

NEVADA STATE  
BOARD OF PHARMACY

BOARD MEETING

JULY 18-19, 2018

HILTON GARDEN INN  
7830 S LAS VEGAS BOULEVARD  
LAS VEGAS, NEVADA



# Nevada State Board of Pharmacy

431 W. PLUMB LANE • RENO, NEVADA 89509  
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July 3, 2018

## AGENDA

### ◆ PUBLIC NOTICE ◆

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, July 18, 2018 at 9:00 am. The meeting will continue, if necessary, on Thursday, July 19, 2018 at 9:00 am or until the Board concludes its business at the following location:

Hilton Garden Inn  
7830 S Las Vegas Boulevard  
Las Vegas, Nevada

#### 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 five minutes per person. The president may allow additional time to a given speaker as time allows and in his or her sole discretion.

**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. 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.

2. Approval of June 6-7, 2018, Minutes **(For Possible Action)**
3. Applications for Out-of-State Pharmacy – Non Appearance **(For Possible Action)**
  - A. East Ridge Rx LLC – Draper, UT
  - B. Haltom Pharmacy – Haltom City, TX
  - C. LegacyRx Pharmacy – Addison, TX
  - D. MP Pharmacy II – Los Alamitos, CA
  - E. Preferred Pharmacy Inc. – Costa Mesa, CA
  - F. Roman Health Pharmacy LLC – New York, NY

Applications for Out-of-State Compounding Pharmacy – Non Appearance  
**(For Possible Action)**

- G. Fresh Rx – Ignacio, CO
- H. Total Care Rx, Inc. – Flushing, NY

Applications for Out-of-State Wholesaler – Non Appearance **(For Possible Action)**

- I. Animal Health International, Inc. – Roanoke, TX
- J. Animal Health International, Inc. – Spanish Fork, UT
- K. Johnson & Johnson Health Care Systems Inc. – Monument, CO
- L. Jubilant HollisterStier LLC – Spokane, WA
- M. Novadoz Pharmaceuticals, LLC – Piscataway, NJ
- N. Remedy Rx Wholesale – Richardson, TX
- O. Sage Therapeutics, Inc. – Cambridge, MA
- P. Top Quality Manufacturing, Inc. – Santa Fe Springs, CA

Applications for Out-of-State Medical, Devices, Equipment and Gases – Non Appearance **(For Possible Action)**

- Q. CP Bracing Supply, Inc. – Largo, FL
- R. Custom Milling Center – Golden, CO
- S. Devotion Medical Supply, Inc. – Fayetteville, GA
- T. Elite Medical Supply – San Diego, CA
- U. FedEx Supply Chain, Inc. – Edwardsville, IL
- V. First Stop Medical Supply, Inc. – Pinellas Park, FL
- W. Halo Wound Solutions – Sussex, WI

- X. Healogics Wound Care Supply, LLC – Jacksonville, FL
- Y. Jackson Medical Supply, Inc. – Largo, FL
- Z. Layne Medical Supply, Inc. – Zephyrhills, FL
- AA. LJH Medical Solutions, Inc. – Largo, FL
- BB. Lucky Medical Supply, Inc. – Clearwater, FL
- CC. Medical Rehab Supply, Inc. – San Diego, CA
- DD. Tesla Medical LLC – Tampa, FL

Applications for Nevada Pharmacy – Non Appearance **(For Possible Action)**

- EE. CVS/pharmacy #8806 – Reno, NV
- FF. Medical and Dental Center of Nevada – Las Vegas, NV
- GG. Safe Pharmacy Corporation – Las Vegas, NV
- HH. Spring Valley Surgery Center – Las Vegas, NV

◆ REGULAR AGENDA ◆

4. 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. | Richard Anderson, R.Ph    | (16-077-RPH-A-S) |
| B. | Ned Monje Quadra, R.Ph    | (16-077-RPH-B-S) |
| C. | Walmart Pharmacy #10-1560 | (16-077-PH-S)    |
| D. | Ivan Goldsmith, MD        | (17-101-CS-S)    |
| E. | David J. Adams, DO        | (17-095-CS-S)    |
| F. | Robert Toledo, DO         | (16-013-PD-S)    |
| G. | Craig Weingrow, MD        | (17-066-CS-S)    |

5. Request for Denied Pharmaceutical Technician in Training License: 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)**

Chelsea R. Flores

6. Request for Dispensing Technician in Training License: 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)**

Eugene T. Miller

7. Request for Renewal of Pharmacist License: 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)**

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8. Applications for Out-of-State Compounding Pharmacy – Appearance  
**(For Possible Action)**

