH, FL 33069
Discipline on File	No
Public Complaint	No

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they will be forwarded to your office immediately upon receipt.
Please accept this on-line verification in the interim

Maria Yeager

From: DoNotReply_CDERS@fda.hhs.gov
Sent: Wednesday, January 29, 2020 12:25 PM
To: elicence
Cc: CDERCollections@fda.hhs.gov; Compounding@fda.hhs.gov; EDRLS@fda.hhs.gov
Subject: FY2020 Outsourcing Facility Acknowledgment - Sincerus Florida, LLC

Good Afternoon,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of \$18,288. Effective January 01, 2020, your facility located at 3265 West McNab Road Pompano Beach, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2020.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>

Thanks
CQA User Fee Staff

⟨795⟩ PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS

INTRODUCTION

The purpose of this chapter is to provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. This chapter and applicable monographs on formulation help define good compounding practices. Furthermore, this chapter provides general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

DEFINITIONS

ACTIVE PHARMACEUTICAL INGREDIENT (API)—Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

ADDED SUBSTANCES—Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredients*, *excipients*, and *pharmaceutical ingredients*.

BEYOND-USE DATE (BUD)—The date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.

COMPONENT—Any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

COMPOUNDER—A professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

COMPOUNDING—The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients

- Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis
- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law

HAZARDOUS DRUG—Any drug identified by at least one of the following six criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity [for examples see current National Institute for Occupational Safety and Health (NIOSH) publications]

MANUFACTURING—The production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis. Manufacturing may also include any packaging or repackaging of the substance(s) or labeling or relabeling of containers for resale by pharmacies, practitioners, or other persons.

PREPARATION—For the purposes of this chapter, a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations; the term *product* will be used to describe manufactured pharmaceutical dosage forms. (For the definitions of *official substance* and *official products*, see *General Notices and Requirements*.)

STABILITY—The extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding (see *Stability Considerations in Dispensing Practice* (1191), the table *Criteria for Acceptable Levels of Stability*).

VEHICLE—A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

CATEGORIES OF COMPOUNDING

In the three general categories of nonsterile compounding described in this section, different levels of experience, training, and physical facilities are associated with each category.

Criteria used to determine overall classification include:

- degree of difficulty or complexity of the compounding process
- stability information and warnings
- packaging and storage requirements
- dosage forms
- complexity of calculations
- local versus systemic biological disposition
- level of risk to the compounder
- potential for risk of harm to the patient

See *Pharmaceutical Compounding—Sterile Preparations* (797) for risk levels associated with sterile preparations. Specialty areas such as radiopharmaceuticals require special training and are beyond the scope of this chapter. Compounders shall acquire and maintain knowledge and skills in all areas (e.g., dosage form, patient population, and medical specialty) for which they compound.

Description of Categories

Simple—Making a preparation that has a *United States Pharmacopeia (USP)* compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution*, *Indomethacin Topical Gel*, and *Potassium Bromide Oral Solution, Veterinary*.

Moderate—Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include *Morphine Sulfate Suppositories*, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.

Complex—Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.

RESPONSIBILITIES OF THE COMPOUNDER

The compounder is responsible for compounding preparations of acceptable strength, quality, and purity and in accordance with the prescription or medication order. The compounder is also responsible for dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with the requirements established by the applicable state agencies, state boards of pharmacy, federal law, and other regulatory agencies where appropriate. Individuals who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature. They shall be knowledgeable about the contents of this chapter and should be familiar with *Pharmaceutical Compounding—Sterile Preparations (797)*, *Pharmaceutical Dosage Forms (1151)*, *Pharmaceutical Calculations in Prescription Compounding (1160)*, *Quality Assurance in Pharmaceutical Compounding (1163)*, *Prescription Balances and Volumetric Apparatus (1176)*, *Stability Considerations in Dispensing Practice (1191)*, *Written Prescription Drug Information—Guidelines (1265)*, and all applicable compounding laws, guidelines, and standards.

To ensure the quality of compounded preparations, compounders shall adhere to the following general principles (additional information on these general principles is provided in the sections that follow).

General Principles of Compounding

1. Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented.
2. Compounding ingredients of the appropriate identity, purity, and quality are purchased from reliable sources and are properly stored according to manufacturer specifications or *USP* standards.
3. Bulk component containers are labeled with appropriate Occupational Safety and Health Administration

(OSHA) hazard communication labels (see OSHA.gov), and Material Safety Data Sheets (MSDSs) are available to compounding personnel for all drugs and chemicals used in compounding.

4. All equipment used in compounding is clean, properly maintained, and used appropriately.
5. The compounding environment is suitable for its intended purpose; and procedures are implemented to prevent cross-contamination, especially when compounding with drugs (e.g., hazardous drugs and known allergens like penicillin) that require special precautions.
6. Only authorized personnel are allowed in the immediate vicinity of the drug compounding operations.
7. There is assurance that processes are always carried out as intended or specified and are reproducible.
8. Compounding conditions and procedures are adequate for preventing errors.
9. All aspects of compounding are appropriately documented.
10. Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or the preparation itself.

COMPOUNDING PROCESS

The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section (additional information on these criteria is provided in the sections that follow).

Criteria When Compounding Each Drug Preparation

1. The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of:
 - the chemical and physical properties of the components
 - dosage form
 - therapeutic appropriateness and route of administration, including local and systemic biological disposition
 - legal limitations, if any
2. A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made. In addition, a Compounding Record should be completed each time a preparation is compounded.
3. Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov). If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used.
4. Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section *Compounding Facilities*).
5. Only one preparation is compounded at one time in a specific workspace.
6. Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used.

7. A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD.
8. Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination.
9. The preparation is made in accordance with this chapter, other official standards referenced in this chapter, and relevant scientific data and information.
10. Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
11. The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record (see chapter (1163)).
12. The preparation is packaged as recommended in the *Packaging and Drug Preparation Containers* section of this chapter.
13. The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information. The labeling should indicate that "this is a compounded preparation."
14. The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use.
15. The preparation is delivered to the patient or caregiver with the appropriate consultation.

COMPOUNDING FACILITIES

Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination. Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see *Pharmaceutical Compounding—Sterile Preparations* (797), *Environmental Quality and Control*).

Potable water shall be supplied for hand and equipment washing. This water meets the standards prescribed in the Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR Part 141). *Purified Water* (see *Purified Water* monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. *Purified Water* should be used for rinsing equipment and utensils. In those cases when a water is used to prepare a sterile preparation, follow the appropriate monographs and general chapters (see *Water for Pharmaceutical Purposes* (1231)).

The plumbing system shall be free of defects that could contribute to contamination of any compounded preparation. Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold

water, soap or detergent, and an air-drier or single-use towels. The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair. Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines.

The entire compounding and storage area should be well lighted. Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity*; and the manufacturers' labeled storage conditions). Appropriate temperature and humidity monitoring should be maintained as required for certain components and compounded dosage forms. All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. The following are references for the safe handling of antineoplastic and hazardous drugs in healthcare settings:

- OSHA Technical Manual—Section VI: Chapter 2, *Controlling Occupational Exposure to Hazardous Drugs*
- NIOSH Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (DHHS (NIOSH) Publication No. 2004-165) and updates.

Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

COMPOUNDING EQUIPMENT

The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity. The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations. The types and sizes of equipment depend on the dosage forms and the quantities compounded (see chapter (1176) and equipment manufacturers' instruction manuals).

Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance. Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use. After use, the equipment shall be appropriately cleaned.

Extra care should be used when cleaning equipment used in compounding preparations that require special precaution (e.g., antibiotics and cytotoxic and other hazardous materials). When possible, special equipment should be dedicated for such use, or when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs. If possible, disposable equipment should be used to reduce chances of bioburden and cross-contamination.

COMPONENT SELECTION, HANDLING, AND STORAGE

The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations.

1. A *United States Pharmacopeia (USP)*, *National Formulary (NF)*, or *Food Chemicals Codex (FCC)* substance is the recommended source of ingredients for compounding all preparations.
2. Compounders shall first attempt to use components manufactured in an FDA-registered facility. When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source.
3. Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled *USP* or *NF* as appropriate.
4. When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society-certified may be used. However, these components should be used cautiously because the standards for analytical reagents or American Chemical Society-grade materials do not consider whether any impurity present raises human or animal safety concerns.
5. For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date (a) when the material is stored in its original container under conditions to avoid decomposition of the chemicals (see chapter (1191) and *Packaging and Storage Requirements* (659), unless other conditions are noted on the label), (b) when there is minimal exposure of the remaining material each time material is withdrawn from the container, and (c) when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container.
6. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions.
7. If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date. When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation

and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components.

8. If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet *USP*, *FCC*, or *NF* standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures.
9. When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials.
10. When compounding for humans, the compounder should consult the list of components that have been withdrawn or removed from the market for safety or efficacy reasons by FDA (see www.FDA.gov). When compounding for food-producing animals, the compounder should consult the list of components prohibited for use in food-producing animals.
11. All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to *USP*, *NF*, or *FCC* monograph requirements, in a clean area, and under appropriate temperature and humidity conditions (controlled room temperature, refrigerator, or freezer). All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled.

Change to read:**STABILITY CRITERIA AND BEYOND-USE DATING**

The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products.

BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:

- the nature of the drug and its degradation mechanism
- the dosage form and its components
- the potential for microbial proliferation in the preparation
- the container in which it is packaged
- the expected storage conditions
- the intended duration of therapy (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*).

When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. Instead, the compounder shall refer to the manufacturer for stability information and

to the literature for applicable information on stability, compatibility, and degradation of ingredients; shall consider stability factors in chapter (1191); and shall use his or her compounding education and experience. All stability data shall be carefully interpreted in relation to the actual compounded formulation.

At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability. For more specific details of some of the common physical signs of deterioration (see chapter (1191), *Observing Products for Evidence of Instability*). However, excessive chemical degradation and other drug concentration loss due to reactions may be invisible more often than visible.

General Guidelines for Assigning Beyond-Use Dates

In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for (RB 1-Jan-2014) nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated (RB 1-Jan-2014) (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling*). Drugs or chemicals known to be labile to decomposition will require shorter BUDs.

BUD by Type of Formulation*
For Nonaqueous Formulations —The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
For Water-Containing Oral Formulations —The BUD is not later than 14 days when stored at controlled cold temperatures.
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations —The BUD is not later than 30 days.

*These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobial preservatives are contraindicated in such compounded preparations, storage of the preparation at controlled cold temperature is necessary; to ensure proper storage and handling of such compounded preparations by the patient or caregiver, appropriate patient instruction and consultation is essential. Antimicrobial preservatives should not be used as a substitute for good compounding practices.

For information on assigning BUDs when repackaging drug products for dispensing or administration, see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Expiration Date and Beyond-Use Date, and Packaging and Repackaging—Single-Unit Containers* (1136).

Assurance of sterility in a compounded sterile preparation is mandatory. Compounding and packaging of sterile drugs (including ophthalmic preparations) requires strict adherence to guidelines presented in chapter (797) and in the manufacturers' labeling instructions.

PACKAGING AND DRUG PREPARATION CONTAINERS

The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet USP requirements (see *Packaging and Storage Requirements* (659); *Containers—Glass* (660); *Containers—Plastics* (661); *Containers—Performance Testing* (671); chapter (1136)); and when available, compounding monographs. Compounders are not expected to perform the tests described in these chapters but should be knowledgeable about the standards described in them. Container suppliers shall supply, upon request, verification of USP container compliance. Containers and container closures intended for the compounding of sterile preparations must be handled as described in chapter (797).

The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation. Container-drug interaction should be considered for substances that have sorptive or leaching properties.

The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area.

COMPOUNDING DOCUMENTATION

Documentation, written or electronic, enables a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation. All compounders who dispense prescriptions must comply with the record-keeping requirements of their state boards of pharmacy. When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

These records should be retained for the same period of time that is required for any prescription under state law. The record may be a copy of the prescription in written or machine-readable form and should include a Master Formulation Record and a Compounding Record.

Master Formulation Record

This record shall include:

- official or assigned name, strength, and dosage form of the preparation
- calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- description of all ingredients and their quantities
- compatibility and stability information, including references when available
- equipment needed to prepare the preparation, when appropriate
- mixing instructions that should include:
 1. order of mixing
 2. mixing temperatures or other environmental controls
 3. duration of mixing
 4. other factors pertinent to the replication of the preparation as compounded
- sample labeling information, which shall contain, in addition to legally required information:

6 (795) Pharmaceutical Compounding—Nonsterile Preparations

Revision Bulletin
Official January 1, 2014

1. generic name and quantity or concentration of each active ingredient
 2. assigned BUD
 3. storage conditions
 4. prescription or control number, whichever is applicable
- container used in dispensing
 - packaging and storage requirements
 - description of final preparation
 - quality control procedures and expected results

Compounding Record

The Compounding Record shall contain:

- official or assigned name, strength, and dosage of the preparation
- Master Formulation Record reference for the preparation
- names and quantities of all components
- sources, lot numbers, and expiration dates of components
- total quantity compounded
- name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation
- date of preparation
- assigned control or prescription number
- assigned BUD
- duplicate label as described in the Master Formulation Record
- description of final preparation
- results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)
- documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver

Standard Operating Procedures

All significant procedures performed in the compounding area should be covered by written standard operating procedures (SOPs). Procedures should be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding. Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel.

Material Safety Data Sheets File

MSDSs shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises. Employees should be instructed on how to retrieve and interpret needed information.

QUALITY CONTROL

The safety, quality, and performance of compounded preparations depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take

appropriate corrective action before the prescription is dispensed to the patient.

Compounding Controls

1. The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented.
2. The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process.
3. The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity.
4. Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.
5. For further guidance on recommended quality control procedures, see chapter (1163).

PATIENT COUNSELING

At the time of dispensing the prescription, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to report any adverse event and to observe and report to the compounder any changes in the physical characteristics of the compounded preparation (see *Stability Considerations in Dispensing* (1191), *Responsibility of Pharmacists*). The compounder shall investigate and document any reported problem with a compounded preparation and shall take corrective action.

TRAINING

All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel should be evaluated at least annually. Steps in the training procedure include the following:

- All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the *USP Pharmacists' Pharmacopeia* and other relevant publications, including how to read and interpret MSDSs.
- All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing.
- All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs. For information on training for personnel who compound hazardous drugs, see the references in *Compounding Facilities* earlier in this chapter.
- All training activities shall be documented. The compounder shall meet with employees to review their

work and answer any questions the employees may have concerning compounding procedures.

- The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder.
- When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation.
- When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained.
- The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed.
- The compounder is solely responsible for the finished preparation.

COMPOUNDING FOR ANIMAL PATIENTS

A compounder's responsibility for providing patients with high-quality compounded preparations extends beyond the human species. All portions of this chapter apply to compounded preparations formulated for animal patients. Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient.

Because humans can consume animal patients as food, care must be taken to prevent drug residues from entering

the human food chain when compounded preparations are used in animal patients. For this reason, all compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients. Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species.

Drug use in any performance animal is strictly regulated by federal and state governments, in addition to the governing bodies of each of the specific disciplines. Penalties for violation of these rules may be severe for all contributing to the violation, including the veterinarian, pharmacist, and caregiver.

The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, compounders making preparations for animals should use, when possible, formulations specifically developed for animal patients. If such formulations are not available, the compounder shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Extrapolating compounding formulations intended for use in humans may not be appropriate for animal species and may contribute to negative outcomes.

Veterinarians and pharmacists making preparations for animal patients should be familiar with all state and federal regulations regarding drug use in animals, including but not limited to the Food, Drug, and Cosmetic Act; the Animal Drug Amendment; the Animal Medicinal Drug Use Clarification Act; and FDA's Compliance Policy Guideline for Compounding of Drugs for Use in Animal Patients.

Maria Yeager

From: Kay Mitchen
Sent: Tuesday, March 15, 2016 11:21 AM
To: Spencer Malkin; Alex Chervinsky; Marc Poirier
Cc: Lynn Swanson; Maria Yeager; Matthew Bernstein
Subject: FW: Confirmation of Registration: Sincerus Florida, LLC

Importance: High

Mazeltov!

From: CDER Electronic Drug Registration and Listing [mailto:EDRLS@fda.hhs.gov]
Sent: Tuesday, March 15, 2016 11:17 AM
To: Kay Mitchen <KMitchen@vividus.com>
Cc: Compounding <Compounding@fda.hhs.gov>
Subject: Confirmation of Registration: Sincerus Florida, LLC

Dear Ms. Mitchen,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of \$16,465. Effective March 10, 2016, your facility located at 3265 West McNab Road, Pompano Beach, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2016.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>

Electronic Drug Registration and Listing (eDRLS Staff)
301-796-3100
eDRLS@fda.hhs.gov

Maria Yeager

From: CDER Collections <CDERCollections@fda.hhs.gov>
Sent: Thursday, December 28, 2017 2:42 PM
To: elicense
Cc: CDER Collections; Compounding; CDER Electronic Drug Registration and Listing
Subject: FY 2018 503B Registration Acknowledgement Letter - Sincerus Florida, LLC (CQA187000350)

Good Afternoon,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of \$17,364. Effective January 01, 2018, your facility located at 3265 West McNab Road Pompano, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2018.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>

Thanks,
Frances Winters
CDER/OM/ DUFMBF
U.S. Food & Drug Administration



Please take a moment to provide specific, immediate, honest, and actionable feedback on the services received by taking this [short survey](#).

Maria Yeager

From: DoNotReply@fda.hhs.gov
Sent: Wednesday, March 20, 2019 1:16 PM
To: elicence
Cc: CDERCollections@fda.hhs.gov; Compounding@fda.hhs.gov; EDRLS@fda.hhs.gov
Subject: FY2019 Outsourcing Facility Acknowledgement - Sincerus Florida, LLC

Good Afternoon,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of \$18,375. Effective January 01, 2019, your facility located at 3265 West McNab Road Pompano Beach, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2019.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>

CDER Collections Staff

Please take a moment to provide specific, immediate, honest, and actionable feedback on the services received by taking a short survey at: https://fdacder.co1.qualtrics.com/jfe/form/SV_1MneD4auUHM9qI



**3265 W McNab Road
Pompano Beach, FL 33069**

**Phone: (561) 404-8885
Fax: (561) 503-4131**

April 20, 2017

Sent Via Certified Mail
Nevada State Board of Pharmacy
431 W Plumb Ln
Reno, NV 89509

To Whom It May Concern:

Please allow this correspondence to serve as formal notification that Mr. Alex Chervinsky has determined that he will no longer hold a position as a corporate officer of Sincerus Florida, LLC, an out-of-state Wholesaler licensed in the state of Nevada permit No.: WH02257. Mr. Chervinsky will continue to be associated with the company as a pharmacist.

Please contact us, if you require additional information.

Cordially,



Maria Yeager
Legal Assistant

Sincerus Florida, LLC
3265 W. McNab Road
Pompano Beach, FL 33069
Phone: (561) 419-9250
Fax: (561) 503-4131
legal@vividus.com

Each sheet can be used for one Certified Mail piece, which can be sent without Physical Return Receipt Service (Option A) or with Physical Return Receipt Service (Option B).

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Sincerus Florida, LLC
3265 W McNab Road
Pompano Beach, FL 33069

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Reno NV 89509-3766

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or Return Address
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Sender

CERTIFIED MAIL

PS Form 3800 6/02

COMPLETE THIS SECTION ON DELIVERY

A. Signature: ☒ Addressee or ☐ Agent

B. Received By: (Please Print Clearly)

C. Date of Delivery

D. Addressee's Address (If Different From Address Used in Service)

Secondary Address / Suite / Apt. / Floor (Please Print Clearly)

Delivery Address

City State ZIP + 4 Code

RETURN RECEIPT REQUESTED
Article Addressed To:

CERTIFIED MAIL

Top of the page

Certified Mail Labels (3500-3510)

Covered by and/or for use with U.S. Patents 6,244,763; 6,868,406; 7,216,110; 7,236,956; 7,236,970; 7,490,065; 7,567,940; 7,613,619; 7,743,043; 7,852,094; 8,027,926; 8,027,927; 8,027,935; 8,041,644; 8,046,823; 8,103,647; 8,195,379; 8,301,572; 8,392,371; and 8,498,943

2029

B

Certified Mail
WITH Physical Return
Receipt Service
(Uses Return Receipt Card)
Instructions

1. Apply address label above to the back of this card.
2. Apply this card to the TOP EDGE of the mailpiece.

← Fold and Tear →

VOID

stamps.com

• Patents 5,053,277 •
• 5,072,636 • 5,072,637 •
• U.S. Patent 5,072,638 •
• USA CMB 134 US 16 •

Delaware

Page 1

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF
DELAWARE, DO HEREBY CERTIFY "SINCERUS FLORIDA, LLC" IS DULY FORMED
UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND
HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS
OF THE SIXTEENTH DAY OF JUNE, A.D. 2020.



5883753 8300

SR# 20205618176

You may verify this certificate online at corp.delaware.gov/authver.shtmlA handwritten signature in black ink, appearing to read "JB", is written over a horizontal line. Below the line, the text "Jeffrey W. Bullock, Secretary of State" is printed.

Jeffrey W. Bullock, Secretary of State

Authentication: 203115462

Date: 06-16-20

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



2031

Ron DeSantis
Governor**Scott A. Rivkees, MD**
State Surgeon General**Vision:** To be the Healthiest State in the Nation

May 20, 2020

Sincerus Florida, LLC
Maria Yeager
3820 NW 23rd Place
Coconut Creek, FL 33066

RE: License Certification for Sincerus Florida, LLC

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH29905
ORIGINAL CERTIFICATION:	02/19/2016
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
OTHER CERTIFICATIONS:	Community Pharmacy

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gerlisia K. Still

Regulatory Specialist II

/gs

**Florida Department of Health**

Division of Medical Quality Assurance • Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX: (850) 245-4791

**Accredited Health Department**
Public Health Accreditation Board

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

May 14, 2020

Maria Yeager
3820 NW 23 Place
Coconut Creek, FL 33066

RE: License Certification for Sincerus Florida, LLC

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH29976
ORIGINAL CERTIFICATION:	03/23/2016
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Susan Harris
Operations Analyst I

/sh



Florida Department of Health

Division of Medical Quality Assurance • Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX: (850) 245-4791



Accredited Health Department
Public Health Accreditation Board

151

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New OUTSOURCING FACILITY

☒ Ownership Change (Provide current license number if making changes:) OUT 00020

☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☐ Partnership - Pages 1-3 & 6

☒ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Wedgewood Connect, LLC

Physical Address: 17 Great Oaks Blvd.

City: San Jose State: CA Zip Code: 95119

Telephone: 855-321-8477 Fax: 800-589-4250

Toll Free Number: 800-216-5005 (Required per NAC 639.708)

E-mail: pyamamoto@wedgewoodpharmacy.com Website: www.wedgewoodpharmacy.com/

Supervising Pharmacist: Paul K Yamamoto Nevada License #: 19734

SERVICES PROVIDED

Yes/No

☒ ☐ Parenteral

☒ ☐ Sterile Compounding

☒ ☐ Non Sterile Compounding

☒ ☐ Mail Service Sterile Compounding

☐ ☐ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY**Page 2**FEI Number (From FDA application): 3003434972

Please provide the name of the facility as registered with the FDA and the registration number:

Previous name: LEITER'S ENTERPRISES, INC dba LEITER'S; New name: Wedgewood Connect, LLCPlease provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Paul K Yamamoto Nevada License Number: 19734A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/AThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Marcy Ann Bliss

Print Name of Authorized Person

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Wedgewood Village Pharmacy, LLC

Address: 405 Heron Dr., Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 480-946-2223 Fax: 800-589-4250

Contact Person: Marcy Ann Bliss

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a)	<u>N/A</u>	
	Name	Address
b)	<u>N/A</u>	
	Name	Address
c)	<u>N/A</u>	
	Name	Address
d)	<u>N/A</u>	
	Name	Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? 05/31/2020

5) Provide a copy of the corporation's stock register evidencing the above information
N/A

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Within the last five (5) years:

Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? **Yes.**

Leiters
17 Great Oaks Blvd., San Jose, CA 95119
Summary of State Actions

- California Board of Pharmacy – CI 2018 83424


On October 8, 2019, the California Board of Pharmacy issued a notice of Citation and Fine for an alleged violation of California pharmacy law. California alleged that Leiters, located at 17 Great Oaks Blvd, San Jose, CA 95119, violated California pharmacy law by compounding cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of 0.9% sodium chloride, as labeled. Leiters disagreed with the allegations, Leiters agreed to settle the matter with the California Board of Pharmacy and pay a fee of \$2500. This agreement was finalized on January 10, 2020.

This is not a discipline by the California Board of Pharmacy, but it is disclosing it out of an abundance of caution.

- California Board of Pharmacy – CI 2016 75140 (LSC 100533); CI 2018 80747 (PHY 55311); CI 2018 80748 (RPH 43950)

On April 28, 2017 the California Board of Pharmacy received a complaint from a compounding pharmacist that Leiters was not a manufacturer and must label their sterile products to "discard 28 days after first use". Leiters was an FDA registered Outsourcing Facility following cGMP requirements. This complaint arose prior to Leiters' licensure as a California outsourcing facility (while Leiters was licensed as a sterile compounding pharmacy), but after the law mandating California Outsourcing licensure was enacted. The same allegation was made against Leiters' pharmacist-in-charge individually. Leiters disagreed with the allegations, but Leiters agreed to settle the matter with the California BOP and pay a fee of \$1000 to the facility, \$500 to the individual. This agreement was finalized on January 29, 2020.

This is not a discipline by the California DOJ, but it is disclosing it out of an abundance of caution.


 Marcy Ann Bliss
 CEO/President/Treasurer/Secretary

does not constitute any admission of wrongdoing by Wedgewood; however, it is being provided out of an abundance of caution. A copy of the citation is attached.



Marcy Ann Bliss
CEO/President/Treasurer/Secretary



California State Board of Pharmacy
 2720 Gateway Oaks Drive, Suite 100
 Sacramento, CA 95833
 Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
 Department of Consumer Affairs
 Gavin Newsom, Governor



October 08, 2019

DATED MATERIAL ENCLOSED

LEITERS
 ATTN: ROBIN HOKE, PRS
 17 GREAT OAKS BLVD
 SAN JOSE, CA 95119

RE: CI 2018 83424
LEITERS
OSF 107

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 07, 2019: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 22, 2019: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 07, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

Page two
LEITERS
CI 2018 83424

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Sincerely



Anne Sodergren
Interim Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 07, 2019**.
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 22, 2019 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 07, 2019 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 518-3013.

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

CITATION AND FINE

Citation Number	Name, License No
CI 2018 83424	LEITERS, OSF 107

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4129.1 subd. (b)/Title 21 CFR § 211.100(a)	Outsourcing facilities; shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities. /Written procedures; deviations (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.	\$5,000.00

CONDUCT:

Outsourcing Facility – License Required: Business and Professions Code section 4129.1 (b) states, an outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities. As related to the Code of Federal Regulations section, CFR 211.100 (a) Written procedures; deviations states; There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

Leiters (OSF 107) was not compliant. Specifically, Leiters, located at 17 Great Oaks Boulevard, San Jose, CA 95119, on 11/2/2018, compounded cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of sterile 0.9% sodium chloride, as labeled. This was a violation of pharmacy law.

CITATION ISSUED ON: October 08, 2019

TOTAL AMOUNT OF FINE(S): \$5,000.00

PAYMENT OF FINE(S) DUE BY: November 07, 2019

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: LEITERS

License No: OSF 107

Citation Number : CI 2018 83424

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) () _____ Residence: () _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
 Attn: Jennifer Sevilla
 2720 Gateway Oaks Drive, Suite 100
 Sacramento, CA 95833
 (916) 518-3013

REQUEST FOR APPEAL

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:

LEITERS

OSF 107

Respondent

Citation Case No : CI 2018 83424

NOTICE OF APPEAL

(Pursuant to sections 11505, and 11506
Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____

(Respondent)

Mailing Address of Respondent:

(Street Address)

(City)

(State) (Zip)

()

(Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name)

(Street Address)

(City)

(State)

(Zip)

()

(Telephone)



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



January 29, 2020

CERTIFIED MAIL

LEITERS

ATTN: ROBIN HOKE, PRS
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

RE: CI 2018 83424
LEITERS
OSF 107

As a result of the explanation and information you provided at the office conference, the amount of the fines assessed in Citation and Fine, CI 2018 83424 have been reduced.

The modified Citation is attached and is hereby issued pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (d).

If you desire a hearing to appeal the attached Citation, you must submit a written request for a hearing to the Board of Pharmacy ("Board") within 30 days of the date this Citation was issued. (See Bus. Prof. Code sec. 125.9, subd. (b)(4), and C.C.R., title 16, sec. 1775.4, subd. (d).). Unless the Board receives a written request within the 30 days, you will be deemed to have waived your right to a hearing in this matter and the Citation shall become the final order of the Board. If a hearing is not requested, the timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

Failure to pay any imposed fine(s) within 30 days of the date the Citation was issued may result in disciplinary action being taken.

Page two
LEITERS
CI 2018 83424

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

If you have any questions regarding this Citation please contact Susan Cappello, Enforcement Manager at (916) 518-3008.

Sincerely

A handwritten signature in black ink that reads "Thomas P. Lenox". The signature is written in a cursive style with a large, looping initial 'T'.

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

Attachments

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
MODIFIED CITATION AND FINE**

Citation Number	Name, License No
CI 2018 83424	LEITERS, OSF 107

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4129.1 subd. (b)/Title 21 CFR § 211.100(a)	Outsourcing facilities; shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities. /Written procedures; deviations (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.	\$2,500.00

CONDUCT:

Outsourcing Facility – License Required: Business and Professions Code section 4129.1 (b) states, an outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities. As related to the Code of Federal Regulations section, CFR 211.100 (a) Written procedures; deviations states; There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

Leiters (OSF 107) was not compliant. Specifically, Leiters, located at 17 Great Oaks Boulevard, San Jose, CA 95119, on 11/2/2018, compounded cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of sterile 0.9% sodium chloride, as labeled. This was a violation of pharmacy law.

CITATION ISSUED ON: January 29, 2020

TOTAL AMOUNT OF FINE(S): \$2,500.00

PAYMENT OF FINE(S) DUE BY: February 28, 2020

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

COPY

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2018 83424	LEITERS, OSF 107

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4129.1 subd. (b)/Title 21 CFR § 211.100(a)	Outsourcing facilities; shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities. /Written procedures; deviations (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.	\$2,500.00

CONDUCT:

Outsourcing Facility – License Required: Business and Professions Code section 4129.1 (b) states, an outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities. As related to the Code of Federal Regulations section, CFR 211.100 (a) Written procedures; deviations states; There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

Leiters (OSF 107) was not compliant. Specifically, Leiters, located at 17 Great Oaks Boulevard, San Jose, CA 95119, on 11/2/2018, compounded cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of sterile 0.9% sodium chloride, as labeled. This was a violation of pharmacy law.