- A. Axtells Rite Value Pharmacy Inc. – Whitesboro, TX
- B. Braun Pharma, LLC – Chicago, IL
- C. Diamondback Drugs – Scottsdale, AZ
- D. Premier Infusion Care – Torrance, CA

9. Applications for Out-of-State Outsourcing Facility – Appearance  
**(For Possible Action)**

- A. JCB Laboratories, LLC – Wichita, KS
- B. Wells Pharmacy Network, LLC – Dyersburg, TN

10. Application for Nevada Medical, Devices, Equipment and Gases – Appearance  
**(For Possible Action)**

TruMobility Inc. – Las Vegas, NV

11. Applications for Nevada Pharmacy – Appearance **(For Possible Action)**

- A. Ken's Professional Compounding Pharmacy – Las Vegas, NV
- B. Vitality Pharmacy – Henderson, NV

12. Request to Engage in the Practice of Pharmacy at a Site Other Than a Licensed Pharmacy – Appearance: **(For Possible Action)**

Juliana Zschoche, R.Ph

13. Request for Reinstatement of Nevada Pharmacist License **(For Possible Action)**

Lisa Harris Baker

14. Request for Pharmaceutical Technician in Training License: 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)**

Maurice R. Lewis

15. Discussion and possible action on request from CVS Health to amend NAC 639.250 regarding the permitted ratio of pharmaceutical technicians to pharmacists.  
**(For Possible Action)**
16. Discussion and possible action on settlement in the matters of *Spring Valley Pharmacy, LLC, a Nevada limited liability company; and Jessica Nguyen, an individual vs. Nevada State Board of Pharmacy*, 8<sup>th</sup> J.D. Case No. A-17-763456-C, and *Nevada State Board of Pharmacy vs. Spring Valley Pharmacy, LLC, a Nevada limited liability company; and Jessica Nguyen, an individual*, Nevada Supreme Court Case No. 74974, including entry of an order amending findings of fact and conclusions of law in Case Nos. 16-015-RPH-A-S, 16-015-PH-S, 16-022-RPH-S, 16-022-PH-S, and dismissing Case No. 17-115-PH-S. Please note that during this agenda item the Board may adjourn the meeting and exclude the public for an attorney-client conference on existing litigation pursuant to NRS 241.015(3)(b)(2); however, any action will be taken in an open meeting. **(For Possible Action)**
17. Discussion and possible action on election of President and Treasurer pursuant to NRS 639.040(1). **(For Possible Action)**
18. Discussion and possible action on approval of Nevada State Board of Pharmacy budget for FY18, including cost of living increase for Board employees based upon Consumer Price Index for All Urban Consumers (CPI-U) for the West Region.  
**(For Possible Action)**
19. Discussion and possible action on authorization for Executive Secretary to enact a merit increase for Board employees not to exceed 4% per employee.  
**(For Possible Action)**
20. General Counsel Report –  
Litigation Update: *Ivan Goldsmith, M.D., an individual vs. Nevada State Board of Pharmacy*, 8<sup>th</sup> J.D. Case No. Case No. A-17-762877-W
21. Discussion and possible action on approval of new Policy Manual.  
**(For Possible Action)**
22. Executive Secretary Report:
  - A. Financial Report:
  - B. Temporary Licenses
  - C. Staff Activities:
    1. AG's Substance Abuse Committee
    2. Interim Health Committee
    3. Legislative Commission on Regulations
    4. Nevada Health Care Roundtable
  - D. Report to Board:
  - E. Board Related News
  - F. Licensing Activities Report

23.. Date and Location of Next Scheduled Board Meeting:

September 5-6, 2018 – Reno, Nevada

24. 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)

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, 431 W Plumb Lane, Reno, NV, 89509, or call Shirley Hunting 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 at [shunting@pharmacy.nv.gov](mailto:shunting@pharmacy.nv.gov) or 431 W Plumb Lane, Reno, Nevada.

Continuing Education credit of 4 hours, including 1 hour of law, will be given per day of Board meeting attendance. You are required to attend the board meeting for a full day to receive CE credit including the law credit.

This notice has been posted at the following locations and is available for viewing at [www.notice.nv.gov](http://www.notice.nv.gov) and **bop.nv.gov**.