CITATION ISSUED ON: January 29, 2020

TOTAL AMOUNT OF FINE(S): \$2,500.00

PAYMENT OF FINE(S) DUE BY: February 28, 2020

REQUEST FOR APPEAL

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

Check ☐ I contest the Citation and request an administrative hearing before an
Administrative Law Judge.

In the Matter of the Citation Against:

LEITERS

OSF 107

Respondent

Citation Case No : CI 2018 83424

NOTICE OF APPEAL

(Pursuant to sections 11505, and 11506
Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a
copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in
said Citation.

DATED _____

(Respondent)

Mailing Address of Respondent:

(Street Address)

(City) (State) (Zip)

()
(Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please
complete the following:

Mailing Address of Attorney

(Attorney's Name)

(Street Address)

(City) (State) (Zip)

()
(Telephone)

California State Board of Pharmacy**DECLARATION OF SERVICE BY CERTIFIED MAIL****Name: LEITERS, OSF 107****Citation and Fine CI 2018 83424**

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On January 29, 2020, I served the attached:

Cover Letter, Citation, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME

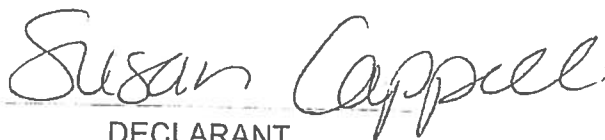
LEITERS
ATTN: ROBIN HOKE, PRS
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

CERTIFIED MAIL NO

7019 1120 0002 2777 0196

I declare under penalty of perjury that the forgoing is true and correct.

Executed on January 29, 2020, at Sacramento, California.



DECLARANT

Susan Cappello
Enforcement Manager



California State Board of Pharmacy
 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

September 10, 2018

DATED MATERIAL ENCLOSED

✓ LEITER'S ENTERPRISES INC DBA LEITER'S 17 GREAT OAKS BLVD SAN JOSE, CA 95119	LEITER'S ENTERPRISES INC DBA LEITER'S C/O ROBIN SMITH HOKE 2134 YORKSHIRE RD COLUMBUS, OH 43221
---	--

**RE: CI 2016 75140
 LEITER'S ENTERPRISES INC DBA LEITER'S
 LSC 100753 (CANCELED)**

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- September 24, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- October 10, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

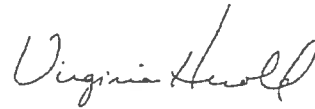
Page two
LEITER'S ENTERPRISES INC DBA LE
CI 2016 75140

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

A handwritten signature in cursive script, appearing to read "Virginia Herold".

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than September 24, 2018 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than October 10, 2018 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Enforcement Analyst, at (916) 574-7925.

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION**

Citation Number	Name, License No
CI 2016 75140	LEITER'S ENTERPRISES INC DBA LEITER'S, LSC 100753 (CANCELED)

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4300.1 Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1751.9 subd.(c)	Single-Dose and Multi-Dose Containers; Limitations on Use; Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture

CONDUCT:

California Code of Regulations section 1751.9 (c) states in pertinent part: Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within 28 days from initial opening or puncture. Leiters was not compliant. Specifically, Leiter's enterprises Inc. DBA Leiter's Compounding located at 17 Great Oaks Boulevard, San Jose, CA 95119 did not label their multi-dose containers of atropine eye drops with a discard after 28 days notation. This was a violation of pharmacy law.

CITATION ISSUED ON: September 10, 2018

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION**

Citation Number	Name, License No
CI 2016 75140	LEITER'S ENTERPRISES INC DBA LEITER'S, LSC 100753 (CANCELED)

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4300.1 Bus. & Prof. Code § 4301, subd. (o)

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CITATION ISSUED ON: September 10, 2018

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: LEITER'S ENTERPRISES INC DBA LEITE

License No: LSC 100753 (CANCELED)

Citation Number : CI 2016 75140

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) () _____ Residence: () _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

1 **REQUEST FOR APPEAL**

2 BEFORE THE
3 BOARD OF PHARMACY
4 DEPARTMENT OF CONSUMER AFFAIRS
5 STATE OF CALIFORNIA

6 Check ☐ I contest the Citation and request an administrative hearing before an
7 Administrative Law Judge.

8 In the Matter of the Citation Against:
9 LEITER'S ENTERPRISES INC DBA LEITER'S
10 LSC 100753 (CANCELED)

11 Respondent

12 Citation Case No : CI 2016 75140
13 NOTICE OF APPEAL
14 (Pursuant to sections 11505, and 11506
15 Government Code)

16 I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a
17 copy of the Citation.

18 I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in
19 said Citation.

20 DATED _____

21 Mailing Address of Respondent:

22 (Respondent)

23 _____
24 (Street Address)

25 _____
26 (City (State) (Zip)

27 _____
(Telephone)

28 Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please
29 complete the following:

30 Mailing Address of Attorney

31 _____
32 (Attorney's Name

33 _____
34 (Street Address)

35 _____
36 (City (State) (Zip)

37 _____
(Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: LEITER'S ENTERPRISES INC DBA LEITER'S, LSC 10075
Citation and Fine CI 2016 75140

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On September 10, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME

CERTIFIED MAIL NO

LEITER'S ENTERPRISES INC DBA LEITER'S
 17 GREAT OAKS BLVD
 SAN JOSE, CA 95119

7017 0530 0000 7764 4850

LEITER'S ENTERPRISES INC DBA LEITER'S
 C/O ROBIN SMITH HOKE
 2134 YORKSHIRE RD
 COLUMBUS, OH 43221

7017 0530 0000 7764 4867

I declare under penalty of perjury that the forgoing is true and correct.

Executed on September 10, 2018, at Sacramento, California.



 DECLARANT
 Christina Metzen
 Associate Enforcement Analyst

Within the last five (5) years:

Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? **Yes.**

**Summary of Actions Related to Applicant's
Owner Wedgewood Village Pharmacy, LLC**

- Minnesota Board of Pharmacy; Michigan Department of Licensing and Regulatory Affairs; Alabama Board of Pharmacy

On March 19, 2015, the Minnesota Board of Pharmacy finalized a Stipulation and Consent Order ("Minnesota Consent Order") with Wedgewood Village Pharmacy ("Wedgewood-NJ"), located in Swedesboro, New Jersey. Wedgewood-NJ subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs ("Michigan LARA") and the Alabama Board of Pharmacy to resolve "sister state" actions that arose out of the Minnesota Consent Order. All three orders are attached.

The underlying facts of the Minnesota Consent Order are as follows. Acting on a reasonable and good faith interpretation of Minnesota law, Wedgewood-NJ had dispensed compounds into Minnesota to a licensed veterinarian pursuant to a veterinarian's order for office use. The Minnesota Board of Pharmacy, however, asserted that Wedgewood-NJ needed a wholesaler license to dispense into Minnesota in this manner. For purposes of settlement only and admitting no wrongdoing, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a \$10,000 civil penalty. Wedgewood subsequently entered into a consent order with Michigan LARA to resolve a "sister state" matter based on the Minnesota Consent Order. Wedgewood-NJ entered into a similar consent order with the Alabama Board of Pharmacy to resolve a sister state action brought by the Alabama Board of Pharmacy based on the Minnesota Consent Order. There was not finding in the Michigan or Alabama consent order that Wedgewood NJ violated any provisions of Michigan or Alabama law outside of these state's prohibition on "sister State" actions.

- California Board of Pharmacy – CI 2018 82132; CI 2016 73882

On March 1, 2019, a citation was affirmed under each of Wedgewood-NJ's two California pharmacy licenses. Under California law these citations are not disciplinary actions and Wedgewood was not administered any fines in connection with the citations. Nonetheless, out of an abundance of caution Wedgewood is hereby notifying you of these citations. A copy of the citations are attached.

- California Board of Pharmacy – CI 2017 77042

On February 27, 2018, Wedgewood-NJ was issued an administrative citation and a \$1,000 fine as a result of an investigation by the California Board of Pharmacy. The citation is not a discipline by the California Board of Pharmacy and payment of the fines

does not constitute any admission of wrongdoing by Wedgewood; however, it is being provided out of an abundance of caution. A copy of the citation is attached.

Marcy Ann Bliss
CEO/President/Treasurer/Secretary



MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837

MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:

Metro and Non-Metro; 800-627-3529

E-Mail Address: Pharmacy.Board@state.mn.us

Web Site: www.pharmacy.state.mn.us

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

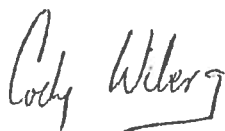
Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,



Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA**BOARD OF PHARMACY**

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

**STIPULATION AND
CONSENT ORDER****STIPULATION**

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.**JURISDICTION**

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.**CONFERENCE**

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.
5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.
6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.**DISCIPLINARY ACTION**

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a **CIVIL PENALTY** in the amount of \$10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.**CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS**

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL



MARCY BLISS, PRESIDENT
Wedgewood

Dated: 1/13/15



KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a **CIVIL PENALTY**, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY



CODY WIBERG
Executive Director

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc. Complaint No. 53-15-137238
License No. 53-01-008041

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED \$500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 53-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division – Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on _____

4-13-16

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.
2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

- A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.
- B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.
- C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read,
understand and agree with the terms of the consent order.

AGREED TO BY:

AGREED TO BY:

Kelly K. Elizondo
Kelly K. Elizondo (P45534)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

Alison Lynch
Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rogalski
Alan T. Rogalski (P44550)
Attorney for Respondent
Dated: 3/31/2016

IN THE MATTER OF:

WEDGEWOOD VILLAGE PHARMACY,)
 LLC)

Non-Resident Pharmacy)
 Permit Number: 112625)

BEFORE THE ALABAMA STATE
 BOARD OF PHARMACY

CASE NO: 16-L-0066

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as Exhibit "A."

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars (\$3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: M. A. Bl...

ITS: President & CEO

Jennifer Clark

Jennifer Clark, attorney for Wedgewood Village
Pharmacy, LLC

DONE this the _____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch

By: Buddy Bunch, R.Ph., President

By: James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:

WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:

WEDGEWOOD VILLAGE PHARMACY,)
LLC)BEFORE THE ALABAMA STATE
BOARD OF PHARMACYNon-Resident Pharmacy)
Permit Number: 112625)

CASE NO: 16-L-0088

STATEMENT OF CHARGES AND NOTICE OF HEARINGTO: Wedgewood Village Pharmacy, LLC
405 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____, 2016 at _____ m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., Issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of

the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, If you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goeiz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Hassford Remle and Rachael G. Pontikes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.
5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.
6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a **CIVIL PENALTY** in the amount of \$10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wilberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

2. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 3. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

M. B.
MARCY KLESS, PRESIDENT
Wedgewood

Karen Bergrud
KAREN BERGRUD
Board Member

Dated: 1/13/15

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

Cody Wiberg
CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remick and Rachael O. Pontikes, Esq., of Duane Morris.

EXHIBIT A page 1 of 2

III.
FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.
5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.
6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.
ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(b) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of \$10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VL

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

M. B. Bless
MARCY BLESS, PRESIDENT
Wedgewood

Dated: 1/13/15

Karen Bergrud
KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

Cody Wiberg
CODY WIBERG
Executive Director

By signing this stipulation, the parties confirm that they have read,
understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo
Kelly K. Elizondo (R48884)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lynch
Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondant
Dated: 5/31/16

Alan T. Rogalski
Alan T. Rogalski (R48860)
Attorney for Respondent
Dated: 5/31/2016

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.

License Number: 53-01-008041

File Number: 53-15-137238

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Gaedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a \$10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

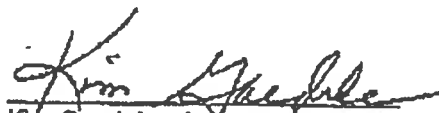
The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 308, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Gaedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30570, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015


Kim Gaedake, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-15-137238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC



California State Board of Pharmacy
 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
 ATTN: MARCY ANN BLISS, CEO
 405 HERON DR, SUITE 200
 SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

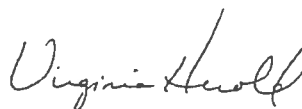
Page two
WEDGEWOOD VILLAGE PHARMACY
CI 2016 73882

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

A handwritten signature in cursive script, appearing to read "Virginia Herold".

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than December 19, 2018 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than January 04, 2019 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Enforcement Analyst, at (916) 574-7925.

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION**

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compounded drug preparation is a reasonable quantity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION**

COPY

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compounded drug preparation is a reasonable quantity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

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CITATION ISSUED ON: December 05, 2018

COPY

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NSC 100970

Citation Number : CI 2016 73882

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

- ☐ I contest the entire Citation or
- ☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) () _____ Residence: () _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

1 **REQUEST FOR APPEAL**

2 BEFORE THE
3 BOARD OF PHARMACY
4 DEPARTMENT OF CONSUMER AFFAIRS
5 STATE OF CALIFORNIA

6 Check ☐ I contest the Citation and request an administrative hearing before an
7 Administrative Law Judge.

8 In the Matter of the Citation Against:
9 WEDGEWOOD VILLAGE PHARMACY LLC
10 NSC 100970

11 Respondent

12 Citation Case No : CI 2016 73882
13 NOTICE OF APPEAL
14 (Pursuant to sections 11505, and 11506
15 Government Code)

16 I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a
17 copy of the Citation.

18 I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in
19 said Citation.

20 DATED _____

21 (Respondent)

22 Mailing Address of Respondent:

23 (Street Address)

24 (City) (State) (Zip)

25 ()
26 (Telephone)

27 Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please
complete the following:

Mailing Address of Attorney

(Attorney's Name)

(Street Address)

(City) (State) (Zip)

()
(Telephone)

California State Board of Pharmacy**DECLARATION OF SERVICE BY CERTIFIED MAIL**

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,


NAME**CERTIFIED MAIL NO**

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.



DECLARANT
Christina Metzen
Associate Enforcement Analyst



California State Board of Pharmacy
 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
 ATTN: MARCY ANN BLISS, CEO
 405 HERON DR SUITE 200
 SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

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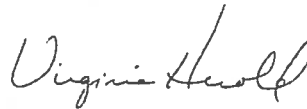
Page two
WEDGEWOOD VILLAGE PHARMACY
CI 2018 82132

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Sincerely

A handwritten signature in cursive script, appearing to read "Virginia Herold".

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

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REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

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REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than January 04, 2019 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Enforcement Analyst, at (916) 574-7925.

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION**

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compounded drug preparation is a reasonable quantity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION**

COPY

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compounded drug preparation is a reasonable quantity for office use...

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California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

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California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2018 82132

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

- ☐ I contest the entire Citation or
☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) () _____ Residence: () _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
 Attn: Jennifer Sevilla
 1625 North Market Boulevard, Suite N219
 Sacramento, CA 95834-1924
 (916) 574-7925

1 **REQUEST FOR APPEAL**

2 BEFORE THE
3 BOARD OF PHARMACY
4 DEPARTMENT OF CONSUMER AFFAIRS
5 STATE OF CALIFORNIA

6 Check ☐ I contest the Citation and request an administrative hearing before an
7 Administrative Law Judge.

8 In the Matter of the Citation Against:
9 WEDGEWOOD VILLAGE PHARMACY LLC
10 NRP 1826

11 Respondent

Citation Case No : CI 2018 82132
NOTICE OF APPEAL
(Pursuant to sections 11505, and 11506
Government Code)

12 I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a
13 copy of the Citation.

14 I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in
15 said Citation.

16 DATED _____

(Respondent)

17 Mailing Address of Respondent:

18 _____
19 (Street Address)

20 _____
21 (City) (State) (Zip)

() _____
(Telephone)

22 Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please
23 complete the following:

24 Mailing Address of Attorney

25 _____
26 (Attorney's Name)

27 _____
(Street Address)

(City) (State) (Zip)

() _____
(Telephone)

California State Board of Pharmacy**DECLARATION OF SERVICE BY CERTIFIED MAIL**

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME

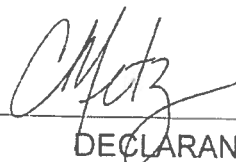
CERTIFIED MAIL NO

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.



DECLARANT

Christina Metzen
Associate Enforcement Analyst



California State Board of Pharmacy
 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
 Phone (916) 574-7900
 Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
 ATTN: MARCY ANN BLISS, CEO
 405 HERON DR SUITE 200
 SWEDESBORO, NJ 08085

**RE: CI 2017 77042
 WEDGEWOOD VILLAGE PHARMACY LLC
 NRP 1826**

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

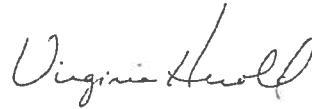
Page two
WEDGEWOOD VILLAGE PHARMACY
CI 2017 77042

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

A handwritten signature in cursive script, appearing to read "Virginia Herold".

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 12, 2017**.
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy

Attn: Ericka Busby

1625 North Market Boulevard, Suite N219

Sacramento, CA 95834-1924

(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 27, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 12, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	\$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017

TOTAL AMOUNT OF FINE(S): \$1,000.00

PAYMENT OF FINE(S) DUE BY: November 12, 2017

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	\$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017	TOTAL AMOUNT OF FINE(S): \$1,000.00
PAYMENT OF FINE(S) DUE BY: November 12, 2017	

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) () _____ Residence: () _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

1 **REQUEST FOR APPEAL**

2 BEFORE THE
3 BOARD OF PHARMACY
4 DEPARTMENT OF CONSUMER AFFAIRS
5 STATE OF CALIFORNIA

6 Check ☐ I contest the Citation and request an administrative hearing before an
7 Administrative Law Judge.

8 In the Matter of the Citation Against:

9 WEDGEWOOD VILLAGE PHARMACY LLC
10 NRP 1826

11 Respondent

Citation Case No : CI 2017 77042

NOTICE OF APPEAL

(Pursuant to sections 11505, and 11506
Government Code)

12 I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a
13 copy of the Citation.

14 I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in
15 said Citation.

16 DATED _____

(Respondent)

17 Mailing Address of Respondent:

18 _____
19 (Street Address)

20 _____
21 (City

(State) (Zip)

22 _____
23 (Telephone)

24 Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please
25 complete the following:

26 Mailing Address of Attorney

27 _____
28 (Attorney's Name

29 _____
30 (Street Address)

31 _____
32 (City

(State)

(Zip)

33 _____
34 (Telephone)

California State Board of Pharmacy**DECLARATION OF SERVICE BY CERTIFIED MAIL**

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On October 13, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME

CERTIFIED MAIL NO

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.


DECLARANT

Christina Metzén

Associate Enforcement Analyst

Wedgewood Connect, LLC
Officer List

Marcy Ann Bliss

Title: CEO/President/Treasurer/Secretary

Address: 405 Heron Drive, Suite 200, Swedesboro, NJ. 08085

Edward Michael Lhee

Title: Asst. Secretary

Address: 1240 Gregory Avenue, Wilmette, Illinois 60091

Jocelyn Rose Stanley

Title: Asst. Secretary

Address: 747 West Dickens Avenue, Chicago, Illinois 60614

Thomas Joseph Formolo

Title: Asst. Secretary

Address: 115 DeWindt Road, Winnetka, Illinois 60093

BOARD OF PHARMACY
LICENSING DETAILS FOR: OSF 107
NAME: LEITERS
LICENSE TYPE: OUTSOURCING FACILITY
LICENSE STATUS: CLEAR
ADDRESS
17 GREAT OAKS BLVD
SAN JOSE CA 95119
SANTA CLARA COUNTY

ISSUANCE DATE
OCTOBER 19, 2017
EXPIRATION DATE
OCTOBER 1, 2020
CURRENT DATE / TIME
APRIL 7, 2020
6:15:10 AM

BakerHostetler



Baker & Hostetler LLP

811 Main Street
Suite 1100
Houston, TX 77002-6111

T 713.751.1600
F 713.751.1717
www.bakerlaw.com

Simone O. Otenaika
direct dial: 713.646.1365
sotenaika@bakerlaw.com

April 27, 2020

VIA OVERNIGHT DELIVERY

Nevada Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Re: *LEITERS - License # PH03129*

Dear Sir or Madam:

Enclosed is a change of ownership application, along with attachments to same and the applicable fees, for the Pharmacy License pertaining to Leiter's Enterprises, Inc., dba Leiter's ("Leiter's" or "Licensee"), a Delaware corporation, located at 17 Great Oaks Blvd., San Jose, CA 95119.

On December 27, 2019, Wedgewood Village Pharmacy, LLC, a Delaware corporation, entered into a Share Purchase Agreement (the "Agreement") with, among others, the Licensee. On June 8, 2020, pursuant to the terms and subject to the conditions set forth in the Agreement, Wedgewood Village Pharmacy, LLC will acquire a 100% ownership interest in the Licensee and convert the Licensee into a Delaware limited liability company with the name Wedgewood Connect, LLC. As such, effective on June 8, 2020, Wedgewood Village Pharmacy, LLC will have a 100% direct ownership interest in the Licensee and the Licensee's new name will be Wedgewood Connect, LLC.

Pursuant to this name change and change of ownership, Wedgewood Village Pharmacy, LLC submits this application on behalf of Wedgewood Connect, LLC. The Licensee will submit this application on or about the same time the Licensee submits a new application to the DEA. Since the Licensee's updated DEA registration has not yet been issued, the Licensee cannot provide a copy with this application. The Licensee will supplement this application once the new DEA registration is issued and such verification becomes available.

Since the Licensee's conversion into Wedgewood Connect, LLC will occur at closing, the Licensee will supplement this application with the following documents as soon as they become available:

Atlanta Chicago Cincinnati Cleveland Columbus Costa Mesa Dallas Denver Houston
Los Angeles New York Orlando Philadelphia San Francisco Seattle Washington, DC

Nevada Board of Pharmacy
April 27, 2020
Page 2

- The Final Bill of Sale
- The Wedgewood Connect, LLC Certificate of Authority
- The Wedgewood Connect, LLC Statement of Information

Please note that while Wedgewood Village Pharmacy, LLC will be the new owner of the Licensee and Wedgewood Connect LLC will be the Licensee's new name, the Licensee's Pharmacist in Charge and Designated Representative will remain the same—thus the Licensee's operations will continue substantially unchanged from its pre-transaction operations. Additionally, the Licensee's FEIN and address will not change as a result of this transaction. If you require any additional information or follow-up, please contact me at (713) 646-1365 or by e-mail at sotenaik@bakerlaw.com.

Sincerely,

A handwritten signature in blue ink that reads "Simone Otenaïke / on". The signature is written in a cursive, flowing style.

Simone O. Otenaïke

Enclosures

16

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206– Reno, NV 89521 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

- ☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH _____)
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.
- ☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b
☒ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Plus One Pharmacy, LLC

Physical Address: 6525 S Fort Apache Rd Suite #140

City: Las Vegas

State: NV Zip Code: 89148

Telephone: 702-591-3099

Fax: N/A

Toll Free Number: N/A

E-mail: anupate17@yahoo.com

Website: N/A

Managing Pharmacist: Serj S. Markanan License Number: 16248

TYPE OF PHARMACY AND

SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail
☐ ☒ Hospital (# beds _____)
☐ ☒ Internet
☐ ☒ Nuclear
☐ ☒ Ambulatory Surgery Center
☒ ☐ Community
☐ ☒ Other: _____

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services
☐ ☒ Parenteral
☐ ☒ Parenteral (outpatient)
☐ ☒ Outpatient/Discharge
☐ ☒ Mail Service
☐ ☒ Long Term Care
☐ ☒ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

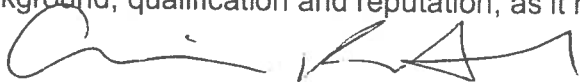
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Anisha Patel
Print Name of Authorized Person

4/12/2020
Date

Board Use Only

Date Processed: _____

Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: N/A

Mailing Address: 3225 McLeod Dr Suite 110

City: Las Vegas State: NV Zip: 89121

Telephone: 702-591-3099 Fax: _____

Contact Person: Anisha Patel

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a) Anisha Patel 3225 McLeod Dr Las Vegas, NV 89121
Name Business Address

b) N/A

Name	Business Address
------	------------------

c) N/A

Name	Business Address
------	------------------

d) N/A

Name Business Address

- 2) Provide the number of shares issued by the corporation. 100

- 3) What was the price paid per share? 0

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: N/A %:

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 7 pm

Saturday 9 am 2 pm

Sunday Closed am pm

24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20201755142

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Anisha Patel

Responsible Person of Plus One Pharmacy LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Anisha Patel

Print Name of Authorized Person

4/12/20

Date

Managing Pharmacist

Pharmacist Name: Serj S. Markarian

License #: 116248

Pharmacy Name: Plus one pharmacy

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions above, please include the following information

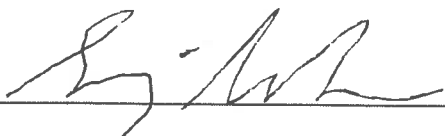
Board Administrative Action: State: CA Date: 5/8/2012 Case #: 3601
 And/or Criminal Action: State: CA Date: 2/6/2008 Case #: 1164534
 County: LA Court: Van Nuys, CA

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature



Date

4-16-20

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 4/17/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Retail Pharmacy
Plus One Pharmacy 6525 S. Port Apache Rd #140 Las Vegas, NV 89148
 Name and Address of Establishment for Which License Is Requested
 If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name Patel First Name Anisha Middle Name _____
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise) N/A
 Present Residence Address-Street or RFD Venficello dr. City Las Vegas State/Zip NV 89138
 Present Business Address _____ City _____ State/Zip _____
 Occupation CPA Dates _____ Phone Residence _____ Business N/A
 Date of Birth _____ Place of Birth (City, County, State) West Covina, CA Sex Female
 Age 39 Social Security Number or ITIN _____
 Color of Eyes Brown Color of Hair Black Complexion medium Weight 105 lbs Build petite Height 5'0"
 Scars, tattoos or distinguishing marks and/or characteristics N/A
 Are you a citizen of the United States? ☒ Yes ☐ No If alien, registration No N/A
 If naturalized, certificate No N/A Date N/A
 Place N/A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ ☒ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial AP

MARITAL INFORMATION-Continued

A. **Current Marriage** 3/4/2009 Dholka, Gujarat India
Date City, County and SS# or ITIN
 Spouse's full name (Maiden) Ritesh R. Patel
 Date of Birth _____ Place of Birth Dholka, India
 Resident address Venticello dr. Las Vegas NV 89138
Street City State Zip
 Telephone: Residence _____ Business 702-527-7977
 Spouse's employer CURRY Leaf Occupation Self-employed
 Address of employer S. Fort Apache Rd #101 Las Vegas, NV 89148
Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Shaan Patel		Las Vegas, NV	Venticello dr. Las Vegas, NV 89138
Riaan Patel		Las Vegas, NV	Venticello dr. Las Vegas, NV 89138
N/A			

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial AP

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Father

Kanu N. Patelchambolle ct. Las Vegas, NV 89144 self-employed

Mother

Jaya K. Patelchambolle ct. Las Vegas, NV 89144 home-maker

Father-in-Law

Ramesh H. PatelKapurwada, Dholka Gujarat India

Mother-in-Law

Milababen PatelVentcello dr. Las Vegas, NV 89138 home-maker**D. Brothers and Sisters:**

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Spouse

Kamalesh PatelAmador Ranch Las Vegas, NV 89149 EngineerMeeta PatelAmador Ranch Las Vegas, NV 89149 pharmacist

Spouse

Rajesh PatelBayhaven ct Las Vegas, NV 89131 self-employedSanka PatelBayhaven ct. Las Vegas, NV 89131 Dentist

Spouse

MANIANIA

Spouse

MA**4. EDUCATION:**

	Name of School	Location	Dates Attended	Graduate
Grammar School	<u>N/A</u>			Yes <input checked="" type="radio"/> No <input checked="" type="radio"/>
High School	<u>Diamond Bar HS</u>	<u>Diamond Bar, CA</u>	<u>1996-1999</u>	Yes <input checked="" type="radio"/> No <input checked="" type="radio"/>
College University	<u>Cal Poly Pomona</u>	<u>Pomona, CA</u>	<u>1999-2002</u>	Yes <input checked="" type="radio"/> No <input checked="" type="radio"/>
Other	<u>University of Las Vegas</u>	<u>Las Vegas, NV</u>	<u>2005-2007</u>	Yes <input checked="" type="radio"/> No <input checked="" type="radio"/>

Type of degree obtained, if any BS in Business Admin / CIS ; MS in AccountancyCollege or university where obtained Cal-Poly Pomona ; UNLV

Applicant's initial

AP

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces?

Yes ☐ No ☒Branch NIA Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☒ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft?

Yes ☐ No ☒County NIA State _____ Date registered _____**6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)**

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)

Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

NIAB. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? NIA city, county and state _____G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? NIA city, county and state _____H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
------	--------------	--------	----------	------

NIANIANIAApplicant's initial AP

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☐ No ☒ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
--	------------	-----------------------	------------------------	------------------

N/A

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
----------------	----------------	---

N/A

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
--------------------------	-------------------	------	-----------------

Present - 06/2018

Ventucello Dr

Las Vegas NV 89138

2002 - 06/2018

1500 chambolle ct.

Las Vegas, NV 89144

1995 - 2002

1628 Fire Hollow dr.

Diamond Bar, CA 91765

N/A

Applicant's initial

AP

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
09/2010 - Present	DOT 1787 W Lake Mead Blvd. LVNV 891106	Pursue other opportunities
Title	Description of Duties	Name of Supervisor
Forensic Accountant	Financial Analysis	Neal Umphress
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
08/2005	Gaming Control Board	FBI Job
Title	Description of Duties	Name of Supervisor
Auditor	Audit Gaming Establishments	Linda Tobin
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
04/2004	McCarran Intl Airport	Gaming Job
Title	Description of Duties	Name of Supervisor
Financial Office Assistant I	Accounts Receivable duties	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
03/2003	Circus Circus Hotel & Casino	County Job
Title	Description of Duties	Name of Supervisor
Database marketing clerk	Database mgmt/mkt	Tom Malloy
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
11/2002	Twin Peaks software Pasadena CA	moved to Las Vegas
Title	Description of Duties	Name of Supervisor
Tech. Support Rep.	Technical Support	Emanuel Nkulilia
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
01/2002	Peninsula Luggage & Gifts Walnut CA	Seasonal Job
Title	Description of Duties	Name of Supervisor
Store clerk	customer service	Urmika Patel
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial AP

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name <u>Nate Nash</u>	Home	<u>Las Vegas</u>	<u>NV</u>	<u>89106</u>		<u>10 years</u>
Employer <u>self employed</u>	Business					
Name <u>Tammi Owens</u>	Home	<u>Reno, NV</u>				<u>15 years</u>
Employer <u>GCB</u>	Business					
Name <u>Parvin Patel</u>	Home	<u>Las Vegas, NV</u>				<u>20 years</u>
Employer <u>Self employed</u>	Business					
Name <u>David Reed</u>	Home	<u>Las Vegas, NV</u>				<u>6 years</u>
Employer <u>Banker</u>	Business	<u>Wells Fargo</u>				
Name	Home					
Employer	Business					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☒ No ☐
If yes, complete the following.

Box Number or Type of Depository	Location	City and State	Authorized Users
<u>N/A</u>			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

CPA - Nevada - 2009 (held since)

12. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

Applicant's initial

XP

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☒ No

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☒ No

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☒ No

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☒ No

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer) Yes ☒ No

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☒ No



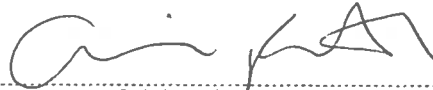
STATE OF Nevada

ss.

COUNTY OF Clark

I, Anisha Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.



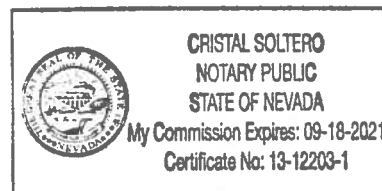
Original Signature of Applicant

Subscribed and Sworn to before me this 17th day of April, 2020



Notary Public

(seal)



Applicant's initial



Page 9

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GENERAL INSTRUCTIONS

1. PERSONAL INFORMATION:

2. MARITAL INFORMATION:

Page 1

A. **Current Marriage** N/A

Spouse's full name (Maiden) N/A Date N/A City, County and State N/A
 S.S. No. N/A

Date of Birth N/A Place of Birth N/A

Resident address N/A Street City State Zip

Telephone: Residence N/A Business N/A

Spouse's employer N/A Occupation N/A

Address of employer N/A Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
Karolin Avakian	10/2003	Los Angeles, CA	Divorced	Los Angeles, CA
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
Unknown					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
N/A			
N/A			
N/A			

B. Child Support Information:

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial SM

District attorney or public agency responsible for enforcing the child support order:

Name N/AAddress N/AContact person N/A**C. Parents:**

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father			
Garegin Soukiazian		N. J. CA 91501	Retired
Mother			
Zartar Tourisian		CA 91501	Retired
Father-in-Law			
N/A			
Mother-in-Law			
N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Souren Soukiazian		Bethany Rd Burbank CA	Engineer
Spouse			
Annette Soukiazian		Bethany Rd Burbank CA	Judge
Arevik Soukiazian		Sepulveda Blvd #3 North Hills, CA	Technician
Spouse			
N/A			
Armine Soukiazian		Sunland Park Dr #45 Sun Valley, CA	City Clerk
Spouse			
N/A			
N/A			
Spouse			
N/A			

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
High School	Burbank High School	Burbank, CA 1988-1991	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	Western University of Health Sciences	Pomona, CA 1998-2002	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Doctor of PharmacyCollege or university where obtained Western University of Health SciencesApplicant's initial SM

5 MILITARY INFORMATION:

2150

A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☒ No ☐

County Los Angeles State CA Date registered 1991

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☒ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
2008	35	Misdemeanor	Los Angeles, CA		Van Nuys Court House

N/A

N/A

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				

N/A

N/A

N/A

Applicant's initial SM

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Plaintiff	01/2019	BC 721862	Superior Court of CA	

N/A

N/A

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
2015 to Current	P.O. E	Las Vegas	NV 89126
Current	312 Antelope Way	Las Vegas	NV 89145
2002 to 2020	7766 N Glenoaks Blvd	Burbank	CA 91504
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			

Applicant's initial SM

8. EMPLOYMENT:

2152

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
06/2007 - 08/2018	Verdugo Care Pharmacy	Full Time
Title	Description of Duties	Name of Supervisor
Owner/Pharmacist		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
03/2005 -12/2007	Reliable Solutions Inc	Part time
Title	Description of Duties	Name of Supervisor
Pharmacist	On Call Pharmacist	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
10/2003-3/2005	Costco Wholesaler Pharmacy	Part time
Title	Description of Duties	Name of Supervisor
Pharmacist	Floater Pharmacist	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
03/2001-10/2003	Kaiser Permanente Pharmacy	Full Time
Title	Description of Duties	Name of Supervisor
Pharmacist	West LA Clinics	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
06/1991-3/2004	Glenoaks Pharmacy	Full Time
Title	Description of Duties	Name of Supervisor
Pharmacy Tech/Pharmacist		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial.....SM

9. CHARACTER REFERENCES:

2153

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Stan Cohen	Home	Las Vegas, NV				6 years
Employer Ameriprise	Business	Finance Office				
Name Hootan Melamed	Home	Los Angeles, CA				22 years
Employer Self Employed	Business	Pharmacentricals				
Name Ed Setaghian	Home	Los Angeles, CA				30 years
Employer Glenoaks Pharmacy	Business	Burbank, CA				
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

Pharmacist Licenses in Nevada and California

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Verdugo Care Pharmacy 8908 Glenoaks Blvd Sun Valley, CA 91352

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No ☐

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

N/A

Applicant's initial SM

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☒ No ☐

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

N/A

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☒ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☒ No ☐

ATTACH PHOTOGRAPH

TAKEN WITHIN LAST

30 DAYS HERE

Date of photograph 4/15/2020

Applicant's initial SM

COUNTY OF Clark County

I, Serj S. Markarian, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

STATE OF CALIFORNIA
COUNTY OF LOS ANGELES


Original Signature of Applicant

Subscribed and Sworn to before me this 17 day of

APRIL 2020




Notary Public

(seal)

Applicant's initial SM

N/A

Applicant's initial SM

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date 4/17/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Retail Pharmacy
 Plus One Pharmacy 6525 S. Fort Apache Rd. Suite 140 Las Vegas, NV 89148
 Nature of Pharmacy or Wholesaler
 Name and Address of Business for Which Designated Representative is Requested
 If applicable Name Under Which It is Now Operated

1. PERSONAL INFORMATION:

Last Name Markarian First Name Serj Middle Name Soukaz

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Seroj Soukiazian

Present Residence Address-Street or RFD P.O. Bo City Las Vegas State/Zip NV 89126

Present Business Address N/A City _____ State/Zip _____

Present Position with the Pharmacy or Wholesaler Pharmacist Phone: Residence (818) 618-2069

Business _____

Date of Birth _____ Place of Birth (City, County, State) Tehran, Iran

Age 46 Social Security Number _____ Sex Male

Color of Eyes Green Color of Hair Brown Complexion White Weight 190 Lbs Build Athletic Height 5'11"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No N/A

If naturalized, certificate No N/A Date N/A

Place N/A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☐ Separated ☐ Divorced ☒ Widowed ☐ Engaged ☐

Applicant's initial SM

MARITAL INFORMATION-Continued

A. **Current Marriage** N/A

Spouse's full name (Maiden) N/A Date N/A City, County and State N/A
 S.S. No. N/A

Date of Birth N/A Place of Birth N/A

Resident address N/A
 Street City State Zip

Telephone: Residence N/A Business N/A

Spouse's employer N/A Occupation N/A

Address of employer N/A
 Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
Karolin Avakian	10/2003	Los Angeles, CA	Divorced	Los Angeles, CA
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
Unknown					
N/A					

3. **FAMILY INFORMATION:**

A. **Children and Dependents:**

List all children, including step-children and adopted children and give the following information.

Name	Birth Date	Birth Place	Residence Address
N/A			
N/A			
N/A			

B. **Child Support Information:**

Please mark the appropriate response:

- ☒ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial SM

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/AAddress N/AContact person N/A**C. Parents:**

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Father			
Garegin Soukiazian	3	CA 91501	Retired
Mother			
Zartar Tourisian	40	CA 91501	Retired
Father-in-Law			
N/A			
Mother-in-Law			
N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Souren Soukiazian		Bethany Rd Burbank CA	Engineer
Spouse			
Annette Soukiazian		Bethany Rd Burbank CA	Judge
Arevik Soukiazian		Sepulveda Blvd #3 North Hills, CA	Technician
Spouse			
N/A			
Armine Soukiazian		Sunland Park Dr #45 Sun Valley, CA	City Clerk
Spouse			
N/A			
N/A			
Spouse			
N/A			

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
High School	Burbank High School	Burbank, CA 1988-1991	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	Western University of Health Sciences	Pomona, CA 1998-2002	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Doctor of PharmacyCollege or university where obtained Western University of Health SciencesApplicant's initial SM

5 MILITARY INFORMATION:

- A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

- B. Have you registered for the draft? Yes ☒ No ☐

County Los Angeles State CA Date registered 1991

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

- A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☒ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
2008	35	Misdemeanor	Los Angeles, CA		Van Nuys Court House
N/A					
N/A					

- B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes, furnish details on page 10.
- C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒
- D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒
- E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒
- F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒ If yes, when? _____ city, county and state _____
- G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒ If yes when? _____ city, county and state _____
- H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial SM

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☒ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
Plaintiff	01/2019	BC 721862	Superior Court of CA	
N/A				
N/A				

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
2015 to Current	P.O.	Las Vegas	NV 89126
Current	312 Antelope Way	Las Vegas	NV 89145
2002 to 2020	7766 N Glenoaks Blvd	Burbank	CA 91504
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			

Applicant's initial SM

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
06/2007 - 08/2018	Verdugo Care Pharmacy	Full Time
Title	Description of Duties	Name of Supervisor
Owner/Pharmacist		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
03/2005 -12/2007	Reliable Solutions Inc	Part time
Title	Description of Duties	Name of Supervisor
Pharmacist	On Call Pharmacist	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
10/2003-3/2005	Costco Wholesaler Pharmacy	Part time
Title	Description of Duties	Name of Supervisor
Pharmacist	Floater Pharmacist	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
03/2001-10/2003	Kaiser Permanente Pharmacy	Full Time
Title	Description of Duties	Name of Supervisor
Pharmacist	West LA Clinics	
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
06/1991-3/2004	Glenoaks Pharmacy	Full Time
Title	Description of Duties	Name of Supervisor
Pharmacy Tech/Pharmacist		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial SM

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Stan Cohen	Home	Las Vegas, NV				6 years
Employer Ameriprise	Business	Finance Office				
Name Hootan Melamed	Home	Los Angeles, CA				22 years
Employer Self Employed	Business	Pharmacentricals				
Name Ed Setaghian	Home	Los Angeles, CA				30 years
Employer Glenoaks Pharmacy	Business	Burbank, CA				
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

Pharmacist Licenses in Nevada and California

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☒ No ☐

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Verdugo Care Pharmacy 8908 Glenoaks Blvd Sun Valley, CA 91352

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No ☐

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

N/A

Applicant's initial SM

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☒ No ☐

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒

N/A

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☒ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☒ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☒ No ☐



STATE OF _____

ss.

COUNTY OF _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this _____ day of _____

Notary Public

(seal)

Applicant's initial _____ SM

BOARD OF PHARMACY

LICENSING DETAILS FOR: RPH 54284

NAME: MARKARIAN, SERJ SOUKAZ

LICENSE TYPE: REGISTERED PHARMACIST

LICENSE STATUS: CANCELLED

SECONDARY STATUS: VOLUNTARY SURRENDER ♦ PROBATION

ADDRESS NOT DISCLOSED

ISSUANCE DATE

MARCH 20, 2003

EXPIRATION DATE

SEPTEMBER 30, 2014

CURRENT DATE / TIME

SEPTEMBER 21, 2020
4:02:12 PM

PUBLIC RECORDS

DISCIPLINARY ACTIONS (2)

DISCLAIMER: DISCIPLINARY ACTIONS

DESCRIPTION: CURRENT WEB SITE INFORMATION ON BOARD OF PHARMACY DISCIPLINARY ACTIONS ONLY GOES AS FAR BACK AS *JANUARY 1998* FOLLOWING THE EFFECTIVE DATE OF THE DISCIPLINARY PENALTY.

DISCIPLINARY ACTIONS RENDERED BY THE BOARD AND PENALTIES IMPOSED BECOME OPERATIVE ON THE EFFECTIVE DATE OF THE ACTION EXCEPT IN SITUATIONS WHERE THE LICENSEE OBTAINS A COURT-ORDERED STAY THROUGH THE APPEAL PROCESS. THIS MAY OCCUR AFTER THE PUBLICATION OF THE INFORMATION ON THIS WEBSITE.

TO OBTAIN INFORMATION PRIOR TO JANUARY 1998 OR FOR INFORMATION ON SPECIFIC DISCIPLINE LISTED SUBMIT A WRITTEN REQUEST TO THE *STATE BOARD OF PHARMACY, 1625 N. MARKET BLVD, SUITE N219, SACRAMENTO, CA 95834, ATTENTION PUBLIC RECORDS DESK.*

PUBLIC DISCLOSURES:

♦ **CASE NUMBER:** AC201200464500

♦ **EFFECTIVE DATE OF ACTION:** JUNE 20, 2014

♦ **DESCRIPTION OF ACTION:** BY HEARING DECISION: THE LICENSE IS REVOKED, REVOCATION STAYED, AND PLACED ON PROBATION FOR 5 YEARS SUBJECT TO THE TERMS AND CONDITIONS IN THE DECISION. 8/15/2014 LICENSE SURRENDERED PER THE TERMS OF PROBATION.

♦ **CASE NUMBER:** AC200900360100

♦ **EFFECTIVE DATE OF ACTION:** JUNE 7, 2012

♦ **DESCRIPTION OF ACTION:** BY STIPULATION: LICENSED REVOKED, REVOCATION STAYED, 5 YEARS PROBATION SUBJECT TO TERMS AND CONDITIONS WHICH INCLUDE: SUSPENDED FROM PRACTICING PHARMACY FOR 60 DAYS, CANNOT SUPERVISE ANY INTERN PHARMACIST PERFORM PRECEPTOR DUTIES OR BE PIC.

PUBLIC DOCUMENTS

DOCUMENTS (2)

CASE NUMBER: AC201200464500

DOCUMENT: LINK

CASE NUMBER: AC200900360100

DOCUMENT: LINK


California State Board of Pharmacy

 1625 N. Market Blvd., N219, Sacramento, CA 95834
 Phone: (916) 574-7900
 Fax: (916) 574-8618
 www.pharmacy.ca.gov

 BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

 RECEIVED
 2014 AUG 11 AM 10:54
 MARKARTIAN

APPLICATION FOR VOLUNTARY SURRENDER OF PHARMACIST / INTERN LICENSE

PLEASE PRINT IN BLACK OR BLUE INK OR TYPE YOUR RESPONSES

Name: <u>SERJ S MARKARTIAN</u>	Case No. <u>4645</u>
Address of Record: <u>7766 N. Glenoaks Blvd.</u> <u>Burbank CA 91504</u>	

Pursuant to the terms and conditions of my probation with the California State Board of Pharmacy (Board) in Case No. 4645, I hereby request to surrender my license, License No. 54284. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, I will no longer be subject to the terms and conditions of probation. I understand that this surrender constitutes a record of discipline and shall become a part of my license history with the Board.

Upon the acceptance of the surrender, I shall relinquish my pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. I understand that I may not reapply for any license from the board for three (3) years from the effective date of the surrender. I further understand that I shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

PLEASE BE ADVISED THAT YOU ARE NOT RELIEVED OF THE REQUIREMENTS OF YOUR PROBATION UNLESS THE BOARD NOTIFIES YOU THAT YOUR REQUEST TO SURRENDER YOUR LICENSE HAS BEEN ACCEPTED.

Applicant's Signature

Executive Officer's Approval

Date

8/5/14
8/15/14

All items on this application are mandatory in accordance with your probationary order and the Board's Disciplinary Guidelines as authorized by Title 16, California Code of Regulations section 1760. Failure to provide any of the requested information or providing unreadable information will result in the application being rejected as incomplete. The information provided on this form will be used to determine eligibility for surrender. The official responsible for information maintenance is the Executive Officer, telephone (916) 574-7900, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. The information you provide may also be disclosed in the following circumstances: (1) in response to a Public Records Act request; (2) to another government agency as required by state or federal law; or, (3) in response to a court or administrative order, a subpoena, or a search warrant. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.40 of the Civil Code.

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation and Petition to
Revoke Probation Against:

Case No. 4645

OAH No. 2013101152

**SERJ SOUKAZ MARKARIAN, AKA SEROJ
SOUKIAZIAN**

7766 N. Glenoaks Blvd.
Burbank, CA 91504

Pharmacist License No. RPH 54284

Respondent.

DECISION AND ORDER

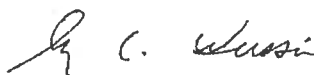
The attached Proposed Decision of the Administrative Law Judge is hereby adopted
by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on June 20, 2014.

It is so ORDERED on May 21, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STAN C. WEISSER
Board President

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation and Petition to
Revoke Probation Against:

SERJ SOUKAZ MARKARIAN, AKA SEROJ
SOUKIAZIAN
Pharmacist License No. RPH 54284

Case No. 4645

OAH No. 2013101152

Respondent.

PROPOSED DECISION

This matter was heard by Laurie R. Pearlman, Administrative Law Judge (ALJ) with the Office of Administrative Hearings, on March 21, 2014, in Los Angeles, California. Complainant was represented by William D. Gardner, Deputy Attorney General. Serj Soukaz Markarian, aka Seroj Soukiazian (Respondent) was represented by Tony J. Park, Attorney at Law.

Oral and documentary evidence was received and argument was heard. The record was closed and the matter was submitted for decision on March 21, 2014.

FACTUAL FINDINGS

1. On September 19, 2013, Complainant Virginia Herold (Complainant) filed the Accusation and Petition to Revoke Probation while acting in her official capacity as Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On March 20, 2003, the Board issued Pharmacist License No. RPH 54284 to Respondent. The Pharmacist License is in full force and effect and will expire on September 30, 2014, unless renewed.

Prior Discipline of Respondent's Pharmacist License

3. Effective June 17, 2012, in Case No. 3601, entitled *In the Matter of the Accusation against Serj Soukaz Markarian* (Prior Decision), the Board revoked Respondent's Pharmacist License. However, the revocation was stayed, his license was suspended for 60 days and Respondent's License was placed on probation for five years under terms and conditions which included the following:

[Condition] 4. Interview with Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

[¶] . . . [¶]

[Condition] 7. Notification to Pharmacist-in-charge

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 3601 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 3601, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

[¶] . . . [¶]

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

[Condition] 17. Mental Health Evaluation

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a

board-appointed or board-approved licensed mental health practitioner. The approved evaluator shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.

[Condition] 18. Pharmacists' Recovery Program

Within thirty (30) days of the effective date of this decision, respondent shall contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

[¶] . . . [¶]

Failure to timely contact or enroll in the PRP, or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

[¶] . . . [¶]

[Condition] 19. Random Drug Screening

Respondent, at his own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any

confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

[¶] . . . [¶]

[Condition] 20. Abstain from Drug and Alcohol Use

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

[¶] . . . [¶]

[Condition] 21. Prescription Coordinator/Monitor

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the facts and circumstances giving rise to Accusation 3601 and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's Accusation and decision. A record of this notification must be provided to the board upon request. . . .

[¶] . . . [¶]

///

///

[Condition] 22. Community Service Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least sixty (60) hours per year for the first three (3) years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

[¶] . . . [¶]

[Condition] 24. Leaving State of California

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

Bases for Discipline

4. In the Accusation, Complainant alleged that Respondent's license is subject to disciplinary action in that he engaged in an act of dishonesty, fraud and/or deceit by making false representations to the Board and by signing a document that falsely represented certain facts to the Board.

5. Complainant established, by clear and convincing evidence, that Respondent engaged in an act of dishonesty, fraud and/or deceit in that on September 6, 2012, he signed a

license renewal application under penalty of perjury which falsely stated that he had successfully completed the hours of continuing education required for renewal. In fact, Respondent had taken the courses prior to the reporting period. During the Board's audit of Respondent's continuing education hours, Respondent made additional false representations to the Board regarding his continuing education hours.

Bases to Revoke Probation

6. In the Petition to Revoke Probation, Complainant alleged several bases for revocation of probation based on Respondent's failure to comply with the terms and conditions of probation. Samim Samari, an Investigator employed by the Board, testified credibly at the hearing. She was assigned to monitor Respondent as a probationer. All of the bases for revocation of probation were established as follows:

(a) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 4 of the Prior Decision in that Respondent failed to appear for an office conference as scheduled on June 22, 2012, and did not contact the Board regarding his absence.

(b) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 7 of the Prior Decision in that he failed to timely submit notification to the Board of his pharmacist-in-charge's acknowledgment that he had read the decision in case number 3601, and the terms and conditions imposed thereby. Such notification was due by July 7, 2012, but was not received by the Board until October 5, 2012.

(c) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 17 of the Prior Decision in that he failed to undergo a psychiatric evaluation within thirty days of the effective date of probation and did not timely submit evidence of completion of such an evaluation.

(d) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 18 of the Prior Decision in that Respondent failed to timely enroll and participate in the Pharmacists Recovery Program (PRP), as he did not contact PRP until December 13, 2012, which was six months after the effective date of probation. Additionally, on January 2, 2013, and January 7, 2013, Respondent failed to report daily to PRP, and on January 3, 2013, January 10, 2013, and March 9, 2013, Respondent failed to test, as scheduled.

(e) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 19 of the Prior Decision in that on January 2, 2013, and January 7, 2013, Respondent failed to report daily to confirm whether a test was required, and on January 3, 2013, January 10, 2013, and March 9, 2013, Respondent failed to test, as scheduled.

(f) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 20 of the Prior Decision in that Respondent tested positive for alcohol on March 11, 2013.

(g) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 21 of the Prior Decision in that Respondent failed to timely establish, or notify the Board that he had established, a practitioner to coordinate and monitor his prescriptions.

(h) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 22 of the Prior Decision in that Respondent failed to timely complete the procedures for submitting a community service program for approval by the Board or timely commence working with a Board-approved community service program.

(i) Complainant established, by clear and convincing evidence, that Respondent violated probationary condition number 24 of the Prior Decision in that Respondent traveled outside of California in excess of ten days during his period of license suspension and failed to timely notify the Board in writing of his absence from California within ten days of his departure or return.

Rehabilitation and Mitigation

7. Rose Safran (Safran), testified credibly on behalf of Respondent. She is licensed in California as a Marriage and Family Therapist and specializes in addiction. Safran has been a recovering addict with 28 years of sobriety. She opened an in-hospital day treatment program and has been a facilitator for an addiction peer-counseling group since 1991. Safran met Respondent when he was participating in the Promises Recovery Program (Promises.) Promises is a residential substance abuse treatment program with a specific track for health care professionals. At Promises, participants spend sixty days under the supervision of Promises' staff, and participate in individual and group therapy with other addicts who are health care professionals. Respondent entered the Promises program after he relapsed on March 11, 2013. His sobriety date is March 18, 2013. Respondent completed the Promises program in May 2013. For over a year, Respondent has consistently participated in Safran's Health Care Professionals Peer Support Group for licensees who are dealing with substance abuse issues. Participants are part of a Board diversion program overseen by Maximus, a contractor of the State of California. The group meets twice a week, for one and a half hours per session. After eighteen months to two years of participation, Safran generally recommends a decrease in attendance at group meetings to once weekly. In her group, participants discuss issues with recovery, jobs and the twelve-step program. Participants are required to remain active in Safran's group until they are out of diversion. In Respondent's case, she expects that he will remain in her group for three to five years. Respondent has submitted to the increased level of testing required by Maximus. His drug test results demonstrate that Respondent has been free of all substances for more than fourteen months. On behalf of Respondent, Safran sends a monthly report to his case manager at Maximus. When he first began his probation, Respondent was still in active

addiction and was "very overwhelmed." He is now "an addict in full, sustained remission" and is remorseful for his actions while in active addiction. Respondent follows a twelve-step program, has a sponsor, and has re-directed his social life so that his friends now consist of other group members who are in recovery and he no longer associates with his former friends with whom he had used alcohol or drugs. Respondent has demonstrated to Safran that he is willing to do whatever is asked of him with enthusiasm and he is now feeling positive about his life and his recovery. Respondent has been in full compliance with all probationary terms since completing the Promises program and would not pose a danger to the public if he were permitted to work as a pharmacist, even given the fact that he owns his own pharmacy. At his own pharmacy, Respondent has another pharmacist-in-charge who is responsible for monitoring Respondent in the workplace.

8. Respondent testified credibly and was respectful of the proceedings. He readily admits that "all of the allegations in the pleading are true" and he does not deny them. Respondent enrolled in Promises in March 2013, and successfully completed the program. All of the violations alleged in the instant Accusation and Petition to Revoke Probation occurred prior to his enrollment at Promises. Before enrolling in Promises, he "was a mess," was in a state of depression and "did not know about addiction at that time." He has been in full compliance with his conditions of probation and realizes that he is in "a life or death situation." It is "not about a job." Respondent wants "to be well physically, mentally, emotionally and spiritually." Because he acknowledges that he is an addict, he recognizes that maintaining his recovery requires "extreme vigilance" on his part. Respondent participates in Safran's Health Care Professionals Support Group from 9:30 a.m. until 11 a.m. two days per week. In addition, he attends six to eight Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) meetings each week. Respondent is the secretary at one meeting and brings in speakers to talk about recovery. He provides "literature service" at another meeting where he talks about the AA magazine. Respondent calls his clinical case manager at Maximus each month. Respondent realized that his "environment needed to change" and his "social life is now different." He no longer maintains friendships with those with whom he "drank and partied socially prior to recovery." He wants "the sobriety and comfort in life" that those in recovery demonstrate and he "will continue on that path." Respondent volunteers at a soccer club in the area as a certified referee. He provides support for his elderly parents, his two divorced sisters, and his five nieces and nephews. His license was suspended for 60 days in 2012 pursuant to probationary condition 1. Due to his unauthorized absence from the State of California, Respondent's license was suspended again from February 2013 through November 2013. The suspension has been lifted, but Respondent is not currently working. He now feels confident in his ability to work as a pharmacist, even at the pharmacy he owns.

9. Five individuals provided character references in support of Respondent's continued licensure. These letters were admitted as administrative hearsay.¹ Each writer emphasized Respondent's commitment to his recovery and the transformation he has made.

¹ The term "administrative hearsay" is a shorthand reference to the provisions of Government Code section 11513, subdivision (d), to the effect that hearsay evidence that is

Costs of Investigation and Prosecution

10. Complainant submitted evidence of costs of investigation and prosecution of this matter, totaling \$1,930. This includes costs for the Accusation, as well as the Petition to Revoke Probation. Complainant attempted to "cull out" those costs related to the Accusation, from those costs related to probation violations (for which costs are not awarded.) Since there is one cause for discipline and nine violations of probation, Complainant seeks one-tenth of the total amount, which is \$193. That amount is reasonable.

LEGAL CONCLUSIONS

1. Cause exists to revoke or suspend Respondent's Pharmacist License, pursuant to Business and Professions Code section 4301, subdivisions (f) and (g), for unprofessional conduct in that Respondent engaged in an act of dishonesty, fraud or deceit by making false representations to the Board and by signing a document that falsely represented certain facts to the Board, as set forth in Factual Findings 4, 5 and 8.

2. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 4 (Interview with Board), as set forth in Factual Findings 3, 6 and 8.

3. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 7 (Notification to Pharmacist-in-charge), as set forth in Factual Findings 3, 6 and 8.

4. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 17 (Mental Health Evaluation), as set forth in Factual Findings 3, 6 and 8.

5. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 18 (Pharmacist Recovery Program), as set forth in Factual Findings 3, 6 and 8.

6. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 19 (Random Drug Screening), as set forth in Factual Findings 3, 6 and 8.

objected to, and is not otherwise admissible, may be used to supplement or explain other evidence but may not, by itself, support a factual finding.

7. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 20 (Abstain from Drug and Alcohol Use), as set forth in Factual Findings 3, 6 and 8.

8. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 21 (Prescription Coordinator/Monitor), as set forth in Factual Findings 3, 6 and 8.

9. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 22 (Community Service Program), as set forth in Factual Findings 3, 6 and 8.

10. Cause exists to revoke Respondent's probation and reimpose the order of revocation of Respondent's Pharmacist License, in that Respondent failed to comply with Probation Term Number 24 (Leaving State of California), as set forth in Factual Findings 3, 6 and 8.

11. Pursuant to Business and Professions Code section 125.3, Complainant is entitled to recover reasonable costs of investigation and prosecution of this matter in the amount of \$193, as set forth in Factual Finding 10.

12. Respondent readily admitted that he violated the terms of his probation and engaged in unprofessional conduct. He has taken full responsibility for his actions and has expressed sincere remorse for his conduct. Respondent has taken concrete steps to change his life, has acted to address his problems with addiction and appears fully committed to his recovery. His drug test results confirm that Respondent has been free of all substances for more than fourteen months. Rehabilitation and mitigation were established and assurance of Respondent's future compliance with probationary terms was provided. Consequently, probation in this matter with carefully structured terms and conditions is appropriate and is likely to ensure adequate public protection.

ORDER

WHEREFORE, THE FOLLOWING ORDERS are hereby made:

1. Pharmacist License No. RPH 54284, issued to Serj Soukaz Markarian, is hereby revoked. However, the revocation is stayed and Respondent is placed on probation for five years on the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms

and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4645 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4645, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4645 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number 4645 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or

any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$193, within 90 days of the effective date of this Decision.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

9. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10)

days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. Mental Health Examination

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health practitioner. The approved evaluator shall be provided with a copy of the board's Accusation and Petition to Probation and this

Decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.

If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's Accusation and Petition to Revoke Probation and this Decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental

health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

17. Pharmacists Recovery Program (PRP)

Within thirty (30) days of the effective date of this decision, respondent shall contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362(c)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

Probation shall be automatically extended until respondent successfully completes the PRP. Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or

dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

18. Random Drug Screening

Respondent, at his own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any

other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

19. Abstain from Drugs and Alcohol Use

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

20. Prescription Coordination and Monitoring of Prescription Use

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the facts and circumstances giving rise to the

Accusation and the Petition to Revoke Probation in Case No. 4645 and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's accusation and petition to revoke probation and this decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board for approval, or to ensure the required reporting thereby on the quarterly reports, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a pharmacist, the practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained.

Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

21. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 60 hours per year for the first three years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

22. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

23. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

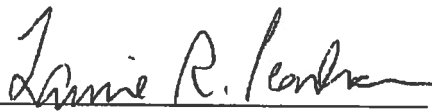
Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

24. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

DATED: April 21, 2014


LAURIE R. PEARLMAN
Administrative Law Judge
Office of Administrative Hearings

1 KAMALA D. HARRIS
 Attorney General of California
 2 KAREN B. CHAPPELLE
 Supervising Deputy Attorney General
 3 WILLIAM D. GARDNER
 Deputy Attorney General
 4 State Bar No. 244817
 300 So. Spring Street, Suite 1702
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 6 Facsimile: (213) 897-2804
Attorneys for Complainant
 7

8 **BEFORE THE**
BOARD OF PHARMACY
 9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA
 10

11 In the Matter of the Accusation and Petition to
 Revoke Probation Against,
 12

Case No. 4645

13 **SERJ SOUKAZ MARKARIAN, AKA**
SEROJ SOUKIAZIAN
 14 7766 N. Glenoaks Blvd.
 Burbank, CA 91504
 Pharmacist License No. RPH 54284
 15

**ACCUSATION AND PETITION TO
 REVOKE PROBATION**

16 Respondent.
 17

18 Complainant alleges:
 19

PARTIES

20 1. Virginia Herold (Complainant) brings this Petition to Revoke Probation solely in her
 21 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
 22 Affairs.

23 2. On or about March 20, 2003, the Board of Pharmacy issued Pharmacist License
 24 Number RPH 54284 to Serj Soukaz Markarian, aka Seroj Soukiazian (Respondent). The
 25 Pharmacist License was in effect at all times relevant to the charges brought herein and will
 26 expire on September 30, 2014, unless renewed.

27 ///

28 ///

3. In a disciplinary action entitled "In the Matter of Accusation Against Serj Soukaz Markarian," Case No. 3601, the Board of Pharmacy, issued a decision, effective June 17, 2012, in which Respondent's Pharmacist License was revoked. However, the revocation was stayed and Respondent's Pharmacist License was placed on probation for a period of five (5) years with certain terms and conditions. A copy of that decision is attached as Exhibit "A" and is incorporated by reference.

JURISDICTION AND STATUTORY

PROVISIONS FOR ACCUSATION

4. This Accusation is brought before the Board of Pharmacy (Board), under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section 4301 of the Code states, in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

....

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COST RECOVERY

7. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Dishonesty/False Representation)

8. Respondent is subject to disciplinary action under section 4301, subdivision (f) and (g), in that Respondent engaged in an act of dishonesty, fraud and/or deceit by making false representations to the Board and signing a document that falsely represented certain facts to the board. The circumstances are that on or about September 6, 2012, Respondent signed under penalty of perjury a license renewal application which falsely stated that he had successfully completed the hours of continuing education required for renewal. During the Board's audit of Respondent's continuing education hours, Respondent made additional false representations to the Board regarding his continuing education hours.

JURISDICTION FOR PETITION TO REVOKE PROBATION

9. This Petition to Revoke Probation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under Probation Term and Condition Number 15 of the Decision and Order In the Matter of Accusation Against Serj Soukaz Markarian, Case No. 3601. That term and condition states as follows:

"If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order

1 that was stayed. Notice and opportunity to be heard are not required for those provisions stating
 2 that a violation thereof may lead to automatic termination of the stay and/or revocation of the
 3 license. If a petition to revoke probation or an accusation is filed against respondent during
 4 probation, the board shall have continuing jurisdiction and the period of probation shall be
 5 automatically extended until the petition to revoke probation or accusation is heard and decided."

6 **FIRST CAUSE TO REVOKE PROBATION**

7 **(Interview with Board)**

8 10. At all times after the effective date of Respondent's probation, Condition 4 stated:

9 "Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
 10 with the board or its designee, at such intervals and locations as are determined by the board or its
 11 designee. Failure to appear for any scheduled interview without prior notification to board staff,
 12 or failure to appear for two (2) or more scheduled interviews with the board or its designee during
 13 the period of probation, shall be considered a violation of probation."

14 11. Respondent's probation is subject to revocation because he failed to comply with
 15 Probation Condition 4, referenced above. The facts and circumstances regarding this violation
 16 are that Respondent failed to appear for an office conference as scheduled on June 22, 2012, and
 17 did not contact the Board regarding his absence.

18 **SECOND CAUSE TO REVOKE PROBATION**

19 **(Notification to Pharmacist-in-charge)**

20 12. At all times after the effective date of Respondent's probation, Condition 7 stated, in
 21 pertinent part:

22 "During the period of probation, respondent shall notify all present and prospective
 23 employers of the decision in case number 3601 and the terms, conditions and restrictions imposed
 24 on respondent by the decision, as follows:

25 "Within thirty (30) days of the effective date of this decision, and within fifteen (15) days
 26 of respondent undertaking any new employment, respondent shall cause his direct supervisor,
 27 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
 28 tenure of employment) and owner to report to the board in writing acknowledging that the listed

1 individual(s) has/have read the decision in case number 3601, and terms and conditions imposed
 2 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
 3 submit timely acknowledgment(s) to the board.

4 ...

5 Failure to timely notify present or prospective employer(s) or to cause that/those
 6 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
 7 probation.

8 'Employment' within the meaning of this provision shall include any full-time, part-
 9 time, temporary, relief or pharmacy management service as a pharmacist or any position for
 10 which a pharmacist license is a requirement or criterion for employment, whether the
 11 respondent is an employee, independent contractor or volunteer."

12 13. Respondent's probation is subject to revocation because he failed to comply with
 13 Probation Condition 7, referenced above. The facts and circumstances regarding this violation
 14 are that Respondent failed to timely submit notification to the Board of the pharmacist in-
 15 charge's acknowledgement that he or she had read the decision in case number 3601, and the
 16 terms and conditions imposed thereby. Such notification was not received by the Board until
 17 October 5, 2012.

18 THIRD CAUSE TO REVOKE PROBATION

19 (Mental Health Evaluation)

20 14. At all times after the effective date of Respondent's probation, Condition 17 stated, in
 21 pertinent part:

22 "Within thirty (30) days of the effective date of this decision, and on a periodic basis as
 23 may be required by the board or its designee, respondent shall undergo, at his own expense,
 24 psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health
 25 practitioner. The approved evaluator shall be provided with a copy of the board's Accusation and
 26 decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a
 27 current diagnosis and a written report regarding the respondent's judgment and ability to function

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1 independently as a pharmacist with safety to the public. Respondent shall comply with all the
2 recommendations of the evaluator if directed by the board or its designee."

3 15. Respondent's probation is subject to revocation because he failed to comply with
4 Probation Condition 17, referenced above. The facts and circumstances regarding this violation
5 are that Respondent failed to undergo a psychiatric evaluation within thirty (30) days of the
6 effective date of probation and, to date, has not submitted evidence of completion of such an
7 evaluation.

8 **FOURTH CAUSE TO REVOKE PROBATION**

9 **(Pharmacists Recovery Program)**

10 16. At all times after the effective date of Respondent's probation, Condition 18 stated, in
11 pertinent part:

12 "Within thirty (30) days of the effective date of this decision, respondent shall contact the
13 Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll,
14 successfully participate in, and complete the treatment contract and any subsequent addendums as
15 recommended and provided by the PRP and as approved by the board or its designee. The costs
16 for PRP participation shall be borne by the respondent.

17 ...

18 Failure to timely contact or enroll in the PRP, or successfully participate in and complete
19 the treatment contract and/or any addendums, shall be considered a violation of probation. . . ."

20 17. Respondent's probation is subject to revocation because he failed to comply with
21 Probation Condition 18, referenced above. The facts and circumstances regarding this violation
22 are as follows:

23 a. Respondent failed to timely enroll and participate in the Pharmacists Recovery
24 Program (PRP), as he did not contact PRP until December 13, 2012, which was six (6) months
25 after the effective date of probation. Additionally, on January 2, 2013, and January 7, 2013,
26 Respondent failed to daily report to PRP, and on January 3, 2013, January 10, 2013, and March 9,
27 2013, Respondent failed to test as scheduled.

28 ///

FIFTH CAUSE TO REVOKE PROBATION

(Random Drug Screening)

18. At all times after the effective date of Respondent's probation, Condition 19 stated, in pertinent part:

"Respondent, at his own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

....

19. Respondent's probation is subject to revocation because he failed to comply with Probation Condition 19, referenced above. The facts and circumstances regarding this violation are that on January 2, 2013, and January 7, 2013, Respondent failed to daily report to confirm whether a test was required, and on January 3, 2013, January 10, 2013, and March 9, 2013, Respondent failed to test as scheduled.

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SIXTH CAUSE TO REVOKE PROBATION

(Abstain from Drug and Alcohol Use)

20. At all times after the effective date of Respondent's probation, Condition 20 stated:

"Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation."

21. Respondent's probation is subject to revocation because he failed to comply with Probation Condition 20, referenced above. The facts and circumstances regarding this violation are that Respondent tested positive for alcohol on March 11, 2013.

SEVENTH CAUSE TO REVOKE PROBATION

(Prescription Coordinator/Monitor)

22. At all times after the effective date of Respondent's probation, Condition 21 stated, in pertinent part:

"Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the facts and circumstances giving rise to Accusation 3601 and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's Accusation and decision. A record of this notification must be provided to the board upon request. . . ."

23. Respondent's probation is subject to revocation because he failed to comply with Probation Condition 21, referenced above. The facts and circumstances regarding this violation are that, to date, Respondent has failed to establish and/or notify the Board that he has established a practitioner to coordinate and monitor his prescriptions.

EIGHTH CAUSE TO REVOKE PROBATION

(Community Service Program)

24. At all times after the effective date of Respondent's probation, Condition 22 stated:

"Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least sixty (60) hours per year for the first three (3) years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation."

25. Respondent's probation is subject to revocation because he failed to comply with Probation Condition 22, referenced above. The facts and circumstances regarding this violation are that, to date, Respondent has not completed the procedures for submitting a community service program for approval by the Board nor has commenced working with a Board-approved community service program.

NINTH CAUSE TO REVOKE PROBATION

(Leaving State of California)

26. At all times after the effective date of Respondent's probation, Condition 24 stated:

"During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the

1 suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days
 2 respondent is absent from California. During any such period of tolling of suspension,
 3 respondent must nonetheless comply with all terms and conditions of probation.

4 Respondent must notify the board in writing within ten (10) days of departure, and must
 5 further notify the board in writing within ten (10) days of return. The failure to provide such
 6 notification(s) shall constitute a violation of probation. Upon such departure and return,
 7 respondent shall not resume the practice of pharmacy until notified by the board that the period of
 8 suspension has been satisfactorily completed."

9 27. Respondent's probation is subject to revocation because he failed to comply with
 10 Probation Condition 24, referenced above. The facts and circumstances regarding this violation
 11 are that Respondent traveled outside the State of California in excess of ten (10) days during his
 12 period of suspension and did he timely not notify the Board in writing within ten (10) days of his
 13 departure or return.

14 PRAYER

15 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
 16 and that following the hearing, the Board of Pharmacy issue a decision:

17 1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 3601
 18 and imposing the disciplinary order that was stayed, thereby revoking Pharmacist License
 19 Number RPH 54284 issued to Serj Soukaz Markarian;

20 2. Revoking or suspending Pharmacist License Number RPH 54284 issued to Serj
 21 Soukaz Markarian;

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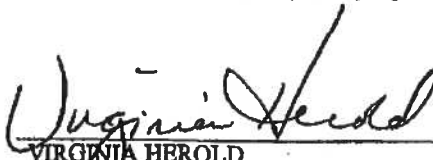
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1 3. Ordering Serj Soukaz Markarian to pay the Board of Pharmacy the reasonable costs
2 of the investigation and enforcement of this case with respect to the Accusation, pursuant to
3 Business and Professions Code section 125.3

4 4. Taking such other and further action as deemed necessary and proper.

5
6 DATED: 9/19/13



VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Exhibit A

Decision and Order

Board of Pharmacy Case No. 3601

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

SERJ SOUKAZ MARKARIAN
7766 N. Glenoaks Blvd.
Burbank, CA 91504

Pharmacist License No. RPH 54284

Respondent.

Case No. 3601

OAH No. L-2011090609

DECISION AND ORDER

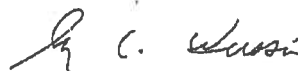
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on June 7, 2012.

It is so ORDERED on May 8, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
 Attorney General of California
 2 KAREN B. CHAPPELLE
 Supervising Deputy Attorney General
 3 WILLIAM D. GARDNER
 Deputy Attorney General
 4 State Bar No. 244817
 300 So. Spring Street, Suite 1702
 5 Los Angeles, CA 90013
 Telephone: (213) 897-2114
 6 Facsimile: (213) 897-2804
Attorneys for Complainant
 7

8 **BEFORE THE**
BOARD OF PHARMACY
 9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA
 10

11 In the Matter of the Accusation Against:

Case No. 3601

12 **SERJ SOUKAZ MARKARIAN**
 7766 N. Glenoaks Blvd.
 13 Burbank, CA 91504
 Pharmacist License No. RPH 54284
 14

OAH No. L-2011090609
STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

15 Respondent.
 16

17 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
 18 entitled proceedings that the following matters are true:

19 **PARTIES**

20 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
 21 She brought this action solely in her official capacity and is represented in this matter by Kamala
 22 D. Harris, Attorney General of the State of California, by William D. Gardner, Deputy Attorney
 23 General.

24 2. Respondent Serj Soukaz Markarian (Respondent) is represented in this proceeding by
 25 attorney Herbert L. Weinberg, whose address is: 1800 Century Park East, 8th Floor, Los
 26 Angeles, CA 90067.

27 3. On or about March 20, 2003, the Board of Pharmacy issued Pharmacist License No.
 28 RPH 54284 to Serj Soukaz Markarian (Respondent). The Pharmacist License was in full force

1 and effect at all times relevant to the charges brought in Accusation No. 3601 and will expire on
2 September 30, 2012, unless renewed.

3 JURISDICTION

4 4. Accusation No. 3601 was filed before the Board of Pharmacy (Board), Department of
5 Consumer Affairs, and is currently pending against Respondent. The Accusation and all other
6 statutorily required documents were properly served on Respondent on June 15, 2011.

7 Respondent timely filed his Notice of Defense contesting the Accusation.

8 5. A copy of Accusation No. 3601 is attached as exhibit A and incorporated herein by
9 reference.

10 ADVISEMENT AND WAIVERS

11 6. Respondent has carefully read, fully discussed with counsel, and understands the
12 charges and allegations in Accusation No. 3601. Respondent has also carefully read, fully
13 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
14 Order.

15 7. Respondent is fully aware of his legal rights in this matter, including the right to a
16 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at
17 his own expense; the right to confront and cross-examine the witnesses against him; the right to
18 present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel
19 the attendance of witnesses and the production of documents; the right to reconsideration and
20 court review of an adverse decision; and all other rights accorded by the California
21 Administrative Procedure Act and other applicable laws.

22 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
23 every right set forth above.

24 CULPABILITY

25 9. Respondent admits the truth of each and every charge and allegation in Accusation
26 No. 3601.

27 10. Respondent agrees that his Pharmacist License is subject to discipline and he agrees
28 to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 54284 issued to Respondent Serj Soukaz Markarian (Respondent) is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

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///

1 **1. Suspension**

2 As part of probation, respondent is suspended from the practice of pharmacy for sixty (60)
3 days beginning the effective date of this decision.

4 During suspension, respondent shall not enter any pharmacy area or any portion of the
5 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
6 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
7 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
8 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
9 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
10 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
11 and devices or controlled substances.

12 Respondent shall not engage in any activity that requires the professional judgment of a
13 pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy.
14 Respondent shall not perform the duties of a pharmacy technician or a designated representative
15 for any entity licensed by the board.

16 Subject to the above restrictions, respondent may continue to own or hold an interest in any
17 licensed premises in which he holds an interest at the time this decision becomes effective unless
18 otherwise specified in this order.

19 Failure to comply with this suspension shall be considered a violation of probation.

20 **2. Obey All Laws**

21 Respondent shall obey all state and federal laws and regulations.

22 Respondent shall report any of the following occurrences to the board, in writing, within
23 seventy-two (72) hours of such occurrence:

- 24 • an arrest or issuance of a criminal complaint for violation of any provision of the
25 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
26 substances laws;
- 27 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
28 criminal complaint, information or indictment;

- a conviction of any crime;
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

6. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

1 7. **Notice to Employers**

2 During the period of probation, respondent shall notify all present and prospective
3 employers of the decision in case number 3601 and the terms, conditions and restrictions imposed
4 on respondent by the decision, as follows:

5 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
6 respondent undertaking any new employment, respondent shall cause his direct supervisor,
7 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
8 tenure of employment) and owner to report to the board in writing acknowledging that the listed
9 individual(s) has/have read the decision in case number 3601, and terms and conditions imposed
10 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
11 submit timely acknowledgment(s) to the board.

12 If respondent works for or is employed by or through a pharmacy employment service,
13 respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
14 licensed by the board of the terms and conditions of the decision in case number 3601 in advance
15 of the respondent commencing work at each licensed entity. A record of this notification must be
16 provided to the board upon request.

17 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
18 (15) days of respondent undertaking any new employment by or through a pharmacy employment
19 service, respondent shall cause his direct supervisor with the pharmacy employment service to
20 report to the board in writing acknowledging that he has read the decision in case number 3601
21 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
22 that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

23 Failure to timely notify present or prospective employer(s) or to cause that/those
24 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
25 probation.

26 "Employment" within the meaning of this provision shall include any full-time, part-
27 time, temporary, relief or pharmacy management service as a pharmacist or any position for

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1 which a pharmacist license is a requirement or criterion for employment, whether the
2 respondent is an employee, independent contractor or volunteer.

3 **8. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
4 **Designated Representative-in-Charge, or Serving as a Consultant**

5 During the period of probation, respondent shall not supervise any intern pharmacist, be the
6 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
7 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
8 unauthorized supervision responsibilities shall be considered a violation of probation.

9 **9. Reimbursement of Board Costs**

10 As a condition precedent to successful completion of probation, respondent shall pay to the
11 board its costs of investigation and prosecution in the amount of \$5,657.50. Respondent shall
12 make said payments in accordance with a payment plan to be determined by the Board

13 There shall be no deviation from this schedule absent prior written approval by the board or
14 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
15 probation.

16 The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to
17 reimburse the board its costs of investigation and prosecution.

18 **10. Probation Monitoring Costs**

19 Respondent shall pay any costs associated with probation monitoring as determined by the
20 board each and every year of probation. Such costs shall be payable to the board on a schedule as
21 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
22 be considered a violation of probation.

23 **11. Status of License**

24 Respondent shall, at all times while on probation, maintain an active, current license with
25 the board, including any period during which suspension or probation is tolled. Failure to
26 maintain an active, current license shall be considered a violation of probation.

27 If respondent's license expires or is cancelled by operation of law or otherwise at any time
28 during the period of probation, including any extensions thereof due to tolling or otherwise, upon

1 renewal or reapplication respondent's license shall be subject to all terms and conditions of this
2 probation not previously satisfied.

3 **12. License Surrender While on Probation/Suspension**

4 Following the effective date of this decision, should respondent cease practice due to
5 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
6 respondent may tender his license to the board for surrender. The board or its designee shall have
7 the discretion whether to grant the request for surrender or take any other action it deems
8 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
9 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
10 record of discipline and shall become a part of the respondent's license history with the board.

11 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
12 the board within ten (10) days of notification by the board that the surrender is accepted.
13 Respondent may not reapply for any license from the board for three (3) years from the effective
14 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
15 of the date the application for that license is submitted to the board, including any outstanding
16 costs.

17 **13. Notification of a Change in Name, Residence Address, Mailing Address or**
18 **Employment**

19 Respondent shall notify the board in writing within ten (10) days of any change of
20 employment. Said notification shall include the reasons for leaving, the address of the new
21 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
22 shall further notify the board in writing within ten (10) days of a change in name, residence
23 address, mailing address, or phone number.

24 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
25 phone number(s) shall be considered a violation of probation.

26 **14. Tolling of Probation**

27 Except during periods of suspension, respondent shall, at all times while on probation, be
28 employed as a pharmacist in California for a minimum of forty (40) hours per calendar month.

Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least forty (40) hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least forty (40) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

15. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If

1 a petition to revoke probation or an accusation is filed against respondent during probation, the
2 board shall have continuing jurisdiction and the period of probation shall be automatically
3 extended until the petition to revoke probation or accusation is heard and decided.

4 16. Completion of Probation

5 Upon written notice by the board or its designee indicating successful completion of
6 probation, respondent's license will be fully restored.

7 17. Mental Health Examination

8 Within thirty (30) days of the effective date of this decision, and on a periodic basis as may
9 be required by the board or its designee, respondent shall undergo, at his own expense,
10 psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health
11 practitioner. The approved evaluator shall be provided with a copy of the board's Accusation and
12 decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a
13 current diagnosis and a written report regarding the respondent's judgment and ability to function
14 independently as a pharmacist with safety to the public. Respondent shall comply with all the
15 recommendations of the evaluator if directed by the board or its designee.

16 If the evaluator recommends, and the board or its designee directs, respondent shall
17 undergo psychotherapy. Within thirty (30) days of notification by the board that a
18 recommendation for psychotherapy has been accepted, respondent shall submit to the board or its
19 designee, for prior approval, the name and qualification of a licensed mental health practitioner of
20 respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall
21 submit documentation to the board demonstrating the commencement of psychotherapy with the
22 approved licensed mental health practitioner. Should respondent, for any reason, cease treatment
23 with the approved licensed mental health practitioner, respondent shall notify the board
24 immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a
25 replacement licensed mental health practitioner of respondent's choice to the board for its prior
26 approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to
27 the board demonstrating the commencement of psychotherapy with the approved replacement.

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1 Failure to comply with any requirement or deadline stated by this paragraph shall be considered a
2 violation of probation.

3 Upon approval of the initial or any subsequent licensed mental health practitioner,
4 respondent shall undergo and continue treatment with that therapist, at respondent's own expense,
5 until the therapist recommends in writing to the board, and the board or its designee agrees by
6 way of a written notification to respondent, that no further psychotherapy is necessary. Upon
7 receipt of such recommendation from the treating therapist, and before determining whether to
8 accept or reject said recommendation, the board or its designee may require respondent to
9 undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or
10 board-approved evaluator. If the approved evaluator recommends that respondent continue
11 psychotherapy, the board or its designee may require respondent to continue psychotherapy.

12 Psychotherapy shall be at least once a week unless otherwise approved by the board.
13 Respondent shall provide the therapist with a copy of the board's Accusation and decision no
14 later than the first therapy session. Respondent shall take all necessary steps to ensure that the
15 treating therapist submits written quarterly reports to the board concerning respondent's fitness to
16 practice, progress in treatment, and other such information as may be required by the board or its
17 designee.

18 If at any time the approved evaluator or therapist determines that respondent is unable to
19 practice safely or independently as a pharmacist, the licensed mental health practitioner shall
20 notify the board immediately by telephone and follow up by written letter within three (3)
21 working days. Upon notification from the board or its designee of this determination, respondent
22 shall be automatically suspended and shall not resume practice until notified by the board that
23 practice may be resumed.

24 **18. Pharmacists Recovery Program (PRP)**

25 Within thirty (30) days of the effective date of this decision, respondent shall contact the
26 Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll,
27 successfully participate in, and complete the treatment contract and any subsequent addendums as
28 ///

1 recommended and provided by the PRP and as approved by the board or its designee. The costs
2 for PRP participation shall be borne by the respondent.

3 If respondent is currently enrolled in the PRP, said participation is now mandatory and as of
4 the effective date of this decision is no longer considered a self-referral under Business and
5 Professions Code section 4362(c)(2). Respondent shall successfully participate in and complete
6 his current contract and any subsequent addendums with the PRP.

7 Failure to timely contact or enroll in the PRP, or successfully participate in and complete
8 the treatment contract and/or any addendums, shall be considered a violation of probation.

9 Probation shall be automatically extended until respondent successfully completes the PRP.

10 Any person terminated from the PRP program shall be automatically suspended by the board.

11 Respondent may not resume the practice of pharmacy until notified by the board in writing.

12 Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a
13 licensed practitioner as part of a documented medical treatment shall result in the automatic
14 suspension of practice by respondent and shall be considered a violation of probation.

15 Respondent may not resume the practice of pharmacy until notified by the board in writing.

16 During suspension, respondent shall not enter any pharmacy area or any portion of the
17 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
18 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
19 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
20 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
21 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
22 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
23 and controlled substances. Respondent shall not resume practice until notified by the board.

24 During suspension, respondent shall not engage in any activity that requires the
25 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
26 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
27 designated representative for any entity licensed by the board.

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1 Subject to the above restrictions, respondent may continue to own or hold an interest in any
2 licensed premises in which he holds an interest at the time this decision becomes effective unless
3 otherwise specified in this order.

4 Failure to comply with this suspension shall be considered a violation of probation.

5 Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not
6 timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid
7 administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

8 **19. Random Drug Screening**

9 Respondent, at his own expense, shall participate in random testing, including but not
10 limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug
11 screening program as directed by the board or its designee. Respondent may be required to
12 participate in testing for the entire probation period and the frequency of testing will be
13 determined by the board or its designee. At all times, respondent shall fully cooperate with the
14 board or its designee, and shall, when directed, submit to such tests and samples for the detection
15 of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its
16 designee may direct. Failure to timely submit to testing as directed shall be considered a violation
17 of probation. Upon request of the board or its designee, respondent shall provide documentation
18 from a licensed practitioner that the prescription for a detected drug was legitimately issued and is
19 a necessary part of the treatment of the respondent. Failure to timely provide such documentation
20 shall be considered a violation of probation. Any confirmed positive test for alcohol or for any
21 drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment
22 shall be considered a violation of probation and shall result in the automatic suspension of
23 practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until
24 notified by the board in writing.

25 During suspension, respondent shall not enter any pharmacy area or any portion of the
26 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
27 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
28 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

1 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
2 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
3 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
4 and controlled substances. Respondent shall not resume practice until notified by the board.

5 During suspension, respondent shall not engage in any activity that requires the
6 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
7 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
8 designated representative for any entity licensed by the board.

9 Subject to the above restrictions, respondent may continue to own or hold an interest in any
10 licensed premises in which he holds an interest at the time this decision becomes effective unless
11 otherwise specified in this order.

12 Failure to comply with this suspension shall be considered a violation of probation.

13 **20. Abstain from Drugs and Alcohol Use**

14 Respondent shall completely abstain from the possession or use of alcohol, controlled
15 substances, dangerous drugs and their associated paraphernalia except when the drugs are
16 lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon
17 request of the board or its designee, respondent shall provide documentation from the licensed
18 practitioner that the prescription for the drug was legitimately issued and is a necessary part of the
19 treatment of the respondent. Failure to timely provide such documentation shall be considered a
20 violation of probation. Respondent shall ensure that he is not in the same physical location as
21 individuals who are using illicit substances even if respondent is not personally ingesting the
22 drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia
23 not supported by the documentation timely provided, and/or any physical proximity to persons
24 using illicit substances, shall be considered a violation of probation.

25 **21. Prescription Coordination and Monitoring of Prescription Use**

26 Within thirty (30) days of the effective date of this decision, respondent shall submit to the
27 board, for its prior approval, the name and qualifications of a single physician, nurse practitioner,
28 physician assistant, or psychiatrist of respondent's choice, who shall be aware of the facts and

1 circumstances giving rise to Accusation 3601 and who will coordinate and monitor any
2 prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs.
3 The approved practitioner shall be provided with a copy of the board's Accusation and decision.
4 A record of this notification must be provided to the board upon request. Respondent shall sign a
5 release authorizing the practitioner to communicate with the board about respondent's
6 treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist
7 shall report to the board on a quarterly basis for the duration of probation regarding respondent's
8 compliance with this condition. If any substances considered addictive have been prescribed, the
9 report shall identify a program for the time limited use of any such substances. The board may
10 require that the single coordinating physician, nurse practitioner, physician assistant or
11 psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine.
12 Should respondent, for any reason, cease supervision by the approved practitioner, respondent
13 shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the
14 name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of
15 respondent's choice to the board or its designee for its prior approval. Failure to timely submit
16 the selected practitioner or replacement practitioner to the board for approval, or to ensure the
17 required reporting thereby on the quarterly reports, shall be considered a violation of probation.

18 If at any time an approved practitioner determines that respondent is unable to practice
19 safely or independently as a pharmacist, the practitioner shall notify the board immediately by
20 telephone and follow up by written letter within three (3) working days. Upon notification from
21 the board or its designee of this determination, respondent shall be automatically suspended and
22 shall not resume practice until notified by the board that practice may be resumed.

23 During suspension, respondent shall not enter any pharmacy area or any portion of the
24 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
25 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
26 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
27 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
28 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the

1 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
2 and controlled substances. Respondent shall not resume practice until notified by the board.

3 During suspension, respondent shall not engage in any activity that requires the
4 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
5 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
6 designated representative for any entity licensed by the board.

7 Subject to the above restrictions, respondent may continue to own or hold an interest in any
8 licensed premises in which he holds an interest at the time this decision becomes effective unless
9 otherwise specified in this order.

10 Failure to comply with this suspension shall be considered a violation of probation.

11 **22. Community Services Program**

12 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
13 board or its designee, for prior approval, a community service program in which respondent shall
14 provide free health-care related services on a regular basis to a community or charitable facility or
15 agency for at least sixty (60) hours per year for the first three (3) years of probation. Within thirty
16 (30) days of board approval thereof, respondent shall submit documentation to the board
17 demonstrating commencement of the community service program. A record of this notification
18 must be provided to the board upon request. Respondent shall report on progress with the
19 community service program in the quarterly reports. Failure to timely submit, commence, or
20 comply with the program shall be considered a violation of probation.

21 **23. No New Ownership of Licensed Premises**

22 Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a
23 manager, administrator, member, officer, director, trustee, associate, or partner of any additional
24 business, firm, partnership, or corporation licensed by the board. If respondent currently owns or
25 has any legal or beneficial interest in, or serves as a manager, administrator, member, officer,
26 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently
27 or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold

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1 that interest, but only to the extent of that position or interest as of the effective date of this
2 decision. Violation of this restriction shall be considered a violation of probation.

3 **24. Tolling of Suspension**

4 During the period of suspension, respondent shall not leave California for any period
5 exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess
6 of the (10) days during suspension shall be considered a violation of probation. Moreover, any
7 absence from California during the period of suspension exceeding ten (10) days shall toll the
8 suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days
9 respondent is absent from California. During any such period of tolling of suspension,
10 respondent must nonetheless comply with all terms and conditions of probation.

11 Respondent must notify the board in writing within ten (10) days of departure, and must
12 further notify the board in writing within ten (10) days of return. The failure to provide such
13 notification(s) shall constitute a violation of probation. Upon such departure and return,
14 respondent shall not resume the practice of pharmacy until notified by the board that the period of
15 suspension has been satisfactorily completed.

16 **25. Ethics Course**

17 Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll
18 in a course in ethics, at respondent's expense, approved in advance by the board or its designee.
19 Failure to initiate the course during the first year of probation, and complete it within the second
20 year of probation, is a violation of probation.

21 Respondent shall submit a certificate of completion to the board or its designee within five
22 days after completing the course.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 2/28/12


SERJ SOUKAZ MARKARIAN
Respondent

I have read and fully discussed with Respondent Serj Soukaz Markarian the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 2/29/12


Herbert L. Weinberg
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
KAREN B. CHAPPELLE
Supervising Deputy Attorney General

WILLIAM D. GARDNER
Deputy Attorney General
Attorneys for Complainant

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SERJ SOUKAZ MARKARIAN
Respondent

I have read and fully discussed with Respondent Serj Soukaz Markarian the terms and conditions and other matters, contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

Herbert L. Weinberg
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 2/29/12

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
KAREN B. CHAPPELLE
Supervising Deputy Attorney General



WILLIAM D. GARDNER
Deputy Attorney General
Attorneys for Complainant

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Attorneys for Complainant

7
 8 **BEFORE THE**
BOARD OF PHARMACY
 9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 3601

11 **SERJ SOUKAZ MARKARIAN**
 12 **7766 N. Gleneaks Blvd.**
 13 **Burbank, CA 91504**
Pharmacist License No. RPH 54284

ACCUSATION

14 Respondent.

15
 16 Complainant alleges:

17 **PARTIES**

- 18 1. Virginia K. Herold (Complainant) brings this Accusation solely in her official
 19 capacity as the Executive Officer of the California State Board of Pharmacy.
 20 2. On or about March 20, 2003, the Board of Pharmacy issued Pharmacist License
 21 Number RPH 54284 to Serj Soukaz Markarian (Respondent). The Pharmacist License was in full
 22 force and effect at all times relevant to the charges brought herein and will expire on September
 23 30, 2012, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board of Pharmacy (Board), under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

4. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender or cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

5. Section 490 of the Code provides, in pertinent part, that a board may suspend or revoke a license on the ground that the licensee has been convicted of a crime substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

6. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

7. Section 4060 of the Code states:

"No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a

1 physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5,
 2 or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of
 3 subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not
 4 apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy,
 5 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified
 6 nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly
 7 labeled with the name and address of the supplier or producer.

8 "Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a
 9 physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs
 10 and devices."

11 8. Section 4301 of the Code states:

12 "The board shall take action against any holder of a license who is guilty of unprofessional
 13 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
 14 Unprofessional conduct shall include, but is not limited to, any of the following:

15

16 "(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
 17 corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
 18 whether the act is a felony or misdemeanor or not.

19

20 "(I) The conviction of a crime substantially related to the qualifications, functions, and
 21 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13
 22 (commencing with Section 801) of Title 21 of the United States Code regulating controlled
 23 substances or of a violation of the statutes of this state regulating controlled substances or
 24 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the
 25 record of conviction shall be conclusive evidence only of the fact that the conviction occurred.
 26 The board may inquire into the circumstances surrounding the commission of the crime, in order
 27 to fix the degree of discipline or, in the case of a conviction not involving controlled substances
 28 or dangerous drugs, to determine if the conviction is of an offense substantially related to the

1 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or
 2 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning
 3 of this provision. The board may take action when the time for appeal has elapsed, or the
 4 judgment of conviction has been affirmed on appeal or when an order granting probation is made
 5 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of
 6 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not
 7 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or
 8 indictment.

9 REGULATORY PROVISIONS

10 9. California Code of Regulations, title 16, section 1770, states:

11 "For the purpose of denial, suspension, or revocation of a personal or facility license
 12 pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a
 13 crime or act shall be considered substantially related to the qualifications, functions or duties of a
 14 licensee or registrant if to a substantial degree it evidences present or potential unfitness of a
 15 licensee or registrant to perform the functions authorized by his license or registration in a manner
 16 consistent with the public health, safety, or welfare."

17 COST RECOVERY

18 10. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
 19 administrative law judge to direct a licensee found to have committed a violation or violations of
 20 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
 21 enforcement of the case.

22 DRUGS

23 11. Pregabalin, also known by the brand name Lyrica, is a Schedule V, non-narcotic
 24 controlled substance under Health and Safety Code section 11058, and is classified as a
 25 dangerous drug pursuant to Business and Professions Code section 4022.

26 12. Eszopiclone, also known by the brand name Lunesta, is a Schedule IV, non-narcotic
 27 controlled substance under Health and Safety Code section 11057, and is classified as a
 28 dangerous drug pursuant to Business and Professions Code section 4022.

1 13. Tadalafil, also known by the brand name Cialis, is not a scheduled drug, but is
2 classified as a dangerous drug pursuant to Business and Professions Code section 4022.

3 14. Celecoxib, also known by the brand name Celebrex, is not a scheduled drug, but is
4 classified as a dangerous drug pursuant to Business and Professions Code section 4022.

5 **FIRST CAUSE FOR DISCIPLINE**

6 **(Substantially Related Convictions)**

7 15. Respondent is subject to disciplinary action under sections 490 and 4301, subdivision
8 (l), of the Code, in conjunction with California Code of Regulation, title 16, section 1770, in that
9 Respondent was convicted of a crime substantially related to the qualifications, functions or
10 duties of a licensed pharmacist. Specifically, on or about September 2, 2008, after pleading nolo
11 contendere, Respondent was convicted of one misdemeanor count of violating Penal Code
12 Section 602.5(B) [entering dwelling without consent] in the criminal proceeding entitled *The*
13 *People of the State of California v. Serj Soukaz Markarian* (Super. Ct. Los Angeles County, 2008,
14 No. 7PY07737). Respondent was placed on probation for 36 months and was ordered to pay a
15 fine.

16 16. The circumstances are that on or about August 17, 2007, while working as a
17 pharmacist at CVS Pharmacy, Respondent was observed concealing the following
18 pharmaceuticals in his bag: Cialis 20 mg, Lyrica 50 mg, Lunesta 3mg and Celebrex 100 mg. A
19 CVS store manager waited for Respondent to exit the store at closing time and contacted him in
20 the parking lot. The store manager checked Respondent's bags and located five (5) bottles of
21 pharmaceuticals that had been taken from the pharmacy without permission and had not been
22 paid for nor prescribed to Respondent.

23 **SECOND CAUSE FOR DISCIPLINE**

24 **(Unprofessional Conduct: Dishonest Act)**

25 17. Respondent is subject to disciplinary action under section 4301, subdivision (f) of the
26 Code in that he committed an act involving moral turpitude, dishonesty, fraud, deceit or
27 corruption. Complainant refers to, and by this reference incorporates, the allegations set forth in
28 paragraphs 15 and 16, as though set forth fully.

THIRD CAUSE FOR DISCIPLINE

(Possession of Controlled Substance Without a Prescription)

18. Respondent is subject to disciplinary action under section 4060 of the Code, in that he possessed controlled substances that were not furnished to him upon prescription of a physician. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 15 and 16, as though set forth fully.

FOURTH CAUSE FOR DISCIPLINE

(Administer/Furnish Controlled Substance to Self)

19. Respondent is subject to disciplinary action under section 11170 of the Health and Safety Code in that he prescribed, administered or furnished a controlled substance to himself. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 15 and 16, as though set forth fully.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacist License Number RPH 54284, issued to Serj Soukaz Markarian;
2. Ordering Serj Soukaz Markarian to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
3. Taking such other and further action as deemed necessary and proper.

DATED: 6/6/11

Virginia K. Herold
 VIRGINIA K. HEROLD
 Executive Officer
 California State Board of Pharmacy
 State of California
 Complainant

LA2010600173
 60622416.doc

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

SERJ SOUKAZ MARKARIAN
7766 N. Glenoaks Blvd.
Burbank, CA 91504

Pharmacist License No. RPH 54284

Respondent.

Case No. 3601

OAH No. L-2011090609

DECISION AND ORDER

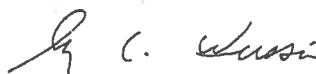
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on June 7, 2012.

It is so ORDERED on May 8, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
 Attorney General of California
 2 KAREN B. CHAPPELLE
 Supervising Deputy Attorney General
 3 WILLIAM D. GARDNER
 Deputy Attorney General
 4 State Bar No. 244817
 300 So. Spring Street, Suite 1702
 5 Los Angeles, CA 90013
 Telephone: (213) 897-2114
 6 Facsimile: (213) 897-2804
Attorneys for Complainant
 7

8 **BEFORE THE**
BOARD OF PHARMACY
 9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA
 10

11 In the Matter of the Accusation Against:

Case No. 3601

12 **SERJ SOUKAZ MARKARIAN**
 7766 N. Glenoaks Blvd.
 13 Burbank, CA 91504
 Pharmacist License No. RPH 54284

OAH No. L-2011090609
STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

14 Respondent.
 15

16
 17 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
 18 entitled proceedings that the following matters are true:

19 **PARTIES**

20 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
 21 She brought this action solely in her official capacity and is represented in this matter by Kamala
 22 D. Harris, Attorney General of the State of California, by William D. Gardner, Deputy Attorney
 23 General.

24 2. Respondent Serj Soukaz Markarian (Respondent) is represented in this proceeding by
 25 attorney Herbert L. Weinberg, whose address is: 1800 Century Park East, 8th Floor, Los
 26 Angeles, CA 90067.

27 3. On or about March 20, 2003, the Board of Pharmacy issued Pharmacist License No.
 28 RPH 54284 to Serj Soukaz Markarian (Respondent). The Pharmacist License was in full force

1 and effect at all times relevant to the charges brought in Accusation No. 3601 and will expire on
2 September 30, 2012, unless renewed.

3 JURISDICTION

4 4. Accusation No. 3601 was filed before the Board of Pharmacy (Board), Department of
5 Consumer Affairs, and is currently pending against Respondent. The Accusation and all other
6 statutorily required documents were properly served on Respondent on June 15, 2011.
7 Respondent timely filed his Notice of Defense contesting the Accusation.

8 5. A copy of Accusation No. 3601 is attached as exhibit A and incorporated herein by
9 reference.

10 ADVISEMENT AND WAIVERS

11 6. Respondent has carefully read, fully discussed with counsel, and understands the
12 charges and allegations in Accusation No. 3601. Respondent has also carefully read, fully
13 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
14 Order.

15 7. Respondent is fully aware of his legal rights in this matter, including the right to a
16 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at
17 his own expense; the right to confront and cross-examine the witnesses against him; the right to
18 present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel
19 the attendance of witnesses and the production of documents; the right to reconsideration and
20 court review of an adverse decision; and all other rights accorded by the California
21 Administrative Procedure Act and other applicable laws.

22 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
23 every right set forth above.

24 CULPABILITY

25 9. Respondent admits the truth of each and every charge and allegation in Accusation
26 No. 3601.

27 10. Respondent agrees that his Pharmacist License is subject to discipline and he agrees
28 to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 54284 issued to Respondent Serj Soukaz Markarian (Respondent) is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

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1 **1. Suspension**

2 As part of probation, respondent is suspended from the practice of pharmacy for sixty (60)
3 days beginning the effective date of this decision.

4 During suspension, respondent shall not enter any pharmacy area or any portion of the
5 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
6 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
7 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
8 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
9 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
10 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
11 and devices or controlled substances.

12 Respondent shall not engage in any activity that requires the professional judgment of a
13 pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy.
14 Respondent shall not perform the duties of a pharmacy technician or a designated representative
15 for any entity licensed by the board.

16 Subject to the above restrictions, respondent may continue to own or hold an interest in any
17 licensed premises in which he holds an interest at the time this decision becomes effective unless
18 otherwise specified in this order.

19 Failure to comply with this suspension shall be considered a violation of probation.

20 **2. Obey All Laws**

21 Respondent shall obey all state and federal laws and regulations.

22 Respondent shall report any of the following occurrences to the board, in writing, within
23 seventy-two (72) hours of such occurrence:

- 24 • an arrest or issuance of a criminal complaint for violation of any provision of the
- 25 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
- 26 substances laws;
- 27 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
- 28 criminal complaint, information or indictment;

- a conviction of any crime;
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

6. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

1 **7. Notice to Employers**

2 During the period of probation, respondent shall notify all present and prospective
3 employers of the decision in case number 3601 and the terms, conditions and restrictions imposed
4 on respondent by the decision, as follows:

5 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
6 respondent undertaking any new employment, respondent shall cause his direct supervisor,
7 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
8 tenure of employment) and owner to report to the board in writing acknowledging that the listed
9 individual(s) has/have read the decision in case number 3601, and terms and conditions imposed
10 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
11 submit timely acknowledgment(s) to the board.

12 If respondent works for or is employed by or through a pharmacy employment service,
13 respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
14 licensed by the board of the terms and conditions of the decision in case number 3601 in advance
15 of the respondent commencing work at each licensed entity. A record of this notification must be
16 provided to the board upon request.

17 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
18 (15) days of respondent undertaking any new employment by or through a pharmacy employment
19 service, respondent shall cause his direct supervisor with the pharmacy employment service to
20 report to the board in writing acknowledging that he has read the decision in case number 3601
21 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
22 that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

23 Failure to timely notify present or prospective employer(s) or to cause that/those
24 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
25 probation.

26 "Employment" within the meaning of this provision shall include any full-time, part-
27 time, temporary, relief or pharmacy management service as a pharmacist or any position for

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1 which a pharmacist license is a requirement or criterion for employment, whether the
2 respondent is an employee, independent contractor or volunteer.

3 **8. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
4 **Designated Representative-in-Charge, or Serving as a Consultant**

5 During the period of probation, respondent shall not supervise any intern pharmacist, be the
6 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
7 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
8 unauthorized supervision responsibilities shall be considered a violation of probation.

9 **9. Reimbursement of Board Costs**

10 As a condition precedent to successful completion of probation, respondent shall pay to the
11 board its costs of investigation and prosecution in the amount of \$5,657.50. Respondent shall
12 make said payments in accordance with a payment plan to be determined by the Board

13 There shall be no deviation from this schedule absent prior written approval by the board or
14 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
15 probation.

16 The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to
17 reimburse the board its costs of investigation and prosecution.

18 **10. Probation Monitoring Costs**

19 Respondent shall pay any costs associated with probation monitoring as determined by the
20 board each and every year of probation. Such costs shall be payable to the board on a schedule as
21 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
22 be considered a violation of probation.

23 **11. Status of License**

24 Respondent shall, at all times while on probation, maintain an active, current license with
25 the board, including any period during which suspension or probation is tolled. Failure to
26 maintain an active, current license shall be considered a violation of probation.

27 If respondent's license expires or is cancelled by operation of law or otherwise at any time
28 during the period of probation, including any extensions thereof due to tolling or otherwise, upon

1 renewal or reapplication respondent's license shall be subject to all terms and conditions of this
2 probation not previously satisfied.

3 **12. License Surrender While on Probation/Suspension**

4 Following the effective date of this decision, should respondent cease practice due to
5 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
6 respondent may tender his license to the board for surrender. The board or its designee shall have
7 the discretion whether to grant the request for surrender or take any other action it deems
8 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
9 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
10 record of discipline and shall become a part of the respondent's license history with the board.

11 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
12 the board within ten (10) days of notification by the board that the surrender is accepted.
13 Respondent may not reapply for any license from the board for three (3) years from the effective
14 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
15 of the date the application for that license is submitted to the board, including any outstanding
16 costs.

17 **13. Notification of a Change in Name, Residence Address, Mailing Address or**
18 **Employment**

19 Respondent shall notify the board in writing within ten (10) days of any change of
20 employment. Said notification shall include the reasons for leaving, the address of the new
21 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
22 shall further notify the board in writing within ten (10) days of a change in name, residence
23 address, mailing address, or phone number.

24 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
25 phone number(s) shall be considered a violation of probation.

26 **14. Tolling of Probation**

27 Except during periods of suspension, respondent shall, at all times while on probation, be
28 employed as a pharmacist in California for a minimum of forty (40) hours per calendar month.

1 Any month during which this minimum is not met shall toll the period of probation, i.e., the
2 period of probation shall be extended by one month for each month during which this minimum is
3 not met. During any such period of tolling of probation, respondent must nonetheless comply
4 with all terms and conditions of probation.

5 Should respondent, regardless of residency, for any reason (including vacation) cease
6 practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California,
7 respondent must notify the board in writing within ten (10) days of the cessation of practice, and
8 must further notify the board in writing within ten (10) days of the resumption of practice. Any
9 failure to provide such notification(s) shall be considered a violation of probation.

10 It is a violation of probation for respondent's probation to remain tolled pursuant to the
11 provisions of this condition for a total period, counting consecutive and non-consecutive months,
12 exceeding thirty-six (36) months.

13 "Cessation of practice" means any calendar month during which respondent is
14 not practicing as a pharmacist for at least forty (40) hours, as defined by Business and
15 Professions Code section 4000 et seq. "Resumption of practice" means any calendar
16 month during which respondent is practicing as a pharmacist for at least forty (40)
17 hours as a pharmacist as defined by Business and Professions Code section 4000 et
18 seq.

19 **15. Violation of Probation**

20 If a respondent has not complied with any term or condition of probation, the board shall
21 have continuing jurisdiction over respondent, and probation shall automatically be extended, until
22 all terms and conditions have been satisfied or the board has taken other action as deemed
23 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
24 to impose the penalty that was stayed.

25 If respondent violates probation in any respect, the board, after giving respondent notice
26 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
27 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
28 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If

1 a petition to revoke probation or an accusation is filed against respondent during probation, the
2 board shall have continuing jurisdiction and the period of probation shall be automatically
3 extended until the petition to revoke probation or accusation is heard and decided.

4 **16. Completion of Probation**

5 Upon written notice by the board or its designee indicating successful completion of
6 probation, respondent's license will be fully restored.

7 **17. Mental Health Examination**

8 Within thirty (30) days of the effective date of this decision, and on a periodic basis as may
9 be required by the board or its designee, respondent shall undergo, at his own expense,
10 psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health
11 practitioner. The approved evaluator shall be provided with a copy of the board's Accusation and
12 decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a
13 current diagnosis and a written report regarding the respondent's judgment and ability to function
14 independently as a pharmacist with safety to the public. Respondent shall comply with all the
15 recommendations of the evaluator if directed by the board or its designee.

16 If the evaluator recommends, and the board or its designee directs, respondent shall
17 undergo psychotherapy. Within thirty (30) days of notification by the board that a
18 recommendation for psychotherapy has been accepted, respondent shall submit to the board or its
19 designee, for prior approval, the name and qualification of a licensed mental health practitioner of
20 respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall
21 submit documentation to the board demonstrating the commencement of psychotherapy with the
22 approved licensed mental health practitioner. Should respondent, for any reason, cease treatment
23 with the approved licensed mental health practitioner, respondent shall notify the board
24 immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a
25 replacement licensed mental health practitioner of respondent's choice to the board for its prior
26 approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to
27 the board demonstrating the commencement of psychotherapy with the approved replacement.

28 ///

1 Failure to comply with any requirement or deadline stated by this paragraph shall be considered a
2 violation of probation.

3 Upon approval of the initial or any subsequent licensed mental health practitioner,
4 respondent shall undergo and continue treatment with that therapist, at respondent's own expense,
5 until the therapist recommends in writing to the board, and the board or its designee agrees by
6 way of a written notification to respondent, that no further psychotherapy is necessary. Upon
7 receipt of such recommendation from the treating therapist, and before determining whether to
8 accept or reject said recommendation, the board or its designee may require respondent to
9 undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or
10 board-approved evaluator. If the approved evaluator recommends that respondent continue
11 psychotherapy, the board or its designee may require respondent to continue psychotherapy.

12 Psychotherapy shall be at least once a week unless otherwise approved by the board.
13 Respondent shall provide the therapist with a copy of the board's Accusation and decision no
14 later than the first therapy session. Respondent shall take all necessary steps to ensure that the
15 treating therapist submits written quarterly reports to the board concerning respondent's fitness to
16 practice, progress in treatment, and other such information as may be required by the board or its
17 designee.

18 If at any time the approved evaluator or therapist determines that respondent is unable to
19 practice safely or independently as a pharmacist, the licensed mental health practitioner shall
20 notify the board immediately by telephone and follow up by written letter within three (3)
21 working days. Upon notification from the board or its designee of this determination, respondent
22 shall be automatically suspended and shall not resume practice until notified by the board that
23 practice may be resumed.

24 **18. Pharmacists Recovery Program (PRP)**

25 Within thirty (30) days of the effective date of this decision, respondent shall contact the
26 Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll,
27 successfully participate in, and complete the treatment contract and any subsequent addendums as

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1 recommended and provided by the PRP and as approved by the board or its designee. The costs
2 for PRP participation shall be borne by the respondent.

3 If respondent is currently enrolled in the PRP, said participation is now mandatory and as of
4 the effective date of this decision is no longer considered a self-referral under Business and
5 Professions Code section 4362(c)(2). Respondent shall successfully participate in and complete
6 his current contract and any subsequent addendums with the PRP.

7 Failure to timely contact or enroll in the PRP, or successfully participate in and complete
8 the treatment contract and/or any addendums, shall be considered a violation of probation.

9 Probation shall be automatically extended until respondent successfully completes the PRP.

10 Any person terminated from the PRP program shall be automatically suspended by the board.

11 Respondent may not resume the practice of pharmacy until notified by the board in writing.

12 Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a
13 licensed practitioner as part of a documented medical treatment shall result in the automatic
14 suspension of practice by respondent and shall be considered a violation of probation.

15 Respondent may not resume the practice of pharmacy until notified by the board in writing.

16 During suspension, respondent shall not enter any pharmacy area or any portion of the
17 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
18 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
19 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
20 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
21 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
22 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
23 and controlled substances. Respondent shall not resume practice until notified by the board.

24 During suspension, respondent shall not engage in any activity that requires the
25 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
26 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
27 designated representative for any entity licensed by the board.

28 ///

1 Subject to the above restrictions, respondent may continue to own or hold an interest in any
2 licensed premises in which he holds an interest at the time this decision becomes effective unless
3 otherwise specified in this order.

4 Failure to comply with this suspension shall be considered a violation of probation.

5 Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not
6 timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid
7 administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

8 **19. Random Drug Screening**

9 Respondent, at his own expense, shall participate in random testing, including but not
10 limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug
11 screening program as directed by the board or its designee. Respondent may be required to
12 participate in testing for the entire probation period and the frequency of testing will be
13 determined by the board or its designee. At all times, respondent shall fully cooperate with the
14 board or its designee, and shall, when directed, submit to such tests and samples for the detection
15 of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its
16 designee may direct. Failure to timely submit to testing as directed shall be considered a violation
17 of probation. Upon request of the board or its designee, respondent shall provide documentation
18 from a licensed practitioner that the prescription for a detected drug was legitimately issued and is
19 a necessary part of the treatment of the respondent. Failure to timely provide such documentation
20 shall be considered a violation of probation. Any confirmed positive test for alcohol or for any
21 drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment
22 shall be considered a violation of probation and shall result in the automatic suspension of
23 practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until
24 notified by the board in writing.

25 During suspension, respondent shall not enter any pharmacy area or any portion of the
26 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
27 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
28 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

1 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
2 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
3 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
4 and controlled substances. Respondent shall not resume practice until notified by the board.

5 During suspension, respondent shall not engage in any activity that requires the
6 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
7 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
8 designated representative for any entity licensed by the board.

9 Subject to the above restrictions, respondent may continue to own or hold an interest in any
10 licensed premises in which he holds an interest at the time this decision becomes effective unless
11 otherwise specified in this order.

12 Failure to comply with this suspension shall be considered a violation of probation.

13 **20. Abstain from Drugs and Alcohol Use**

14 Respondent shall completely abstain from the possession or use of alcohol, controlled
15 substances, dangerous drugs and their associated paraphernalia except when the drugs are
16 lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon
17 request of the board or its designee, respondent shall provide documentation from the licensed
18 practitioner that the prescription for the drug was legitimately issued and is a necessary part of the
19 treatment of the respondent. Failure to timely provide such documentation shall be considered a
20 violation of probation. Respondent shall ensure that he is not in the same physical location as
21 individuals who are using illicit substances even if respondent is not personally ingesting the
22 drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia
23 not supported by the documentation timely provided, and/or any physical proximity to persons
24 using illicit substances, shall be considered a violation of probation.

25 **21. Prescription Coordination and Monitoring of Prescription Use**

26 Within thirty (30) days of the effective date of this decision, respondent shall submit to the
27 board, for its prior approval, the name and qualifications of a single physician, nurse practitioner,
28 physician assistant, or psychiatrist of respondent's choice, who shall be aware of the facts and

1 circumstances giving rise to Accusation 3601 and who will coordinate and monitor any
2 prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs.
3 The approved practitioner shall be provided with a copy of the board's Accusation and decision.
4 A record of this notification must be provided to the board upon request. Respondent shall sign a
5 release authorizing the practitioner to communicate with the board about respondent's
6 treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist
7 shall report to the board on a quarterly basis for the duration of probation regarding respondent's
8 compliance with this condition. If any substances considered addictive have been prescribed, the
9 report shall identify a program for the time limited use of any such substances. The board may
10 require that the single coordinating physician, nurse practitioner, physician assistant or
11 psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine.
12 Should respondent, for any reason, cease supervision by the approved practitioner, respondent
13 shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the
14 name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of
15 respondent's choice to the board or its designee for its prior approval. Failure to timely submit
16 the selected practitioner or replacement practitioner to the board for approval, or to ensure the
17 required reporting thereby on the quarterly reports, shall be considered a violation of probation.

18 If at any time an approved practitioner determines that respondent is unable to practice
19 safely or independently as a pharmacist, the practitioner shall notify the board immediately by
20 telephone and follow up by written letter within three (3) working days. Upon notification from
21 the board or its designee of this determination, respondent shall be automatically suspended and
22 shall not resume practice until notified by the board that practice may be resumed.

23 During suspension, respondent shall not enter any pharmacy area or any portion of the
24 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
25 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
26 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
27 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
28 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the

1 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs
2 and controlled substances. Respondent shall not resume practice until notified by the board.

3 During suspension, respondent shall not engage in any activity that requires the
4 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
5 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
6 designated representative for any entity licensed by the board.

7 Subject to the above restrictions, respondent may continue to own or hold an interest in any
8 licensed premises in which he holds an interest at the time this decision becomes effective unless
9 otherwise specified in this order.

10 Failure to comply with this suspension shall be considered a violation of probation.

11 **22. Community Services Program**

12 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
13 board or its designee, for prior approval, a community service program in which respondent shall
14 provide free health-care related services on a regular basis to a community or charitable facility or
15 agency for at least sixty (60) hours per year for the first three (3) years of probation. Within thirty
16 (30) days of board approval thereof, respondent shall submit documentation to the board
17 demonstrating commencement of the community service program. A record of this notification
18 must be provided to the board upon request. Respondent shall report on progress with the
19 community service program in the quarterly reports. Failure to timely submit, commence, or
20 comply with the program shall be considered a violation of probation.

21 **23. No New Ownership of Licensed Premises**

22 Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a
23 manager, administrator, member, officer, director, trustee, associate, or partner of any additional
24 business, firm, partnership, or corporation licensed by the board. If respondent currently owns or
25 has any legal or beneficial interest in, or serves as a manager, administrator, member, officer,
26 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently
27 or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold

28 ///

1 that interest, but only to the extent of that position or interest as of the effective date of this
2 decision. Violation of this restriction shall be considered a violation of probation.

3 **24. Tolling of Suspension**

4 During the period of suspension, respondent shall not leave California for any period
5 exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess
6 of the (10) days during suspension shall be considered a violation of probation. Moreover, any
7 absence from California during the period of suspension exceeding ten (10) days shall toll the
8 suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days
9 respondent is absent from California. During any such period of tolling of suspension,
10 respondent must nonetheless comply with all terms and conditions of probation.

11 Respondent must notify the board in writing within ten (10) days of departure, and must
12 further notify the board in writing within ten (10) days of return. The failure to provide such
13 notification(s) shall constitute a violation of probation. Upon such departure and return,
14 respondent shall not resume the practice of pharmacy until notified by the board that the period of
15 suspension has been satisfactorily completed.

16 **25. Ethics Course**

17 Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll
18 in a course in ethics, at respondent's expense, approved in advance by the board or its designee.
19 Failure to initiate the course during the first year of probation, and complete it within the second
20 year of probation, is a violation of probation.

21 Respondent shall submit a certificate of completion to the board or its designee within five
22 days after completing the course.

23 ///

24 ///

25 ///


26 ///

27 ///

28 ///

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 2/28/12

 SERJ SOUKAZ MARKARIAN
 Respondent

I have read and fully discussed with Respondent Serj Soukaz Markarian the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 2/29/12

 Herbert L. Weinberg
 Attorney for Respondent
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

Respectfully submitted,

KAMALA D. HARRIS
 Attorney General of California
 KAREN B. CHAPPELLE
 Supervising Deputy Attorney General

WILLIAM D. GARDNER
 Deputy Attorney General
 Attorneys for Complainant

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ACCEPTANCE

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DATED: _____

SERJ SOUKAZ MARKARIAN
Respondent

I have read and fully discussed with Respondent Serj Soukaz Markarian the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

Herbert L. Weinberg
Attorney for Respondent


ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 2/29/12

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
KAREN B. CHAPPELLE
Supervising Deputy Attorney General


WILLIAM D. GARDNER
Deputy Attorney General
Attorneys for Complainant

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60733410.doc

1 KAMALA D. HARRIS
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 2 MARC D. GREENBAUM
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 Deputy Attorney General
 4 State Bar No. 242920
 300 So. Spring Street, Suite 1702
 5 Los Angeles, CA 90013
 Telephone: (213) 897-2533
 6 Facsimile: (213) 897-2804
Attorneys for Complainant

7
 8 **BEFORE THE**
BOARD OF PHARMACY
 9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 3601

11 **SERJ SOUKAZ MARKARIAN**
 12 **7766 N. Glenoaks Blvd.**
 13 **Burbank, CA 91504**
Pharmacist License No. RPH 54284

ACCUSATION

14 Respondent.

15
 16 Complainant alleges:

17 **PARTIES**

- 18 1. Virginia K. Herold (Complainant) brings this Accusation solely in her official
 19 capacity as the Executive Officer of the California State Board of Pharmacy.
 20 2. On or about March 20, 2003, the Board of Pharmacy issued Pharmacist License
 21 Number RPH 54284 to Serj Soukaz Markarian (Respondent). The Pharmacist License was in full
 22 force and effect at all times relevant to the charges brought herein and will expire on September
 23 30, 2012, unless renewed.

24 ///

25 ///

26 ///

27 ///

JURISDICTION

3. This Accusation is brought before the Board of Pharmacy (Board), under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

4. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender or cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

5. Section 490 of the Code provides, in pertinent part, that a board may suspend or revoke a license on the ground that the licensee has been convicted of a crime substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

6. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

7. Section 4060 of the Code states:

"No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a

1 physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5,
 2 or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of
 3 subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not
 4 apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy,
 5 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified
 6 nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly
 7 labeled with the name and address of the supplier or producer.

8 "Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a
 9 physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs
 10 and devices."

11 8. Section 4301 of the Code states:

12 "The board shall take action against any holder of a license who is guilty of unprofessional
 13 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
 14 Unprofessional conduct shall include, but is not limited to, any of the following:

15

16 "(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
 17 corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
 18 whether the act is a felony or misdemeanor or not.

19

20 "(l) The conviction of a crime substantially related to the qualifications, functions, and
 21 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13
 22 (commencing with Section 801) of Title 21 of the United States Code regulating controlled
 23 substances or of a violation of the statutes of this state regulating controlled substances or
 24 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the
 25 record of conviction shall be conclusive evidence only of the fact that the conviction occurred.
 26 The board may inquire into the circumstances surrounding the commission of the crime, in order
 27 to fix the degree of discipline or, in the case of a conviction not involving controlled substances
 28 or dangerous drugs, to determine if the conviction is of an offense substantially related to the

1 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or
2 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning
3 of this provision. The board may take action when the time for appeal has elapsed, or the
4 judgment of conviction has been affirmed on appeal or when an order granting probation is made
5 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of
6 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not
7 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or
8 indictment.

9 REGULATORY PROVISIONS

10 9. California Code of Regulations, title 16, section 1770, states:

11 "For the purpose of denial, suspension, or revocation of a personal or facility license
12 pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a
13 crime or act shall be considered substantially related to the qualifications, functions or duties of a
14 licensee or registrant if to a substantial degree it evidences present or potential unfitness of a
15 licensee or registrant to perform the functions authorized by his license or registration in a manner
16 consistent with the public health, safety, or welfare."

17 COST RECOVERY

18 10. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
19 administrative law judge to direct a licensee found to have committed a violation or violations of
20 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
21 enforcement of the case.

22 DRUGS

23 11. Pregabalin, also known by the brand name Lyrica, is a Schedule V, non-narcotic
24 controlled substance under Health and Safety Code section 11058, and is classified as a
25 dangerous drug pursuant to Business and Professions Code section 4022.

26 12. Eszopiclone, also known by the brand name Lunesta, is a Schedule IV, non-narcotic
27 controlled substance under Health and Safety Code section 11057, and is classified as a
28 dangerous drug pursuant to Business and Professions Code section 4022.

1 13. Tadalafil, also known by the brand name Cialis, is not a scheduled drug, but is
2 classified as a dangerous drug pursuant to Business and Professions Code section 4022.

3 14. Celecoxib, also known by the brand name Celebrex, is not a scheduled drug, but is
4 classified as a dangerous drug pursuant to Business and Professions Code section 4022.

5 **FIRST CAUSE FOR DISCIPLINE**

6 **(Substantially Related Convictions)**

7 15. Respondent is subject to disciplinary action under sections 490 and 4301, subdivision
8 (l), of the Code, in conjunction with California Code of Regulation, title 16, section 1770, in that
9 Respondent was convicted of a crime substantially related to the qualifications, functions or
10 duties of a licensed pharmacist. Specifically, on or about September 2, 2008, after pleading nolo
11 contendere, Respondent was convicted of one misdemeanor count of violating Penal Code
12 Section 602.5(B) [entering dwelling without consent] in the criminal proceeding entitled *The*
13 *People of the State of California v. Serj Soukaz Markarian* (Super. Ct. Los Angeles County, 2008,
14 No. 7PY07737). Respondent was placed on probation for 36 months and was ordered to pay a
15 fine.

16 16. The circumstances are that on or about August 17, 2007, while working as a
17 pharmacist at CVS Pharmacy, Respondent was observed concealing the following
18 pharmaceuticals in his bag: Cialis 20 mg, Lyrica 50 mg, Lunesta 3mg and Celebrex 100 mg. A
19 CVS store manager waited for Respondent to exit the store at closing time and contacted him in
20 the parking lot. The store manager checked Respondent's bags and located five (5) bottles of
21 pharmaceuticals that had been taken from the pharmacy without permission and had not been
22 paid for nor prescribed to Respondent.

23 **SECOND CAUSE FOR DISCIPLINE**

24 **(Unprofessional Conduct: Dishonest Act)**

25 17. Respondent is subject to disciplinary action under section 4301, subdivision (f) of the
26 Code in that he committed an act involving moral turpitude, dishonesty, fraud, deceit or
27 corruption. Complainant refers to, and by this reference incorporates, the allegations set forth in
28 paragraphs 15 and 16, as though set forth fully.

THIRD CAUSE FOR DISCIPLINE

(Possession of Controlled Substance Without a Prescription)

18. Respondent is subject to disciplinary action under section 4060 of the Code, in that he possessed controlled substances that were not furnished to him upon prescription of a physician. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 15 and 16, as though set forth fully.

FOURTH CAUSE FOR DISCIPLINE

(Administer/Furnish Controlled Substance to Self)

19. Respondent is subject to disciplinary action under section 11170 of the Health and Safety Code in that he prescribed, administered or furnished a controlled substance to himself. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 15 and 16, as though set forth fully.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacist License Number RPH 54284, issued to Serj Soukaz Markarian;
2. Ordering Serj Soukaz Markarian to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
3. Taking such other and further action as deemed necessary and proper.

DATED: 6/6/11

Virginia K. Herold
 VIRGINIA K. HEROLD
 Executive Officer
 California State Board of Pharmacy
 State of California
 Complainant

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BARBARA K. CEGAVSKE
Secretary of State

STATE OF NEVADA



OFFICE OF THE
SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138
North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

KIMBERLEY PERONDI
Deputy Secretary for
Commercial Recordings

Business Entity - Filing Acknowledgement

04/06/2020

Work Order Item Number: W2020040601195 - 509159
Filing Number: 20200591384
Filing Type: Articles of Organization
Filing Date/Time: 04/06/2020 14:43:48 PM
Filing Page(s): 2

Indexed Entity Information:

Entity ID: E5913852020-9

Entity Name: Plus One Pharmacy, LLC

Entity Status: Active

Expiration Date: None

Commercial Registered Agent

ANDERSON REGISTERED AGENTS

3225 MCLEOD DRIVE #110, LAS VEGAS, NV 89121, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

BARBARA K. CEGAVSKE
Secretary of State

BARBARA K. CEGAVSKE
Secretary of State

STATE OF NEVADA



**OFFICE OF THE
SECRETARY OF STATE**

Commercial Recordings Division
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North Las Vegas, NV 89030
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KIMBERLEY PERONDI
Deputy Secretary for
Commercial Recordings

Business Entity - Filing Acknowledgement

04/06/2020

Work Order Item Number: W2020040601195 - 509160
Filing Number: 20200591386
Filing Type: Initial List
Filing Date/Time: 04/06/2020 14:43:48 PM
Filing Page(s): 2

Indexed Entity Information:

Entity ID: E5913852020-9

Entity Name: Plus One Pharmacy, LLC

Entity Status: Active

Expiration Date: None

Commercial Registered Agent

ANDERSON REGISTERED AGENTS

3225 MCLEOD DRIVE #110, LAS VEGAS, NV 89121, USA

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Respectfully,

BARBARA K. CEGAVSKE
Secretary of State



BARBARA K. CEGAUSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
 (775) 684-5708
 Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of

Barbara K. Cegauske

Secretary of State
 State Of Nevada

Business Number

E5913852020-9

Filing Number

20200591384

Filed On

04/06/2020 14:43:48 PM

Number of Pages

2

Formation - Limited-Liability Company

- ☒ NRS 86 - Articles of Organization Limited-Liability Company ☐ NRS 86.544 - Registration of Foreign Limited-Liability Company
- ☐ NRS 89 - Articles of Organization Professional Limited-Liability Company ☐ NRS 86.555 - Registration of Professional Foreign Limited-Liability Company

1. Name Being Registered in Nevada: (See instructions)	Plus One Pharmacy, LLC		
2. Foreign Entity Name: (Name in home jurisdiction)			
3. Jurisdiction of Formation: (Foreign Limited-Liability Companies)	3a) Jurisdiction of formation:		3b) Date formed:
	3c) I declare this entity is in good standing in the jurisdiction of its formation.		<input type="checkbox"/>
4. Registered Agent for Service of Process*: (check only one box)	<input checked="" type="checkbox"/> Commercial Registered Agent (name only below) <input type="checkbox"/> Noncommercial Registered Agent (name and address below) <input type="checkbox"/> Office or position with Entity (title and address below)		
	ANDERSON REGISTERED AGENTS Name of Registered Agent OR Title of Office or Position with Entity 3225 MCLEOD DRIVE #110 LAS VEGAS Nevada 89121 Street Address City Zip Code Mailing Address (If different from street address) City Nevada Zip Code		
4a. Certificate of Acceptance of Appointment of Registered Agent:	I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form. X A.T. Mathis 04/06/2020 Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity Date		
5. Management: (Domestic Limited-Liability Companies only)	Company shall be managed by: (check one box) <input checked="" type="checkbox"/> Manager(s) OR <input type="checkbox"/> Member(s)		
6. Name and Address of each Manager(s) or Managing Member(s): (NRS 86 and NRS 86.544. see instructions) Name and Address of the Original Manager(s) and Member(s): (NRS 89. see instructions) IMPORTANT: A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing.	1) Anisha Patel Name 3225 McLeod Drive, Suite 100 Las Vegas NV 89121 Address City State Zip Code		
7. Dissolution Date: (Domestic only)	Latest date upon which the company is to dissolve (if existence is not perpetual):		



BARBARA K. CEGAVSKE
 Secretary of State
 202 North Carson Street
 Carson City, Nevada 89701-4201
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Formation - Limited-Liability Company

Continued, Page 2

8. Profession to be Practiced: (NRS 89 only)				
9. Series and/or Restricted Limited-Liability Company: (Optional)	Check box if a Series Limited-Liability Company <input type="checkbox"/> Domestic Limited-Liability Company's only: The Limited-Liability Company is a Restricted Limited-Liability Company <input type="checkbox"/>			
10. Records Office: (Foreign Limited-Liability Companies)	Address Country	City	State	Zip code
11. Street Address of Principal Office: (Foreign Limited-Liability Companies)	Address Country	City	State	Zip code
12. Name, Address and Signature of the Organizer: (NRS 86, NRS 89 -Each Organizer must be a licensed professional.) Name and Signature of Manager or Member: (NRS 86, 544 only) See instructions	<p>*Foreign Limited-Liability Company - In the event the designated Agent for Service of Process resigns and is not replaced or the agent's authority has been revoked or the agent cannot be found or served with exercise of reasonable diligence, then the Secretary of State is hereby appointed as the Agent for Service of Process.</p> <p>I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.</p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> Amanda Phillips </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;">Name</div> <div style="width: 40%;">Country</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div style="width: 40%;">Address</div> <div style="width: 15%;">City</div> <div style="width: 15%;">State</div> <div style="width: 30%;">Zip/Postal Code</div> </div> <div style="display: flex; align-items: center; margin-top: 5px;"> X <div style="flex-grow: 1;"> Amanda Phillips </div> <div style="margin-left: 10px;">(attach additional page if necessary)</div> </div>			

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:

(attach additional page(s) if necessary)



BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Plus One Pharmacy, LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: Read instructions before completing and returning this form.

Please indicate the entity type (check only one):

- ☐ Corporation
- ☐ This corporation is publicly traded the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☒ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of <i>Barbara K. Cegavske</i>	Business Number E5913852020-9
Secretary of State State Of Nevada	Filing Number 20200591386
	Filed On 04/06/2020 14:43:48 PM
	Number of Pages 2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B 020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is \$200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee
Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. § 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit \$200.00 for the state business license.

- ☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. § 501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****



BARBARA K. CEGAVSKE
 Secretary of State
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www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE <u>MANAGER</u> :			
<input style="width: 95%;" type="text" value="Anisha Patel"/>	<input style="width: 95%;" type="text" value="USA"/>		
Name	Country		
<input style="width: 40%;" type="text" value="3225 McLeod Drive, Suite 100"/>	<input style="width: 95%;" type="text" value="Las Vegas"/>	<input style="width: 20%;" type="text" value="NV"/>	<input style="width: 95%;" type="text" value="89121"/>
Address	City	State	Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X Amanda Phillips

Signature of Officer, Manager, Managing
 Member, General Partner, Managing Partner,
 Trustee, Member, Owner of Business,
 Partner or Authorized Signer FORM WILL BE RETURNED IF

UNSIGNED

Organizer

Title

04/06/2020

Date

SECRETARY OF STATE



DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Plus One Pharmacy, LLC** did, on 04/06/2020, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/06/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200406712233

You may verify this certificate
online at <http://www.nvsos.gov>

SECRETARY OF STATE



NEVADA STATE BUSINESS LICENSE

Plus One Pharmacy, LLC

Nevada Business Identification # NV20201755142

Expiration Date: 04/30/2021

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.

Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.

License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/06/2020.

Barbara K. Cegavske

Certificate Number: B20200406712234

You may verify this certificate
online at <http://www.nvsos.gov>

BARBARA K. CEGAVSKE
Secretary of State

17

APPLICATION BY RECIPROCATATION AS A PHARMACIST

If you are requesting licensure by reciprocatation (i.e. you have a current pharmacist license from another state and wish to transfer license information and only need to take the Nevada MPJE), complete this application:

Total Fee: \$330.00 (non-refundable, money order or cashier's check only, no cash)

Money Order or Cashier's Check made payable to: **Nevada State Board of Pharmacy**

Complete Name (no abbreviations):

First: Sathish Middle: — Last: Ariarra Cariappa

Mailing Address: Highland Trl

City: Bullhead city State: AZ Zip Code: 86442

Telephone: — E-mail Address: —

Date of Birth: — Place of Birth: India

Social Security Number: — Sex: ☒ M or ☐ F
(Full Number Required)

Original State of Licensure you are reciprocating from must be active and issued by exam;

State: Arizona Date of Issuance: May 2008

College of Pharmacy Information

Graduation Date: June 2000
(mm/dd/yy)

Degree Received: ☐ PharmD ☒ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: Kakatiya University

Location of School: WARANGAL, INDIA

If you are a **foreign graduate** you must attach a copy of your FPGEC certificate to THIS APPLICATION. You also need to complete the college of pharmacy information

Board Use Only

Processed: SEP 23 2019 Amount: 330.00 Entity #: —
Email — MPJE —

Other states where you are (or were) licensed as a pharmacist or print "none"

State	Lic #	Is the license active?	State	Lic #	Is the license active?
<u>TX</u>	<u>48211</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	<u>DE</u>	<u>A1-0003993</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<u>PA</u>	<u>RP450294</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			Yes <input type="checkbox"/> No <input type="checkbox"/>

**Attach separate sheet if needed

Have you ever served in the military, either active, reserve or retired? Yes ☐ No ☒

Branch: _____

Military Occupation/Specialty: _____

Dates of Service: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NONE

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. Been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Been the subject of a board citation or an administrative action or board citation whether completed or pending in <u>any</u> state?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation & documentation:

Board Administrative Action:	State	Date:	Case #:		
		/ /			
Criminal Action:	State	Date:	Case #:	County	Court
		/ /			

FEDERALLY MANDATED REQUIREMENTS

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications.

4. Are you the subject of a court order for the support of a child?..... Yes ☐ No ☒
4a. If you marked Yes, to the question 4. are you in compliance with the court order?..... Yes ☐ No ☐

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

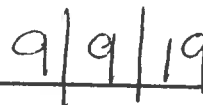
No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, its members, servants or employees because or by reason of the use of the authorization.

I attest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices.

I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.



Original Signature, no copies or stamps accepted



Date

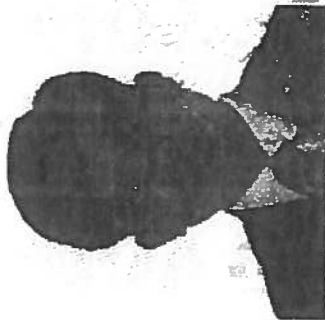
FPGEC CERTIFICATE



National Association of Boards of Pharmacy
Foreign Pharmacy Graduate Examination Committee
1800 Feehanville Drive, Mount Prospect, IL 60056

I hereby affix the seal of the National Association of Boards of Pharmacy® for the Foreign Pharmacy Graduate Examination Committee™, and certify that

SATHISH ARIARRA CARIAPPA



SATHISH ARIARRA CARIAPPA
EE# 203-2173

whose photograph and name have been so sealed on this Certificate, has passed the Foreign Pharmacy Graduate Equivalency Examination®, the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™, or the TOEFL Internet-based Test, and has met all other requirements for Certification.

This is not a license to practice pharmacy. Before using this Certificate in the licensing process, its authenticity should be verified in writing through the National Association of Boards of Pharmacy.

Carmen, A. Calzone, Executive Director/Secretary

MARCH 30, 2008

Date

Candy Nally

email 9/30
needs to appear

From: Pharmacy Board
Sent: Monday, September 30, 2019 10:41 AM
To: Candy Nally
Subject: FW: Sathish A Cariappa eProfile 338200

From: NABP Competency Assessment [mailto:CompAssess@nabp.pharmacy]
Sent: Monday, September 30, 2019 9:23 AM
To: David Wuest <dwuest@pharmacy.nv.gov>
Cc: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Subject: Sathish A Cariappa eProfile 338200



847/391-4405
Fax: 847/375-11

1600 Fernhill
Mount Prospect,
help@nabp.phar

September 30, 2019

Sathish A. Cariappa:
NABP e-profile # 338200

Dear Executive Director Dave Wuest:

Sathish A. Cariappa contacted the National Association of Boards of Pharmacy® (NABP®) regarding a registration for the Multistate Pharmacy Jurisprudence Examination® (MPJE®). NABP records show that the candidate has five failed attempts at the MPJE. In accordance with NABP's testing policy, the board of pharmacy must provide approval to NABP for requests that exceed the five-time testing limit before a candidate is permitted to register for the examination.

The testing limit was put in place in keeping with NABP's mission to protect public health by assisting its member boards of pharmacy and offer programs that promote safe pharmacy practices for the benefit of consumers.

NABP member boards retain the authority to determine a candidate's eligibility to test for the NAPLEX and MPJE. **If a candidate has not passed the NAPLEX or MPJE within five attempts and a member board deems**

this candidate eligible to take the NAPLEX or MPJE after the fifth attempt, NABP will deliver the NAPLEX or MPJE to the candidate in accordance with NABP standards.

Attempts were for the jurisdiction of Nevada.

DATE	SCORE
2/7/2009	72
6/29/2009	72
10/20/2015	73
6/13/2016	73
8/7/2018	68

Please provide NABP with the board's decision and justification regarding this request.

Sincerely,

NABP Competency Assessment

National Association of Boards of Pharmacy

1600 Feehanville Dr, Mount Prospect, IL 60056

www.nabp.pharmacy | CompAssess@nabp.pharmacy





NABP
National Association of
Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

Date Completed : 9/5/2019

To : Nevada Board of Pharmacy

The applicant below is seeking Licensure in your State

State(s) of Examination : Arizona

License No : S016571

License Being Used as the Basis of Transfer : Arizona

Date of Issue : 05/30/2008

APPLICANT DETAILS

e-Profile ID:	338200	Customer ID:	
Name:	Mr. Sathish Ariarra Cariappa	Mailing Address:	Highland Trl Bullhead City, AZ 86442
Maiden and / or Other Name(s):		Phone Number:	
Gender:	Male	Email Address:	YAHOO.COM
Date of Birth:		Citizenship:	Other H1b visa
SSN:			

PHARMACY EDUCATION

Name/Location of First Pharmacy School:	Kakatiya University India	Name/Location of Additional Pharmacy School:	
Graduation Date:	06/01/2000	Graduation Date:	
Degree Received:	Foreign Pharmacy Degree (non-US obtained)	Degree Received:	
Intern Hours:	1500		
EE Number:	203-2173	FPGEC Certified:	Yes
		FPGEC Certification Date:	3/30/2006

PHARMACY EXAM INFORMATION

				Five-Part NABPLEX				
State	Date of Exam	NAPLEX	Integrated NABPLEX	Chemistry	Mathematics	Pharmacology	Pharmacy	Practice of Pharmacy
	Exam Date	Score	Score	Score	Score	Score	Score	Score
AZ	11/5/2007	64.00						
AZ	3/25/2008	89.00						

MPJE: AZ-72, AZ-77, DE-70, DE-74, DE-76, NV-72, NV-73, NV-73, NV-68, PA-69, PA-79, TX-78

Additional Information:

e-Profile ID : 338200

Sathish Ariarra Cariappa

e-LTP Application

Customer ID : 231835

EMPLOYMENT HISTORY**Last Three Years of Employment**

Name of Employer	Address	Job Title	Start Date	End Date
Walgreens Pharmacy	2530 Hwy 95 Bullhead City, Arizona 86442	Intern/Pharmacist	10-2006	Present

PHARMACIST'S LICENSES


State	License Number	Exam Name	Obtained By	Issue Date	Expiration Date	Board Action	License Status
Arizona	S016571	NAPLEX	Exam	05/30/2008	10/31/2019	No	Active/Good Standing
Delaware	A1-0003993	MPJE	License Transfer	11/16/2009	09/30/2020	No	Active/Good Standing
Pennsylvania	RP450294	MPJE	License Transfer	11/25/2015	09/30/2020	No	Active/Good Standing
Texas	48211	MPJE	License Transfer	12/03/2009	10/31/2019	No	Active/Good Standing

DISCLOSURES

Question	Answer
1. Have you ever voluntarily surrendered your pharmacist license or any pharmacist registration issued by a federal or state controlled substance authority? If yes, provide details.	No
2. Has your pharmacist license in any jurisdiction ever been revoked, suspended, restricted, terminated, or otherwise been subject to disciplinary action (public or private) by any board of pharmacy or other state authority? If yes, provide details.	No
3. Are you presently under investigation or is there any disciplinary action pending against you by any licensing jurisdiction, the federal Food and Drug Administration, the federal Drug Enforcement Administration, or any state drug enforcement authority for violation of any state or federal pharmacy, liquor, or drug laws? If yes, provide details.	No
4. Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense? If yes, provide details.	No
5. Do you currently have any condition or impairment including, but not limited to, substance or alcohol abuse or dependency, that in any way affects your ability to practice pharmacy in a safe and competent manner? If yes, provide details.	No
6. Have you ever had any application for initial licensure, renewal licensure, or licensure by transfer denied by any licensing authority whether in pharmacy or any other profession? If yes, provide details.	No

Additional Comments:

The National Association of Board of Pharmacy (NABP) hereby certifies that information submitted in this application has been verified under verification procedures established by NABP through the Disciplinary Clearinghouse maintained by NABP, including license and disciplinary information, which is verified through the appropriate state Board of Pharmacy or Regulatory agency


 Mr. Carmen A Catizone, Executive Director/Secretary

e-Profile ID : 338200

Sathish Ariarra Cariappa

e-LTP Application

Customer ID : 231835

18

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy #206 – Reno, NV 89521

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE - PRESCRIBE

REGISTRATION FEE: \$80.00 (non-refundable money order or cashier's check only)

First: Natalie Middle: Rae Last: LynnHome Address: Milpas LaneCity: Las Vegas State: NV Zip Code: 89102S _____ Date of Birth: _____ Sex: ☐ M or ☒ FTelephone: _____ E-mail address: gmail.com

PRACTICING LOCATION (Required)

Practice Name (if any): Dispatch Health Urgent CarePhysical Address: 3411 W Charleston Blvd #203 Suite #: 203City: Las Vegas State: NV Zip Code: 89102Telephone: 720-647-5329 702-848-4443 Fax: 720-603-9592Nursing Board #: 815950 Issued: 12/17/2018 Expires: 12/21/2021

☒ Check this box if you are a APRN who intends to apply for DEA Registration. Board Staff will notify DEA and you of the required information and provide a letter with your pending number to allow you to apply for the DEA in Nevada-(Do not apply to DEA before receiving your pending letter.)

You must have a current Nevada license with your respective BOARD before we will process this application. The Nevada license must remain current to keep the controlled substance registration.

		Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?.....		<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.	Been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2.	Been the subject of a board citation, administrative action whether completed or pending in <u>any</u> state?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.	Had your license subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation & documentation:			
Board Administrative Action:	State	Date:	Case #:
		/ /	
Criminal Action:	State	Date:	Case #:
		/ /	
		County	Court

It is a violation of Nevada law to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

I understand that Nevada law requires a licensed APRN who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

[Signature]
Original Signature of APRN, no copies or stamps accepted

1/29/2020
Date

COLLABORATING PHYSICIAN's name (If required): _____

Original Signature of Collaborating Physician, no copies or stamps accepted

Date

Board Use Only: Date Processed _____

Amount 80

Explanation

1. *Been charged, arrested or convicted of a felony or misdemeanor in any state?*

YES.

On February 26, 2019, I was arrested in Las Vegas on suspicion of driving under the influence, possession of a dangerous drug without a prescription, possession of a controlled substance without a prescription, and failing to maintain a travel lane. On July 19, 2019, I was charged with misdemeanor driving under the influence and failing to maintain a travel lane only. That case (No. 19M12821X) is currently pending before the Las Vegas Justice Court. Arrest records and the criminal complaint are attached.

On the night of February 25-26, 2019, I was pulled over while driving and taken into custody on suspicion of driving under the influence. Due to my pending criminal matter, I have been advised by my counsel not to provide further details on that issue.

As part of that arrest, my vehicle and purse were searched. The officer discovered a prescription bottle in my purse with twenty (20) pills of zolpidem tartrate, 10mg (generic for Ambien), a Schedule IV controlled substance. The bottled was labeled for my mother, Patricia Mortel, and dated September 20, 2010. I was in the process of moving, and my mother had left her prescription at my house. I had her prescription in my purse so that I could return it to her. It is obviously an old prescription of hers, and given that twenty (20) pills remained in the bottle, it was pretty clear that her prescription was not being abused or diverted. The early charges of possession of a dangerous drug without a prescription and possession of a controlled substance without a prescription were dropped with no complaint filed.

As stated above, my criminal case on the remaining charges is pending. I have had no other felony or misdemeanor charges, arrests, or convictions in any other state.

JUSTICE COURT, LAS VEGAS TOWNSHIP
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

NATALIE RAE WYNN, aka,
Natalie Rae Mortel #5686794,

Defendant.

CASE NO: 19M12821X

DEPT NO: 13

CRIMINAL COMPLAINT

The Defendant above named having committed the crimes of DRIVING UNDER THE INFLUENCE (Misdemeanor - NRS 484C.110, 484C.400, 484C.105 - NOC 53900) and FAILURE TO MAINTAIN TRAVEL LANE (Misdemeanor - NRS 484B.223 - NOC 53788), in the manner following, to wit: That the said Defendant, on or about the 26th day of February, 2019, at and within the County of Clark, State of Nevada,

COUNT 1 - DRIVING UNDER THE INFLUENCE

did then and there willfully and unlawfully drive and/or be in actual physical control of a motor vehicle on a highway or on premises to which the public has access at U.S. Highway 95 and Craig, Las Vegas, Clark County, Nevada, Defendant being responsible in one or more of the following ways and/or under one or more of the following theories, to wit: 1) while under the influence of intoxicating liquor to any degree, however slight, which rendered her incapable of safely driving and/or exercising actual physical control of a vehicle, 2) while she had a concentration of alcohol of .08 or more in her blood, and/or 3) when she was found by measurement within two (2) hours after driving and/or being in actual physical control of a vehicle to have a concentration of alcohol of .08 or more in her blood.

COUNT 2 - FAILURE TO MAINTAIN TRAVEL LANE

did then and there willfully and unlawfully fail to drive a motor vehicle as nearly as practicable entirely within a single lane while operating a motor vehicle at U.S. Highway 95 and Craig, Las Vegas, Clark County, Nevada, a highway with two or more clearly marked lanes for traffic traveling in one direction.

1 All of which is contrary to the form, force and effect of Statutes in such cases made and
2 provided and against the peace and dignity of the State of Nevada. Said Complainant makes
3 this declaration subject to the penalty of perjury.

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27 19M12821X/ml
28 NHP EV# 190202314
(TK12)

NOTICE OF INTENT TO USE AFFIDAVIT OR DECLARATION

Please be advised that, pursuant to NRS 50.315 and 50.325, upon the trial of this matter, the State of Nevada intends to offer into evidence the affidavit or declaration made under penalty of perjury of the person who withdrew the sample of whole blood from the Defendant for the purposes set forth in NRS 50.315(4). A copy of said affidavit or declaration is included in the discovery provided in this matter.

The person who withdrew the sample of whole blood in this matter is:

S. WILSON

LABCORP

UNIVERSITY MEDICAL CENTER

1800 West Charleston Boulevard

Las Vegas, Nevada 89102

*PAGE 1 OF 1 UOF ☐ BODY CAM ☐ LAS VEGAS METROPOLITAN POLICE DEPARTMENT
 *ID/CS# 5886794 ☐ NEW ID ☐ **TEMPORARY CUSTODY RECORD**
 (* DENOTES OFFICER REQUIRED FIELD)

*ARREST DATE: 2/26/2019 *ARREST TIME: 0245
 *EVENT #: 190202314
 *CO-DEF: N

CO. SGT APPROVAL ☐ REBOOK ☐ ABSENTIA ☐ FORM 6 ☐ NDOC ☐ EXT TO LAS VEGAS ☐ LVC ☐ HND ☐ NLV ☐ COURTESY HOLD ☐ DETAINER

*INTAKE NAME (AKA, ALIAS, ETC.)		LAST		WYNN		FIRST		MIDDLE		TRUE NAME		Natalie Mortel		MIDDLE		Kae					
*ADDRESS (STREET # AND STREET NAME)										CITY		STATE		ZIP		PLACE OF BIRTH		CARMICHAEL, CALIFORNIA			
*DATE OF BIRTH		*RACE		*HSP ETHN		*SEX		*WEIGHT		*HEIGHT		*HAIR		*EYES		*BLU		*BLN			
1		W		NH		F		505		155		BLV		BLU		BLN		BLV			
*LOCATION OF CRIME (STREET ADDRESS, CITY, STATE, ZIP)										CITY		STATE		ZIP		PLACE OF BIRTH		CARMICHAEL, CALIFORNIA			
US95/CRAIG LAS VEGAS, NV 89129										LAS VEGAS		NV		89131		CARMICHAEL, CALIFORNIA		CARMICHAEL, CALIFORNIA			
*WARRANT # / CASE #										*COURT JURIS		*NO. CODE		*M. G. F.		*CHARGE LITERAL		*ORD / NRS		*EVENT# / NIC#	
1										JC		51358		M		POSS DANG DRUG W/O P-SCRIPT		454.316.1		190202314	
1										JC		51127		M		POSS SCH I, II, III, IV C/S, (1ST/2ND)		453.336.2A		190202314	
1										JC		53800		M		DUI (1ST) alcohol/drugs		484C.110		190202314	
1										JC		53788		M		FAIL MAINT LANE/IMPROPER LANE CHANGE		484B.223.1		190202314	
*OTHER JURISDICTION:										PC - PROBABLE CAUSE		BS - BONDSMAN SURRENDER		BNW - BENCH WARRANT		AW - ARREST WARRANT		RM - REMAND		GJ - GRAND JURY INDICTMENT	

TIME STAMP AT BOOKING		2/26/2019 7:30 AM		TIME STAMP AT RELEASING		19F03529X - MORTEL, NATALIE	
*ARRESTING OFFICER SIGNATURE		C BLACK		*PRINTED NAME		NHP	
*TRANSPORTING OFFICER SIGNATURE		C BLACK		*PRINTED NAME		NHP	
*EMERGENCY CONTACT		Patricia		*RELATIONSHIP		mom	
*PHONE NUMBER		702		*RELEASE ID		DNA 3FO	
*EMAIL ADDRESS				*DATE		FEB 26 2019	
*POLICE RECORDS COPY		<input type="checkbox"/>		*COURTS COPY		<input type="checkbox"/>	
*DSD RECORDS COPY		<input type="checkbox"/>		*PROCESSING COPY		<input type="checkbox"/>	
*DOC DIST #		1:1		*POLICE RECORDS COPY		<input type="checkbox"/>	
*POLICE RECORDS COPY		<input type="checkbox"/>		*COURTS COPY		<input type="checkbox"/>	
*DSD RECORDS COPY		<input type="checkbox"/>		*PROCESSING COPY		<input type="checkbox"/>	
*REL REV #		875496		*SCORE		NO 111	

**NEVADA HIGHWAY PATROL
DECLARATION OF ARREST**

PAGE 1

ID: 5696794

EVENT: 190202314

TRUE NAME: WYNN, NATALIE RAE	DATE OF ARREST: 02/26/2019	TIME OF ARREST: 0245
OTHER CHARGES RECOMMENDED FOR CONSIDERATION:		
NONE		

THE UNDERSIGNED MAKES THE FOLLOWING DECLARATIONS SUBJECT TO THE PENALTY FOR PERJURY AND SAYS: That I am a State Trooper with the Nevada Department of Public Safety, Highway Patrol, Las Vegas, being so employed for a period of 16 months.

That I learned the following facts and circumstances which lead me to believe that **Natalie Rae Wynn** committed (or was committing) the offense(s) of (see TCR) at the location of US95/Craig.

That the offense(s) occurred at approximately 0226 hours on the 26th day of February, 2019.

On February 26th, 2019 at approximately 0226, I, Trp. C. Black P#434, was patrolling US 95 southbound near Craig when I observed a silver Kia Sorento bearing NV registration 416YMU failing to maintain its lane. I observed the vehicle cross from the #3 to the #4 travel lane before correcting back to the #3. The vehicle then crossed back from the #3 travel lane to the #4 travel lane and was straddling the lane line. The vehicle corrected back into the #3 travel lane and crossed into the #4 travel lane once more. I initiated a traffic stop on the vehicle using emergency lights and siren. The vehicle pulled to the right shoulder.

I made a passenger side approach to the vehicle and contacted the driver, identified by her NV driver license as Natalie Rae Wynn, DOB . NV license # . I immediately noticed an odor of unknown intoxicating beverage coming from within the vehicle. I also noticed Wynn had bloodshot eyes. Wynn stated that she and her passenger were on their way down the road to get some food. I asked how much Wynn had to drink tonight and she said one beer a few hours ago. I asked Wynn if she would be willing to step out to perform field sobriety tests to which she agreed.

I asked Wynn to sit on the front push bumper of my patrol car. Wynn stated she was not currently seeing a doctor for any reason, had no physical injuries that would keep her from walking or balancing normally, was not taking any over the counter medications and was not diabetic or taking insulin for any reason. Wynn stated that she was taking a few different prescription medications including Xanax, Topamax, Seroquel, Ambien, Omeprazole and "Zomig" (Zolmitriptan). I asked how often she takes those medications and she stated "as needed thru ought the day". I asked what the last medication she took was and she stated she took a Xanax at about 7pm yesterday. Wynn stated that she saw an optometrist about three months ago and was currently wearing glasses because she was far sighted and had stigmatism in both eyes. Wynn stated that both her eyes were real but that she was "clinically blind" without her glasses. I asked her to

NEVADA HIGHWAY PATROL
DECLARATION OF ARREST
PAGE 2

ID: 5686794

EVENT: 190202314

explain what that meant and she stated that her optometrist told her she was clinically blind without her glasses but could see with them on and could drive with her glasses. Wynn also stated that she had been diagnosed with natural nystagmus in both eyes by her optometrist about three months ago. I asked her if she could explain to me what nystagmus, which she did. I asked if she could still see me without her glasses on and she said "vaguely". I asked her to put her glasses back on.

I explained the horizontal gaze nystagmus test. Wynn stated that she understood my instructions and had no questions regarding the test. I observed equal pupil size and equal tracking in both eyes. After the first two passes, Wynn did not follow my finger. She appeared to just be looking at my chest. I asked if she understood what I was asking her to do and she said yes. I continued the test and observed lack of smooth pursuit in both eyes. I attempted three more passes but Wynn would not follow my finger. (2 clues)

I instructed and demonstrated the walk and turn test. Wynn stated she felt comfortable attempting the test on the flat dry asphalt surface we were standing on in the sneakers she was wearing. Wynn stated she understood my instructions and had no questions regarding the test. I observed Wynn exit the instructional stance, begin the test before being instructed to do so, raise her arms for balance, fail to touch heel to toe multiple times and step off line multiple times. (5 clues)

I instructed and demonstrated the one leg stand test. Wynn stated she understood my instructions and had no questions regarding the test. I observed Wynn raise her right leg. Wynn raised her arms for balance and swayed while balancing. Wynn hopped and then put her foot down after approximately 18 seconds and looked at me. I asked if she understood what I was asking her to do. Wynn stated she would like me to explain the test again. I explained and demonstrated the test again. Wynn stated she understood my instructions and had no questions regarding the test. I observed Wynn raise her right foot and raise her arms for balance. After approximately 10 seconds I stopped the test for her safety. Wynn was swaying while balancing and hopped towards the travel lanes. (4 clues)

I asked if Wynn would be willing to continue with further tests which were not standardized field sobriety tests. Wynn agreed to continue. I instructed the Romberg balance test. Wynn stated she understood my instructions and had no questions regarding the test. Wynn estimated the passage of 30 seconds in approximately 22 seconds. During the test, I observed distinct eyelid tremors in both eyes. I also observed Wynn swaying side to side during the test.

I asked Wynn to sit on the front push bumper of my patrol car and instructed the lack of convergence test. Wynn stated she understood my instructions and had no questions regarding the test. I performed the test twice. On the first attempt, Wynn did not follow my finger in towards her face. On the second attempt, I observed distinct lack of convergence in her left eye.

**NEVADA HIGHWAY PATROL
DECLARATION OF ARREST**

PAGE 3

ID: 5686794EVENT: 190202314

I asked if Wynn would be willing to take a preliminary breath test. Wynn stated that she would rather just get her blood drawn and refused the PBT.

At approximately 0245, I placed Wynn in my custody using a rear passive technique, checked the handcuffs for tightness and double locked them. I performed a rear-standing search for weapons and contraband with negative findings. Wynn was then placed in the rear of my patrol car. I asked Wynn if there was anything in the car that she would like to take with her and she stated that she wanted her purse.

I retrieved her purse from the vehicle, which was the only purse in the vehicle and performed a search of the contents. In the bottom of her purse was an orange prescription pill bottle addressed to a "Patricia Mortel" dated 09/20/2010 containing 20 round white pills stamped "74" on one side and "TEVA" on the other. A drugs.com search of the pill identified it as "Zolpidem Tartrate 10mg", used to treat insomnia. Drugs.com classified the pill as a schedule 4 controlled substance and listed the pill availability as by prescription only. Wynn was then transported to the City of Las Vegas Detention Center.

Upon arrival to the jail, I read Wynn her rights for a DUI arrest to which she agreed to take a blood test. After several failed attempts by the medical staff at the jail to draw blood, Wynn was transported to UMC Trauma Center. At the hospital, I observed lab technician Sabrina Wilson draw two vials of blood from Wynn's right forearm at approximately 0417. I took custody of the vials and sealed them appropriately in the blood kit box. Wynn was then transported back to the City of Las Vegas Detention Center.

Upon arrival to the jail, I realized I had made a mistake regarding the type of charges on Wynn. The city jail will not accept felony charges. Due to the state statues regarding possession of a controlled substance, Wynn was then transported to the Clark County Detention Center where she was booked appropriately without incident. The blood kit and pill bottle were both booked appropriately at the NHP Southern Command Evidence Vault.

Wherefore, the declarant prays that a finding be made by a magistrate that probable cause exists to hold said person for preliminary hearing (if charges are a felony or gross misdemeanor) or for trial (if charges are misdemeanor).

DECLARANT: Trp. C. Black #434

Involvements

Date	Type	Description	Relationship
03/02/19	Name	WYNN, NATALIE RAE	Arrestee
03/02/19	Vehicle	SIL 2013 KIA SOR NV	Vehicle
02/26/19	Offense	51358 454.316.1 - G - 1 count	Charged With
02/26/19	Offense	51127 453.336.2a - F - 1 count	Charged With
02/26/19	Offense	53900 484C.110.1a - M - 1 count	Charged With
02/26/19	Offense	53788 484B.223.1 - M - 1 count	Charged With
02/26/19	Cad Call	02:26:27 02/26/19 TRAFFIC STOP PS	Initiating Call

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19A

July 20, 2020

Dear NV State Board of Pharmacy Members,

I am submitting this letter of request to provide Medication Therapy Management (MTM) services to patients as part of the Dignity Health, Quality Technical and Assistance Center (QTAC) initiative to incorporate pharmacists into patient-centered team-based care at the Roseman Medical Group, the Clinical Practice of Roseman University of Health Sciences. I would like to request an appearance before the Board at the September 2020 meeting for review of services provided. The pharmacy services are provided at alternate sites than a licensed pharmacy, I am including the following details as requested per NAC 639.403 sections (a) through (k):

(a) The name of the pharmacist: KayLynn Bowman, PharmD, MS, MEd

(b) A description of the services that the pharmacist intends to provide at the site;
MTM pharmacy services provided to patients with chronic disease states including, but not limited to, Diabetes, High Blood Pressure, High Cholesterol and Congestive Heart Failure. Services will include collection of patient demographics, social history, health history, medical conditions, allergies, immunization history, available lab work data, medication and non-medication history. Services provided at the site may include Roseman Medical Group medical residents and/or Roseman University of Health Science, College of Pharmacy student interns.

Services Provided Include:

Poly-pharmacy, medication optimization, medication adherence are addressed during each visit. Pharmacist consultations as requested. Group classes on healthy heart, DSMES services, Medication Management, Fall Prevention, Smoking Cessation, Exercise, Diet and Nutrition. Dignity Health Quality, Technical and Assistance Center (QTAC) disease management program initiatives. Medication Reconciliation: along with patient disease state education.

(c) The location at which the pharmacist will provide the services;
Roseman Medical Group, the Clinical Practice of Roseman University of Health Sciences
5380 S Rainbow Blvd #120, Las Vegas, NV 89118
Phone: 702-463-4040, Fax: 702-968-5681

(d) An identification of the types of patients or other persons to whom the pharmacist intends to provide the services;
Patients with chronic disease states, including diabetes, high blood pressure, and high cholesterol and located in urban and underserved areas of Southern Nevada.

(e) An identification of the types of pharmacies or other entities to whom the pharmacist intends to provide the services;
Roseman Medical Group practice serves a wide variety of patients eligible for services living in Southern Nevada in urban and underserved areas in Clark County.

(f) A description of all resources, both paper and electronic, that will be available to the pharmacist in the course of providing the services;

Roseman Medical Group EHI and charting, LexiComp, Ovid, Global RPh, Up to Date, Pharmacist's Letter, and other evidence-based sources of medical information.

(g) The days and hours during which the pharmacist intends to provide the services;

Rosmean Medical Group: Monday - Friday by appointment

(h) An explanation of the policy of the pharmacist for users of the services when the pharmacist is unavailable;

The pharmacist is available by appointment only, all referrals are submitted to the pharmacists and appointments are made for MTM services utilizing the Roseman Medical Group appointment system. There are clinic hours offered during the month to be determined by appointment needs. When not available, patients will be provided contact information or leave a message at Roseman Medical Group Office Number 702-463-4040 and/or Pharmacist's mobile number 702-218-1456. In the case of an emergency, the patient will be directed to emergency services.

(i) An explanation of the policy of the pharmacist regarding the confidentiality and security of the patient data that will be gathered, made and maintained as part of the services which are provided, including, without limitation, paper and electronic records;

Electronic medical records are stored and accessed through the Roseman Medical Group electronic medical records.

(j) Whether the services provided will be affiliated with, an adjunct of or otherwise related to a licensed pharmacy; The services provided are not affiliated with a licensed pharmacy.

(k) A description of the business plan for the services provided.

No business plan is needed. MTM services are covered by CDC grant initiatives and objectives.

Please contact me if any additional information is needed.

Thank You,

KayLynn Bowman, PharmD, MS, MEd

Rx Healthy Living LLC, Owner

Nevada Pharmacy License 17134

MTM Pharmacy Services, Consultant Pharmacist

Dignity Health, QTAC

2651 Paseo Verde Parkway, Suite 180

Henderson, NV 89074

Office: (702) 616-4914

Fax: (702) 616-4909

Cell:

ema

[mail.com](mailto:ema@mail.com)

Roseman Medical Group Medication Therapy Management Protocol
Developed by: KayLynn Bowman, PharmD

1. Identification and referral of eligible patients from Primary Care Providers at Roseman Medical Group (RMG) that have not achieved clinical goals of therapy.
2. Coordinate care with RMG providers and prescribers for referral of eligible MTM candidates and to make recommendations and discuss identified drug related problems.
3. Understand the patient's personal medication experience/history and preferences/beliefs. Identify actual use patterns of all medication, including OTC, supplements, herbals, and prescribed medications.
4. Employ intensive patient education efforts aimed at addressing adherence, barriers, including a comprehensive understanding of why each medication is prescribed. Assess each medication for appropriateness, effectiveness, safety, and adherence. Focus on achievement of clinical goals for each therapy.
5. Document the opportunities that were addressed with the patient, including any gaps in therapy preventing optimal outcomes. Address financial barriers to adherence such as high drug costs by potentially switching to generics or less expensive formulary alternatives.
6. Develop a care plan addressing recommendations, including therapeutic changes needed to achieve optimal outcomes. Document the quality and safety of prescribing as part of the MTM intervention. Provide patients with a complete list of prescribed medications.
7. Patient agrees and understands the care plan which is communicated through the electronic medical record to the care team (providers, prescribers) for his or her consent/support following the MTM appointment.
8. Follow-up evaluation with patients is critical to determine the effects of changes, reassess actual outcomes and recommend further therapeutic changes to achieve desired clinical goals/outcomes: allow 2 weeks for recommended therapy interventions, allow 1 month for evaluating patient-centered clinical/educational goals/outcomes.
9. Use efficient communication methods to convey medication recommendations to prescribers, including video/tele-communications and electronic medical records.
10. Leverage all available data sources (EHR, registries, claim data) to determine whether gaps in medical care are present, including preventive care and maintenance related to the patient's specific medication condition based on standards of care.

Deliverables:

PMR - Patient Medication Review provides a patient with a complete list of their medications
MAP - Medication Action Plan provides a patient-centered document containing a list of actions for the patient to track progress and self-management.
Intervention and/or Referral - consultative services for pharmacy interventions for drug related problems.

Roseman Medical Group Medication Therapy Management Protocol
Developed by: KayLynn Bowman, PharmD

Evaluation of Program Goals:

Therapy Goals are individualized based on measurable standards of care such as A1C, BMI, blood pressure etc. Economic measures include hospitalization prevention, emergency room visits eliminated, clinical visits avoided, fewer sick days used, and any impact on drug costs.

MTM is a reiterative process: Care is coordinated with other team members and personalized (patient unique) goals of therapy and understood by all team members.

References:

American Pharmacists Association; National Association of Chain Drug Stores Foundation. Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model. Version 2.0. J Am Pharm Assoc (2003). 2008;48:341-353.

Centers for Medicare & Medicaid Services. Medicare Part D medication therapy management (MTM) programs: 2018 fact sheet. Updated August 20, 2018. Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2018-MTM-Fact-Sheet.pdf>. Accessed January 21, 2019.

McInnis T, Webb CE, Strand LM. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes, Patient-Centered Primary Care Collaborative, June 2012. Available at: <http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>. Accessed January 21, 2019.

Protocol Developed By:

KayLynn Bowman, PharmD, MS, MEd
Rx Healthy Living LLC, Owner
Nevada Pharmacy License 17134
MTM Pharmacy Services, Consultant Pharmacist
Dignity Health, QTAC
2651 Paseo Verde Parkway, Suite 180
Henderson, NV 89074
Office: (702) 616-4914
Fax: (702) 616-4909
Cell
ema [jmail.com](mailto:kylb@rxhealthy.com)

19B

Dear NV State Board of Pharmacy Members,

I am submitting this letter to request approval to perform work as a pharmacist at an off-site. I would like to request an appearance before the Board for review of my services at an alternate site other than a licensed pharmacy.

- Pharmacist Name: James H Kim, PharmD
- A brief description of the services the pharmacist intends to provide at the site:
 - **Site 1 – Hometown Health or Home**
 - Medication therapy Management services per Centers for Medicare & Medicaid Services per Requirements for Medication Therapy Management Programs (MTMP): Under 423.153(d) for a Part D sponsor
 - Managed Care Services
 - Formulary Management
 - Prior Authorizations review
 - Utilization management
 - Patient Safety Monitoring
 - Analysis of therapeutic outcomes
 - **Site 2 – Department of Human Health Services or Home**
 - My main role for DHHS is to oversee and provided reporting for the states Drug Transparency Program according to NRS 439B.630, NRS 439B635, and NRS, 436B.660.
 - This work includes but is not limited to reviewing Medicaid claims, Drug pricing, working with Pharma and drug manufactures to meet reporting guidelines.
- Location of sites:
 - Hometown Health – 10315 Professional Cir, Reno NV 89521
 - DHHS – 4150 Technology Way Carson City, NV 89706
 - Home – Address available upon request
- An identification of the types of patients or other persons to whom the pharmacist intends to provide the services:
 - Hometown health- Members of the insurance
 - DHHS – N/A
- An Identification of the types of pharmacies or other entities to whom the pharmacist intends to provide services with:
 - Site 1
 - Renown Health
 - Maxor Plus
 - Medimpact
 - Agadia
 - Sinfonia

- Site 2 – Not applicable
- A description of all resources –
 - Site 1 – A computer with VPN access to hometown health network. Access to Epic EMR, SQL servers for analytics, Medication Claims systems through PBMs. MTM platform through Sinfonia –Rx companion
 - Site 2 – A computer with VPN access to DHHS drug transparency program.
- Schedule:
 - Site 1 – MTM will only be provider during business hours 8-5 pm, All other work can be performed anytime
 - Site 2 – Anytime
- An explanation of the policy of the pharmacist for users of the services when the pharmacist is unavailable:
 - Not applicable
- An explanation of the policy of the pharmacist regarding the confidentiality and security of the patient data:
 - Policy per HIPPA regulations for both sites
 - MTM information of be documented per RX companion software which meets all HIPPA regulations
- Services will not be affiliated with an adjunct of or otherwise related to a licensed pharmacy.

Thank You,

James Kim, PharmD

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Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
(775) 850-1440
bop.nv.gov

NEVADA
(For locations located in the State of Nevada)
WHOLESALE APPLICATION
INFORMATION AND CHECKLIST

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

Failure to submit a complete application will result in significant delays in the processing of the application and issuance of the license.

Submission of the application just prior to the deadline date does not guarantee placement on the board agenda.

Please understand we cannot and will not accept incomplete applications. If there is not an appropriate response, so state with N/A. Review the checklist and return all required fees and documentation with the completed application.

Please note the application/documentation deadline date is on the board meeting schedule listed on the website. The deadline date is the LAST DAY completed applications may be accepted for that particular board meeting. If the application and all pertaining documentation is not complete and enclosed, (NO EXCEPTIONS) the application will be returned. Confirmation of personal data may require review.

REQUIRED DOCUMENTS FOR ALL TYPES OF OWNERSHIP

You will also be required to submit additional information depending on your ownership type. Details regarding the additional information are included with the application.

- Complete all required pages of the application. Must be original signature(s), no copies or stamps
- Fee made payable to: *Nevada State Board of Pharmacy*
- Applications or Fingerprint Cards that are not properly completed will be rejected and your application will not be processed. The Application and any payments will be returned.

REQUIRED INFORMATION FOR ALL TYPES OF OWNERSHIP

Before you operate as a wholesaler, you must receive board approval and be inspected by Board of Pharmacy personnel. Please know that the receipt of drugs prior to licensing will be deemed a violation of Nevada Revised Statutes (NRS) 454.316 which provides possession of a drug unlawful and is a category E felony.

Your application may be placed on the agenda of the next regularly scheduled board meeting. APPEARANCE(S) AT THE BOARD MEETING MAY BE REQUIRED. If an appearance is required, your company will be notified in writing two (2) weeks prior to the meeting. Otherwise assume appearance will not be necessary. Upon board approval and a satisfactory inspection a certificate of registration will be issued. This registration is renewed in October of even numbered years. A license is usually issued and mailed within 10 days from the board meeting date, if approved.

Any change of ownership and/or location change, will require a new application and \$500.00 fee. If the address changes, a pre-opening inspection will be required

This license is renewed in October of even numbered years, no matter when the license is issued. Fees are not pro-rated.

Please access the applicable laws on the website under "Nevada Statues & Regulations" tab.

If the application is approved at the scheduled board meeting a letter with the information needed to schedule the required inspection will be mailed within 10 days from the date of the last meeting.

If you have any questions, contact the licensing specialist in the Reno office at (775) 850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY
 985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
APPLICATION FOR NEVADA WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
 (non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler ☐ Ownership Change ☐ Name Change ☐ Location Change
 (Please provide current license number if making changes: WH_____)

☐ Publicly Traded Corporation – Page 1,2,3,4 ☐ Partnership - Page 1,2,3,6,6a
☐ Non Publicly Traded Corporation – Page 1,2,3,5,5a,5b ☐ Sole Owner – Page 1,2,3,7,7a
 Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION

Facility Name: _____

Physical Address: _____

Mailing Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: _____ Fax: _____

Toll Free Number: _____

E-mail: _____ Website: _____

Facility Manager: _____

Professional qualifications and experience of facility manager: _____

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☐ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR NEVADA WHOLESALER LICENSE

Is your company VAWD certified by NABP?
(If yes, provide a copy of the certificate.)

Yes ☐ No ☐

Licensed as a Manufacturer by the FDA?
(If yes, provide a copy of the FDA registration)

Yes ☐ No ☐

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction?

Yes ☐ No ☐

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

1)	_____	
	Name	Address

	Business	
2)	_____	
	Name	Address

	Business	
3)	_____	
	Name	Address

	Business	
4)	_____	
	Name	Address

	Business	

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☐
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☐
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

APPLICATION FOR NEVADA WHOLESALER LICENSE

This page must be submitted for all types of ownership.

- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☐
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Authorized Person

Date

Board Use Only

Received: _____

Amount: _____

APPLICATION FOR NEVADA WHOLESALER LICENSE**OWNERSHIP IS A PUBLICLY TRADED CORPORATION**

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

Ownership Information – Complete Section 1 or 2

Do not use N/A in this section – Section 1 or 2 must be completed.**Section 1:** List the corporations four largest shareholders:
(Name and percentage of ownership)

1. _____ %: _____

2. _____ %: _____

3. _____ %: _____

4. _____ %: _____

Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

*Date of Incorporation: _____

*Registration number issued: _____

*Stock Exchange: _____

Include with the application for a publicly traded corporationList of officers and directors.Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

APPLICATION FOR NEVADA WHOLESALER LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List any persons to whom the shares were issued by the corporation?

a) _____
Name Addressb) _____
Name Addressc) _____
Name Addressd) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

Application for Nevada Wholesaler License

Include with the application for a non-publicly traded corporation

List of officers and directors.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Designated representative form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an examination on law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee.

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the documents for wholesalers only.

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the documents for wholesalers only.

***If your company is not VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Complete personal history record for each stockholder. Must be original signature(s), no copies or stamp. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.
- Submit fingerprints – Please refer to Fingerprint Submission Instructions

<http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf>.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.
- Copy of a bond in an amount of \$100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for wholesalers only*.

APPLICATION FOR NEVADA WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP.

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

Include with the application for a partnership

Complete personal history record for each stockholder. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*. Must be original signature(s), no copies or stamp.

Designated representative form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an examination on law **prior** to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee.

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the documents for wholesalers only.

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the documents for wholesalers only.

***If your company is not VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Complete personal history record for each stockholder. Must be original signature(s), no copies or stamp. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.
- Submit fingerprints – Please refer to Fingerprint Submission Instructions

<http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf>.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.
- Copy of a bond in an amount of \$100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for wholesalers only*.

APPLICATION FOR NEVADA WHOLESALER LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: _____

Business Name: _____

Current Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Include with the application for a sole owner

Complete personal history record. Must be original signature(s), no copies or stamps. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

Designated representative form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*. The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an examination on law **prior** to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the documents for wholesalers only.

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the documents for wholesalers only.

***If your company is not VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Complete personal history record for each stockholder. Must be original signature(s), no copies or stamp. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.
- Submit fingerprints – Please refer to Fingerprint Submission Instructions

<http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf>.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.
- Copy of a bond in an amount of \$100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for wholesalers only*.

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
775-850-1440
bop.nv.gov

**OUT-OF-STATE
(For locations shipping to the State of Nevada)
WHOLESALE APPLICATION
INFORMATION AND CHECKLIST**

**This application cannot be returned by fax or email.
We must have an original signature and fee to process.**

Failure to submit a complete application will result in significant delays in the processing of the application and issuance of the license.

Please understand we cannot and will not accept incomplete applications. Review the application and return all required fees and documentation with the completed application.

Submission of the application just prior to the deadline date does not guarantee placement on the board agenda.

Please note the application/documentation deadline date on the board meeting schedule listed on the website. The deadline date is the LAST DAY completed applications may be accepted for that particular board meeting. If the application and all pertaining documentation is not complete and enclosed, (NO EXCEPTIONS) the application will be returned. Confirmation of personal data may require review.

REQUIRED DOCUMENTS FOR ALL TYPES OF OWNERSHIP

You will also be required to submit additional information depending on your ownership type. Details regarding the additional information are included with the application.

- Complete all required pages of the application. Must be original signature(s), no copies or stamps.
- Fee made payable to: *Nevada State Board of Pharmacy*
- Applications or Fingerprint Cards that are not properly completed will be rejected and your application will not be processed. The Application and any payments will be returned.

- Letter of good standing from the state or regulatory board in which your company is located. The form on the website under documents for all types of businesses may be sent to your state board or a separate letter is acceptable.
- **Copy of current license or registration** for the wholesaler in the state of residence.
- Copy of your DEA certificate, if applicable.

Your application may be placed on the agenda of the next regularly scheduled board meeting. Please go to the website below for the current board meeting schedule and deadline dates.

http://bop.nv.gov/board/ALL/Board_Meeting_Schedule/

APPEARANCE(S) AT THE BOARD MEETING MAY BE REQUIRED. If an appearance is required, you will be informed by way of confirmation letter. Otherwise assume appearance will not be necessary. Upon board approval a certificate of registration will be issued.

Any change of ownership will require a new application and \$500.00 fee.

This license is renewed in October of even numbered years, no matter when the license is issued. Fees are not pro-rated.

Please access the website under the tab "Nevada Statutes & Regulations" for the applicable laws.

If you have any questions, contact the Reno office at (775) 850-1440.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH _____)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership - Pages 1,2,3,7,8
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: _____

Physical Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____ Fax Number: _____

Toll Free Number: _____

E-mail: _____ Website: _____

Facility Manager: _____

Professional qualifications and experience of facility manager: _____

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☐ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

* This page must be submitted for all types of ownership

Is your company VAWD certified by NABP?

Yes ☐ No ☐

(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA?

Yes ☐ No ☐

(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Yes ☐ No ☐

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?

Yes ☐ No ☐

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☐

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Authorized Person

Date

Board Use Only

Date Processed: _____

Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) _____
Name Business Addressb) _____
Name Business Addressc) _____
Name Business Addressd) _____
Name Business Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporationList of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Include with the application for a non-publicly traded corporation continued

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

***If your company is **not** VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Submit fingerprints – Please refer to Fingerprint Submission Instructions

<http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf>.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.
- Copy of a bond in an amount of \$100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General _____ Limited _____

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Partnership Name: _____

Mailing Address: _____

City, State Zip Code: _____

Telephone Number: _____ Fax Number: _____

Contact Person: _____

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a partnership

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

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- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

***If your company is **not** VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Submit fingerprints – Please refer to Fingerprint Submission Instructions

<http://bop.nv.gov/uploadedFiles/bopnvqov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf>.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.
- Copy of a bond in an amount of \$100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: _____

Business Name: _____

Current Business Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: _____ Fax: _____

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a sole owner

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

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- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of \$25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

***If your company is **not** VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Submit fingerprints – Please refer to Fingerprint Submission Instructions

<http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf>.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.
- Copy of a bond in an amount of \$100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date _____

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for _____

Nature of License _____

Name and Address of Establishment for Which License Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name First Name Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Present Residence Address-Street or RFD City State/Zip

Present Business Address Dates City State/Zip

Occupation Dates

Phone:
Residence _____

Business _____

Date of Birth Place of Birth (City, County, State)

Age Social Security Number or ITIN Sex

Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics

Are you a citizen of the United States? Yes ☐ No ☐ If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial _____

MARITAL INFORMATION-Continued

A. Current Marriage

Spouse's full name (Maiden) _____ Date _____ City, County and State _____
 SS# or ITIN _____

Date of Birth _____ Place of Birth _____

Resident address _____
 Street _____ City _____ State _____ Zip _____

Telephone: Residence _____ Business _____

Spouse's employer _____ Occupation _____

Address of employer _____
 Street _____ City _____ State _____ Zip _____

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:**A. Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address

B. Child Support Information:

Please mark the appropriate response:

- ☐ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial _____

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-

in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Father _____

Mother _____

Father-in-Law _____

Mother-in-Law _____

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Spouse _____

Spouse _____

Spouse _____

Spouse _____

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School			Yes <input type="checkbox"/> No <input type="checkbox"/>
High School			Yes <input type="checkbox"/> No <input type="checkbox"/>
College			Yes <input type="checkbox"/> No <input type="checkbox"/>
University			Yes <input type="checkbox"/> No <input type="checkbox"/>
Other			Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any _____

College or university where obtained _____

Applicant's initial _____

5 MILITARY INFORMATION:A. Have you ever served in any armed forces? Yes ☐ No ☐

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☐

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
----------------	-----	--------	-------------------------	-----------------	------------------

--	--	--	--	--	--

--	--	--	--	--	--

--	--	--	--	--	--

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☐ If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☐

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☐

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☐ If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☐ If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☐ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
------	--------------	--------	----------	------

--	--	--	--	--

--	--	--	--	--

--	--	--	--	--

Applicant's initial _____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?

Yes ☐ No ☐ (Other than divorces)

If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?

Yes ☐ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County

Applicant's initial _____ Page 5

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial _____

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☐
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☐

If yes, state type, where and years held

.....

.....

.....

12. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☐

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

.....

.....

.....

Applicant's initial _____ Page 7

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☐

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☐

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☐

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☐

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer) Yes ☐ No ☐

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☐

ATTACH PHOTOGRAPH

TAKEN WITHIN LAST

30 DAYS HERE

Date of photograph _____

Applicant's initial _____

STATE OF _____

ss.

COUNTY OF _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this _____ day of

Notary Public

(seal)

Applicant's initial _____

ADDITIONAL INFORMATION

[illegible]

Applicant's initial_

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date _____

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for _____

Nature of Pharmacy or Wholesaler

Name and Address of Business for Which Designated Representative Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name _____ First Name _____ Middle Name _____

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise) _____

Present Residence Address-Street or RFD _____ City _____ State/Zip _____

Dates

Present Business Address _____ City _____ State/Zip _____

Dates

Present Position with the Pharmacy or Wholesaler _____

Phone:
Residence _____

Business _____

Date of Birth _____ Place of Birth (City, County, State) _____

Age _____ Social Security Number or ITIN _____ Sex _____

Color of Eyes _____ Color of Hair _____ Complexion _____ Weight _____ Build _____ Height _____

Scars, tattoos or distinguishing marks and/or characteristics _____

Are you a citizen of the United States? Yes ☐ No ☐ If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial _____

MARITAL INFORMATION-Continued

A. Current Marriage

Spouse's full name (Maiden) _____ Date _____ City, County and State _____
 SS# or ITIN _____

Date of Birth _____ Place of Birth _____

Resident address _____
 Street _____ City _____ State _____ Zip _____

Telephone: Residence _____ Business _____

Spouse's employer _____ Occupation _____

Address of employer _____
 Street _____ City _____ State _____ Zip _____

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City	County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:**A. Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address

B. Child Support Information:

Please mark the appropriate response:

- ☐ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial _____

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name _____

Address _____

Contact person _____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Father

Mother

Father-in-Law

Mother-in-Law

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
---------------	------------	---------	------------

Spouse

Spouse

Spouse

Spouse

4. EDUCATION:

Name of School	Location	Dates Attended	Graduate
Grammar School			Yes <input type="checkbox"/> No <input type="checkbox"/>
High School			Yes <input type="checkbox"/> No <input type="checkbox"/>
College			Yes <input type="checkbox"/> No <input type="checkbox"/>
University			Yes <input type="checkbox"/> No <input type="checkbox"/>
Other			Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any _____

College or university where obtained _____

Applicant's initial _____

5 MILITARY INFORMATION:

- A. Have you ever served in any armed forces? Yes ☐ No ☐

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

- B. Have you registered for the draft? Yes ☐ No ☐

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

- A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

- B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☐ If yes, furnish details on page 10.

- C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☐

- D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐

- E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☐

- F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☐ If yes, when? _____ city, county and state _____

- G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☐ If yes when? _____ city, county and state _____

- H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☐ If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial _____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

- I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
 Yes ☐ No ☐ (Other than divorces)
 If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

- J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
 Yes ☐ No ☐ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
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Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial _____

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					
Name	Home					
Employer	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☐

If yes, state type, where and years held

.....

.....

.....

11. Have you ever applied for a city, county or state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☐

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

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.....

.....

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☐

.....

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☐

.....

If yes to the above, state where, when and for what reason:

.....

.....

Applicant's initial _____ Page 7

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☐

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☐

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler) Yes ☐ No ☐

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☐

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☐ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☐ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☐ No ☐

ATTACH PHOTOGRAPH

TAKEN WITHIN LAST

30 DAYS HERE

Date of photograph _____

Applicant's initial _____

STATE OF _____

ss.

COUNTY OF _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this _____ day of

Notary Public

(seal)

Applicant's initial _____

ADDITIONAL INFORMATION

[illegible]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

NRS 639.016 "Wholesaler" defined. "Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person other than the consumer or patient. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Print and mail the completed application with a **non-refundable fee** of \$500.00 paid for by credit or debit card or a check made payable to the **Nevada State Board of Pharmacy**. Credit and debit card payments are charged a **5% processing fee**. Send the completed application to the address indicated on top of this application.

All incomplete applications will be returned. Please ensure all requirements of the application are completed before submission. The deadline date for an application to be considered during a particular board meeting is posted on our website. If a completed application is not received by our office by the deadline, the application will not be considered until the next scheduled board meeting. **Please note that an application received just prior to the deadline date does not guarantee placement on the board agenda.** Upon receipt of a completed application, the application will be placed on the agenda of the next regularly scheduled Board meeting. For application deadlines and meeting schedule please visit bop.nv.gov.

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Where is the facility located? <input type="checkbox"/> Nevada <input type="checkbox"/> Out-of-State	
Type of Application (check applicable box)	Wholesaler Business Type (check applicable box)
<input type="checkbox"/> New Wholesaler <input type="checkbox"/> Ownership Change <input type="checkbox"/> Location Change (in-state only)	<input type="checkbox"/> Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) <input type="checkbox"/> Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) <input type="checkbox"/> Partnership (complete sections 1, 2, 3, 6, 8, 9) <input type="checkbox"/> Sole Owner (complete sections 1, 2, 3, 7, 8, 9)
* If making a change, provide current license number: WH _____	
Is your facility a reverse distributor? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Section 1: General Information	
Facility Name: _____	
Physical Address: _____	
City: _____	State: _____ Zip: _____
Mailing Address (if different from physical address): _____	
City: _____	State: _____ Zip: _____
Telephone: _____	Website: _____
Name of Designated Representative (DR): _____	
Licensing Company Email: _____	DR Email: _____
Entities the Wholesaler will Serve	Products to be Handled or Wholesaled
<input type="checkbox"/> Pharmacies <input type="checkbox"/> Practitioners <input type="checkbox"/> Hospitals <input type="checkbox"/> Wholesalers <input type="checkbox"/> Others: _____	<input type="checkbox"/> Legend Pharmaceuticals, Supplies or Devices <input type="checkbox"/> Controlled Substances <input type="checkbox"/> Hypodermic Devices <input type="checkbox"/> Veterinary Legend Pharmaceuticals <input type="checkbox"/> Others: _____

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.		

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____	Address: _____	City: _____	State: _____	Zip: _____
Name: _____	Address: _____	City: _____	State: _____	Zip: _____
Name: _____	Address: _____	City: _____	State: _____	Zip: _____
Name: _____	Address: _____	City: _____	State: _____	Zip: _____
Name: _____	Address: _____	City: _____	State: _____	Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration: _____	SEC Registration Number: _____	Stock Exchange Symbol: _____
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Section 5: Non-Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration		Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:			
1. Copy of Certification 2. Copy of a bond in an amount of \$25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the Surety Bond form at http://bop.nv.gov/Services/newapps/Business/ .			
Is your company licensed as a Manufacturer by the FDA? If yes, provide:			
1. Copy of FDA registration 2. Copy of a bond in an amount of \$25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the Surety Bond form at http://bop.nv.gov/Services/newapps/Business/ .			

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• List of <u>all</u> Officers and Directors.	✓	✓		
• List the <u>top four</u> corporation shareholders and their percent ownership.	✓			
• List of <u>all</u> corporation shareholders and their percent ownership.		✓		
• List of <u>all</u> partners and their percent ownership.			✓	
• Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• Designated Representative form must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• Personal History Record Application must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Copy of DEA certificate if handling controlled substances	✓	✓	✓	✓
• Copy of current SEC 10K or 8K	✓			
• A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• Submit Fingerprints following instructions found at: http://bop.nv.gov/uploadedFiles/bopnv.gov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf .		✓	✓	✓
• Copy of a bond in an amount of \$100,000 made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the Surety Bond form at http://bop.nv.gov/Services/newapps/Business/ .		✓	✓	✓

I hereby certify, under penalty of perjury, that the information on this application and attached document are true, accurate and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized wholesaler may be grounds for the revocation of this permit of authorization. I hereby authorize, the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date

Board Use Only	Date Received: _____	Amount: _____



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

Applicant Name: _____

Payment: Pay application fee by providing your credit or debit card information below, or by submitting a check made payable to **Nevada State Board of Pharmacy**.

Credit Cards are charged a 5% processing fee

Credit Type:

- ☐ Visa ☐ MasterCard ☐ Discover
☐ American Express

Credit Card #:

Expiration Date:

___/___/___ (MM/YY)

CVV (3 digits on back of card):

License Amount:

\$ _____

Name on Card:

Billing Address:

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FILED

JUL 23 2020

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY****NEVADA STATE BOARD OF PHARMACY,****Petitioner,****v.****JEVONS WANG, PT,
Certificate of Registration No. PT21836,****Respondent.****CASE NO. 20-008-PT-S****FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, July 15, 2019, in Las Vegas, Nevada. Brett Kandt, Esq., appeared and prosecuted the case before the Board. Respondent Jevons Wang, Certificate of Registration No. PT121836 (Wang), failed to appear. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The allegations against Wang, as stated in the Notice of Intended Action and Accusation (Accusation) on file herein, and upon which the Board makes findings of fact, are as follows:

1. At the time of the events set forth herein, Wang was a pharmaceutical technician registered by the Board.
2. On January 17, 2019, the Board approved Wang's application for registration as a pharmaceutical technician, subject to the requirement that Wang enroll in the Professionals Reaching Nevada-Pharmacist/Tech Recovery Network (PRN-PRN) program for one year and comply with all terms and conditions of the PRN-PRN contract, due to a history of substance abuse.
3. On January 15, 2020, Wang was terminated from the PRN-PRN program due to lack of attendance.

4. On or about February 21, 2020, Wang was served with the Accusation and Statement to Respondent and Notice of Hearing. Service was by U.S. certified mail addressed to Wang at his last address of record with the Board.

5. Wang failed to file an Answer and Notice of Defense to the Accusation.

6. Wang failed to appear at the March 18, 2020, hearing.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and this respondent, because at the time of the events herein, Wang was a pharmaceutical technician registered with the Board.
2. Wang was served notice in compliance with NRS 622A.300 and NRS 639.242.
3. By failing comply with all terms and conditions of the PRN-PRN contract, Wang's Certificate of Registration No. PT21836 is subject to revocation or suspension pursuant to NRS 639.210(5).

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Jevons Wang, Certificate of Registration No. PT121836, is hereby revoked pursuant to NRS 639.255(1)(d).
2. Wang may not work for any facility licensed by the Board, including a pharmacy, in any capacity unless and until he has petitioned the Board for reinstatement pursuant to NRS 622A.410 and NRS 639.257 and the Board reinstates his certificate of registration.
3. Wang may not petition for reinstatement of his certificate of registration for a period of one (1) year from the effective date of this Order.
4. In the event Wang applies for reinstatement, or for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

5. This Order is effective on the date it is executed below.

IT IS SO ORDERED.

Entered this 5th day of July, 2020.



Helen Park, President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jevons Wang
Pinley Spring Street
Las Vegas, NV 89113


SHIRLEY HUNTING



To whom it may concern:

My name is Jevons Wang and my case number is 20-008-PT-S. I am writing to request a rehearing/appeal for the determination made on my case during the July 15th, 2020 at the Nevada Board of Pharmacy meeting. I apologize for the common language. Due to the fact that I am unable to afford representation, I will be representing myself in all matters. Before I discuss the issues within the determination I received, I want to be clear that I do not wish to have my license reinstated. I merely want to request that the Board not consider this a disciplinary action.

First, I would like to say that I have made some mistakes regarding how I personally handled this situation. To start from the beginning, I appeared before the Board as a new resident of Nevada with an Oregon pharmacy technician license and national PTCB certification. I wanted to obtain my pharmacy technician license to get a job in Nevada, so I agreed at the January 2019 meeting to enroll in the PRN-PRN program. I initially attended the program regularly and was willing to participate in the program. As time went on and only being able to find work as a temporary pharmacy technician for around 2 months, I decided to go back to school. In August of 2019, I informed Larry Esposito at the PRN-PRN program that I would need to adjust my schedule with him because of my classes. We both agreed and I continued with the program. It was around November or December of 2019 that I went to Larry again and told him that I did not want to complete the program. I told him that I wasn't working as a pharmacy technician and I was not interested in finding a job as a pharmacy technician anymore. I was also going to school, so I could not afford to participate in the program as it cost around \$200 per month. In all honesty, I was having a hard time paying for the program since September 2019, but Larry was kind and let me continue. That is my side of the story to the current events unfolding in my case with the Board. I did not keep in contact with Larry after that, which was a mistake that I had made. To add, I was able to fulfill all requirements of the PRN-PRN program while I was in attendance (no positive drug tests).

To address my shortcomings regarding my case, I'm not sure why I didn't contact the Board directly. I guess I didn't think it was going to be categorized as a disciplinary action on my license. I don't know much about what I should have done legally. But in all honesty, I assumed that if I dropped out of the program, my license would just be revoked. I didn't realize that it would count as a disciplinary action or else I would have taken care of this matter differently. I only worked one job while holding my Nevada pharmacy technician license and I worked at ACRX Specialty Pharmacy with no complaints from customers or my employer. The job was just a couple months long and then I decided to not pursue this pharmacy technicians license anymore. I urge you to consider all aspects of my case. Thank you.

Lastly, I would like to address the errors in the notice I received from the Nevada Board of Pharmacy. Whether or not the Board decides to rehear my case, I need to correct a few things in the notice. The first item I would like to correct in the notice is my failure to appear at the meeting. I was notified by phone only that the Spring 2020 meeting was cancelled, and I was told a new date would be given to me when it was finalized. I did not receive any further

communication. I understand that there was certified mail sent to me, but I did not receive it, nor did I receive a phone call like when the Spring 2020 meeting was cancelled. If I had known of the new meeting time in July, I would have been able to notify the Board that I have medical conditions that put me at high risk for severe complications if I contract COVID-19. If the Board would like a physician's note, I am able to provide one. I also want to point out that the notice states the meeting was March 18, 2020. It was not, because that meeting time was cancelled. The first paragraph of the notice also states that I failed to appear at some meeting on April 15, 2019, which is also incorrect. I was in attendance at the meeting where this matter was brought up in 2019 and there was no other meeting that year that I was requested to appear at.

Thank you for your time and attention to this matter.

Sincerely,

Jevons Wang

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

CONTROLLED SUBSTANCE APPLICATION Registration Fee: \$200.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

(This application cannot be used by PA's or APRN's)

First: Kim Middle: DeWayne Last: Kemmerly
 Practice Name (if any): Pointe North Dental
 Nevada Address: 4690 W. Ann Road Suite #: 4
(This must be a practicing address, we will not issue a license to a home address or to a PO Box only)
 City: North Las Vegas State: NV Zip Code: 89031
 PO Box: _____ SS# or ITIN: _____
 E-mail address: _____ gmail.com
 Work Telephone: (702) 515-7737 Personal Phone: (318) 332-6347
 Fax: _____ Degree: DMD
 Date of Birth: _____ Sex: ☒ M or ☐ F
 Practitioner License Number: 7322 Specialty: General Dentistry

You must have a current Nevada license with your respective BOARD before we will process this application. The Nevada license must remain current to keep the controlled substance registration.

		Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?...		<input type="checkbox"/>	<input checked="" type="checkbox"/>
1. Been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? ...		<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?.....		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation and documentation:			
Board Administrative Action:		State	Date: / /
		Case #:	
Criminal Action:	State	Date:	Case #:
		County	Court

It is a violation of Nevada law to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

I understand that Nevada law requires a licensed physician who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Kim D. Kemmerly DMD
 Original Signature, no copies or stamps accepted.

Date

Board Use Only: Date Processed: _____ Amount: 200.00

Prior Arrest and Dispositions:

On November 10th, 1975 I was arrested, in Shreveport, Louisiana, for possession of marijuana. I completed the 1-year probation sentence. The court no longer has any record of the incident.

June 17th, 1977, I was arrested, in Bossier Parish, Louisiana, for pandering. The charges were dismissed. The court no longer has any record of the incident.

November 10th, 1977, I was arrested, in Saint Mary Parish, Louisiana, for unauthorized use of a motor vehicle. The charge was dropped.

April 14th, 1979, I was arrested, in Bossier City, Louisiana, for reckless operation of a vehicle and simple criminal damage. I paid fines, costs, and restitution. Case #3069 & #79-2095.

August 12th, 1979, I was arrested, in Shreveport Louisiana, for driving while intoxicated and resisting an officer. I completed the sentence. The court has no record of the incident.

December 20th, 1979, I was arrested in Bossier City, Louisiana, for misdemeanor theft. I completed the 1-year probation sentence, paid fines and costs. Case #57,243.

January 9th, 1981, I was arrested, in Caddo Parish, Louisiana, for introduction of contraband into a state hospital. I completed the sentence. The court has no record of the incident.

April 4th, 1981, I was arrested, in Shreveport, Louisiana, for property damage. I completed the sentence. The court has no record of the incident.

July 25th, 1981, I was arrested, in Shreveport Louisiana, for driving while intoxicated, driving under suspension, and speeding. I completed the sentence. The court has no record of the incident.

July 28th, 1981, I was arrested, in Shreveport, Louisiana, for driving under suspension, littering, and failure to register a vehicle. I completed the sentence. The court has no record of the incident.

October 18th, 1981, I was arrested, in Shreveport, Louisiana, for simple burglary. I completed the 4-year prison sentence. Case #00119712.

June 26th, 1990, I was arrested, in Bossier City, Louisiana, for driving while intoxicated and open container. I completed the 90-day jail sentence. Case #1990-DWI-00114307 & #1990-TFC-114308.

June 18th, 1997, I was arrested, in Grandview Heights, Ohio, for operating a vehicle under the influence. I completed the sentence. Case #97TRC00685

December 25th, 2006, I was arrested, in Bossier City, Louisiana, for possession of schedule II, possession of drug paraphernalia, and resisting an officer. Completed diversion program and charges were dismissed. Case #CR 150595, #CR 150596, & #CR 150597.



CITY OF SHREVEPORT • MUNICIPAL COURT

1244 TEXAS AVENUE • SHREVEPORT, LOUISIANA 71101 • FAX: (318) 673-5813

R. LEE IRVIN
JUDGE, DIVISION "A"
(318) 673-5870

CHARLES W. KELLY, IV
JUDGE, DIVISION "B"
(318) 673-5885

PAMMELA LATTIER
JUDGE, DIVISION "C"
(318) 673-5873

SHEVA M. SIMS
JUDGE, DIVISION "D"
(318) 673-5878

June 26, 2012

Re: Kemmerly, Kim

DOB:

S.S.N. #

To Whom It May Concern:

The Shreveport City Court has Criminal Records from 1976 through present, Traffic Records from 2007 through present, and Peace Bond Records from 1999 through present. The Court has Criminal and DWI computer records from 1983 to present and Traffic computer records from 2000 through present. Any records prior to the mentioned years are no longer available.

The court has NO CASES closed or pending on the above defendant.

If you have further questions or concerns, please don't hesitate to contact our office at 318-673-5857.

Krystal Mcader
Deputy Clerk of Court
Criminal Clerk's Office



J. SCHUYLER MARVIN

District Attorney
TWENTY-SIXTH JUDICIAL DISTRICT
BOSSIER PARISH

R. LANE PITTARD
FIRST ASSISTANT
DISTRICT ATTORNEY

PRE-TRIAL DIVERSION PROGRAM

June 19, 2012

P.O. 69
BENTON, LA 71006
PHONE (318) 965-2332
FAX (318) 965-2233

KIM DEWAYNE KEMMERLY
TARLTON DR, #527
Natchitoches, LA 71457

RE: Pre-Trial Diversion

Case: C-07000164

Charges: POSSESSION OF DRUG PARAPHERNALIA, POSSESSION OF A CDS
SCHEDULE II and RESISTING AN OFFICER

Dear KIM DEWAYNE KEMMERLY:

This will serve as notification of your satisfactory completion of the Pre-Trial Diversion Program.

Your record will show no conviction for the charges in question. However, if you are interested in removing the record of your arrest from the agency involved you will need to contact an attorney to file proper pleadings on your behalf. (Once the appropriate time delays have expired).

Sincerely,

Kathryn Brooks
Diversion Coordinator

CRIMINAL DOCKET

STOCK FORM CRIMINAL DOCKET

NUMBER OF CASE	STATE OF LOUISIANA	ATTORNEY	OFFENSE	DATE OF FILING		
				Month	Day	Year
	VS. Merle F. Kemmerly, Jr. Merle F. Kemmerly III Kim Kemmerly		Pandering (3 Cts)	6	17	1977
DATE OF ORDERS						
7/13/77	<p>Defendant Kemmerly, Jr. in open Court, represented by counsel, Cecil Campbell, defendant Kemmerly III in open Court, represented by counsel, Frank Harlow and defendant Kim Kemmerly in open Court, represented by counsel, Ford Stinson, are formally arraigned and plead not guilty to all three counts. Case is set for trial on September 26, 1977.</p> <p>Defendant Kemmerly, Jr. in open Court, represented by counsel, J. B. Wells, defendant Kemmerly III in open Court, represented by counsel, Frank Harlow and defendant Kim Kemmerly in open Court, represented by counsel, F. E. Stinson. Motion for severance of defendants is argued and submitted on authorities. Cecil Campbell withdraws as counsel for defendant Kemmerly, Jr. Motion for severance of offenses is argued and submitted. Motion for bill of particulars is argued and submitted.</p> <p>Defendants are given 15 days to file for writs on motion for severance rulings.</p> <p>On oral motion of the District Attorney, this case is not prossed. (Lowe)</p>					
9/20/77						
9/26/77						
7/23/82						

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Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
453.NEW PMP Regulations	07/18/19	07/19/19	R035-19	09/25/19	10/22/19	12/05/19	01/29/20	02/07/20
639.NEW & 453.190 – Payment of Fees	07/18/19	07/19/19	R033-19	08/27/19	10/22/19	12/05/19	01/29/20	02/07/20
639.220 – Schedule of Fees	07/18/19	07/19/19	R034-19	08/02/19	08/03/19	09/05/19	09/06/19	10/30/19
639.240-242-7425 – Applicant with Criminal Conviction	09/05/19	09/12/19	R072-19	10/07/19	10/22/19	12/05/19	01/29/20	02/07/20
639.NEW – Managing Pharmacist CE Requirement	09/05/19							
639.NEW – NPDB Reporting	09/05/19	09/12/19	R070-19	10/22/19	11/01/19	12/05/19	01/29/20	02/07/20
453.NEW – Inactive Status	09/05/19	09/12/19	R071-19	10/16/19	10/22/19	12/05/19	01/29/20	02/07/20
453.510 – Schedule I	09/05/19	09/12/19	R073-19	LCB combined with R090-20				
639.NEW – Criminal Conviction/ Administrative Action Reporting (Licensee)	10/10/19	10/18/19	R094-19	11/29/19	01/29/20 06/09/20	03/19/20 Postponed per Brett		
453.510 – Schedule I - Etizolam	10/10/19	10/18/19	R093-19	11/29/19	01/29/20	03/19/20	05/06/20	06/08/20
639.NEW - Petition for review of criminal history	12/05/19 01/16/20	02/13/20 – On hold due to Nevada Department of Public Safety notice.						
639.NEW – Treatment of Partners	01/16/20	01/21/20	R008-20	03/03/20	04/28/20	06/03/20	08/28/20	
639.NEW – Delivery of a Prescription to Practitioner	01/16/20	01/21/20	R009-20	02/27/20	06/09/20	Postponed per Brett		
453.520: Schedule II - 4-ANPP; despropionyl fentanyl	03/19/20 06/03/20	6/16/20	R084-20	07/20/20	07/31/20	09/03/20	09/25/20	
639.NEW – Licensing/regulating wholesalers.	03/19/20	3/24/20	R040-20	05/19/20	06/09/20	07/16/20	07/22/20	08/26/20
639.NEW - licensing and regulation of a facility to dispense controlled substances and dangerous drugs if the	03/19/20 – postponed to	6/16/20	R085-20	09/17/20				

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
facility is licensed by the State Board of Health	06/03/20							
639.NEW - licensing and regulating the practice of pharmacy (appearance requirements)	03/19/20	3/24/20	R041-20	05/14/20	06/09/20	07/16/20	07/22/20	08/26/20
453.550 – Deschedule Epidiolex	06/03/20	6/16/20	R090-20 R073-19 R083-20	07/30/20	09/11/20	10/15/20		
639.NEW – CS Electronic Transmission Exemption	06/03/20	6/16/20						
639.464 & 639.468 – P&T Committee vs CPA	06/03/20							
639.NEW – PT Administer Immunizations	07/16/20	07/21/20	R142-20	08/20/20	08/03/20	09/03/20	09/15/20	09/21/20
453.510 – Schedule I - Designer Benzos	07/16/20	07/21/20	R143-20					
453.510 – Schedule II - Kratom	07/16/20	07/21/20	R144-20					
NAC 639.742, 639.743, 639.744. and 639.745: Dispensing Practitioners.	09/03/20							

EXECUTIVE SECRETARY REPORT – October 14th 2020

- **FINANCIAL REPORT**
- **TEMPORARY LICENSES**
- **STAFF ACTIVITIES**
 - Meetings with Other Health Care Boards
 - COVID-19
 - Emergency Regulation Update
 - Courtney Lee – NABP Attorney Forum
- **REPORT TO BOARD**
 - Licensing software update
- **BOARD RELATED NEWS**
 - Investigator update
- **ACTIVITIES REPORT**
 - Covid Vaccine update
 - Remdesivir

TEMPORARY LICENSES
(Issued since last board meeting)
Updated 9/30/2020

Pharmacist

Bradly Lende

Pharmacy

Lucile Packard Children's Hospital Outpatient Pharmacy



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

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NEVADA STATE BOARD OF PHARMACY

ACTIVITIES REPORT

SEPTEMBER 2-3, 2020 BOARD MEETING HELD IN LAS VEGAS, NEVADA

This report is prepared and presented to keep interested legislators and others abreast of the activities of the Nevada State Board of Pharmacy. Following is a summary of the September 2020 Board meeting.

Licensing Activity:

- 14 licenses were granted for Out-of-State pharmacies.
- 5 licenses were granted for Out-of-State Compounding pharmacies.
- 1 license was granted for Out-of-State Outsourcing Facility.
- 1 license was granted for Nevada MDEG companies.
- 1 license was granted for Nevada pharmacies.
- 29 licenses were granted for Out-of-State Wholesalers
- 1 license was granted for Nevada Wholesaler
- 1 registration renewal was granted for Pharmaceutical Technicians
- 1 registration renewal was granted for Pharmacists
- 2 registrations were granted for APRN Prescribe
- 1 registration was granted for Interns
- 3 registrations were granted for Pharmacists
- 3 registrations were granted for Controlled Substance

Disciplinary Actions:

- APRN SJ shall receive a public reprimand, pay a \$1,000 fine and pay \$950 in attorney's fees and costs for unlawfully prescribing controlled substances/dangerous drugs in Dr. AQ's name and credentials.
- Walmart Pharmacy #10-3728 shall pay a \$1,000 fine and pay \$1,000 in attorney's fees and costs as the pharmacy owner responsible for actions of its employees in which two unauthorized refills were dispensed.
- RPH PL's registration was revoked for diverting drugs from his employing pharmacy.
- Dr. VW shall pay a \$14,000 fine and pay \$1,962.87 in attorney's fees and costs for writing multiple controlled substance prescriptions while her license to practice medicine in Nevada was inactive. Dr. VW falsely represented to the Board that she held an active and current Nevada license with the NSBME on her CS renewal applications for the years 2010, 2012, 2014, 2016 and 2018.

Other Activity:

- The usual Board business reports were given, including recent and future speaking engagements; reports on national meetings; and collaboration with other state agencies.
- Licensing software update was provided.

Public Hearing:

1. **Amendment of Nevada Administrative Code (NAC) 453.520 Schedule II.** The proposed amendment adds such drug products to the list of controlled substances in schedule II in conformity with the federal regulations of the Uniform Controlled Substances Act. (LCB File No. R084-20)
2. **Amendment of Nevada Administrative Code (NAC) 639: Pharmacy Technician Ability to Administer Immunizations.** The proposed amendment will authorize a pharmacy technician with appropriate training to administer immunizations under the direct supervision of a pharmacist. (LCB File No. R142-20)

Workshop:

1. **Amendment of Nevada Administrative Code (NAC) 639.742, 639.743, 639.744, and 639.745: Dispensing Practitioners.** The proposed amendments will modify the supervision of dispensing technician by dispensing practitioners. These amendments will authorize dispensing practitioners in group practices to share inventory of certain medications and centralize activities. The proposed amendments will increase the fees for the application for an initial registration, and the biennial renewal of a registration, as a registered dispensing technician.

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**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R090-20

July 30, 2020

EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted.

AUTHORITY: §§1 and 2, NRS 453.146 and 639.070.

A REGULATION relating to pharmacy; adding certain substances to schedule I; providing that certain drug products that contain CBD are not a controlled substance; removing certain drug products that contain CBD from the list of controlled substances on schedule V; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the practice of pharmacy. (NRS 639.070) The Board is also authorized to add, delete or reschedule controlled substances listed in schedules I, II, III, IV or V by regulation. (NRS 453.146) Existing regulations list various controlled substances on schedule I. (NAC 453.510) **Section 1** of this regulation adds numerous substances to the list of controlled substances on Schedule I. **Section 1** also specifies that a drug product is not a controlled substance if the drug product: (1) is approved by the United States Food and Drug Administration; (2) contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and (3) contains not more than 0.1 percent residual THC by weight.

Existing regulations list as a controlled substance on schedule V a drug product which: (1) is approved by the United States Food and Drug Administration; (2) contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and (3) contains not more than 0.1 percent residual THC by weight. (NAC 453.550) **Section 2** of this regulation removes such a drug product from schedule V.

Section 1. NAC 453.510, as amended by LCB File Number R093-19, is hereby amended to read as follows:

453.510 1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-acetylmethadol, levomethadyl acetate or "LAAM");

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethadol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxadine;

4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) (some trade or other names: para-fluoroisobutyryl fentanyl);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Ketobemidone;

Levomoramide;

Levophenacymorphan;

3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);

3-Methylthiofentanyl (N-[(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Methoxyacetyl fentanyl (2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidiny]propanamide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphane;

Phenoperidine;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidiny]propanamide);

Tilidine; ~~to~~

Trimeperidine ~~H~~; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphenol;

Methyl-desorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine
(some trade or other names: Etizolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18;
BTM-8; RCS-8);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphetamine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N-o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy-N, N-dimethyltryptamine; 4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4-ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluoropentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine ~~†~~ *(some trade or other names: MMDA)*;

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; "STP");

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

~~3,4-methylenedioxyamphetamine;~~

~~3,4-methylenedioxymethamphetamine~~ *Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA)*;

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

~~[3,4-methylenedioxy]~~ *Methylenedioxy*-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl

(2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-

phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as *Datura*, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound,

manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha-pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha-pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methyamino)butan-1-one, β -keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha-aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone;

N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethyl-

β-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-

(dimethylamino)propan-1-one; bk-MDDMA);

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3-

benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Fenethylamine;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-

fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-

fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4-

FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-(methylamino)propan-1-

one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)-

2-(methylamino)propan-1-one, 2-FMC);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N-Methylcathinone, cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethylbenzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α-methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolypentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1
cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6
cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of
the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances,
derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule ~~H~~ *and except as otherwise provided in subsection 11*, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. of synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

↪ is not a controlled substance.

Sec. 2. NAC 453.550, as amended by LCB File Number R149-16 and R198-18, is hereby amended to read as follows:

453.550 1. Schedule V consists of the drugs and other substances listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base alkaloid, containing one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone, in quantities:

- (a) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
- (b) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
- (c) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
- (d) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;
- (e) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams; or
- (f) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

3. Unless specifically excepted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pyrovalerone having a stimulant effect on the central nervous system, including their salts, isomers and salts of isomers.

4. Unless specifically excepted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pregabalin having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers.

5. Brivaracetam.

6. Lacosamide.

~~{7. A drug product which:~~

- ~~—(a) Has been approved by the United States Food and Drug Administration;~~
- ~~—(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and~~
- ~~—(c) Contains not more than 0.1 percent residual THC by weight.]~~

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26A

Documentation for this Agenda Item will be provided at a later date.

26B

Documentation for this Agenda Item will be provided at a later date.

26C

Documentation for this Agenda Item will be provided at a later date.

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