Elko County Courthouse – Elko  
Washoe County Courthouse – Reno

Nevada Board of Pharmacy – Reno & Las Vegas  
Mineral County Courthouse – Hawthorne



# NEVADA STATE BOARD OF PHARMACY

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## MINUTES

June 7 & 8, 2018

## BOARD MEETING

Hyatt Place  
1790 E Plumb Ln  
Reno, Nevada

### Board Members Present:

Leo Basch	Wayne Mitchell	Jason Penrod	Melissa Shake
Robert Sullivan	Kirk Wentworth		

### Board Members Absent:

Kevin Desmond

### Board Staff Present:

Larry Pinson	Dave Wuest	Paul Edwards	Shirley Hunting
Brett Kandt	Yenh Long	Joe Depczynski	Sarah Bradley
Kristopher Mangosing			

President Basch 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.

Mr. Pinson introduced and congratulated Wayne Mitchell as Governor Sandoval's newest appointment to the Nevada State Board of Pharmacy for a three-year term.

### 1. Public Comment June 6, 2018, 9:00 AM

There was no public comment.

### 2. Approval of April 11-12, 2018, Minutes

Kirk Wentworth recused from participation in this matter due to his absence at the April 2018 Board Meeting.

Jason Penrod recused from participation from the April 12, 2018, Meeting Minutes due to his absence.

Board Action:

Motion: Jason Penrod moved to approve the April 11, 2018, Meeting Minutes as presented.

Second: Melissa Shake

Action: Passed unanimously

Board Action:

Motion: Melissa Shake moved to approve the April 12, 2018, Meeting Minutes as presented.

Second: Robert Sullivan

Action: Passed unanimously.

3. Applications for Out-of-State Pharmacy – Non Appearance
  - A. 904 Prospect Pharmacy Inc. (Boca Pharmacy) – Bronx, NY
  - B. Affinity Rx – Houston, TX
  - C. Alta Rx LLC – Sandy, UT
  - D. Binh Dan Pharmacy – Westminster, CA
  - E. B & Y Pharmacy – Philadelphia, PA
  - F. CHD Pharmacy – St Louis, MO
  - G. CRx Specialty Solution Pharmacy – Natchitoches, LA
  - H. Edpharmalle – Marshalls Creek, PA
  - I. Encompass Rx – Atlanta, GA
  - J. Georgetown Rx, LLC – Bethesda, MD
  - K. Hillcrest Pharmacy – Midvale, UT
  - L. HPC Specialty Pharmacy – Mobile, AL
  - M. Imperial RX LLC – Londonberry, NH
  - N. Medcrafters RX Pharmacy LLC – Berkley, MI
  - O. MXP Pharmacy – Amarillo, TX
  - P. North Halstead LLC – Ocean Springs, MS
  - Q. Pharmacy Express & Medical Supplies – Clearwater, FL
  - R. RaRx II LLC – Nashville, TN
  - S. Rx-Direct Home Delivery – Arlington, TX
  - T. Tee Pharmacy – Flushing, NY
  - U. ValiSureRx – New Haven, CT
  - V. Westlake Health Mart Pharmacy – Fort Worth, TX
  - W. WIRX Pharmacy – Fort Washington, PA
  - X. WIRX Pharmacy II – Philadelphia, PA

### Applications for Out-of-State Compounding Pharmacy – Non Appearance

- Y. Chinook Healthcare Pharmacy – Lafayette, CO
- Z. Clinical Specialty Infusions of Dallas, LLC – Wake Village, TX
- AA. John's Pharmacy in Albany, LLC – Albany, NY
- BB. MEDPHARMA LLC – Philadelphia, PA
- CC. Pharmaneek Inc. – Indianapolis, IN
- DD. Pharmacy of Tampa – Tampa, FL
- EE. Sterling Specialty Pharmacy – Mendota Heights, MN
- FF. United Rx LLC – Hillside, IL

### Applications for Out-of-State Wholesaler – Non Appearance

- GG. Ablynx, Inc. – Conshohocken, PA
- HH. Ascent Pharmaceuticals, Inc. – Central Islip, NY
- II. Bausch and Lomb, Inc. – Woodruff, SC
- JJ. Bioverativ U.S. LLC – Waltham, MA
- KK. Boston Medical Products, Inc. – Shrewsbury, MA
- LL. Boston Scientific Corporation – San Jose, CA
- MM. Catalent San Diego, Inc. – San Diego, CA
- NN. Colossal Health Inc. – Plainfield, IL
- OO. C.R. Bard, Inc. – Covington, GA
- PP. Golden State Medical Supply, Inc. – Camarillo, CA
- QQ. HLS Therapeutics (USA), Inc. – Rosemont, PA
- RR. Kedrion Biopharma Inc. – Fort Lee, NJ
- SS. Noden Pharma USA, Inc. – Orlando, FL
- TT. NUMED – Brooklyn, NY
- UU. Tolmar, Inc. – Windsor, CO
- VV. Premier Rx Wholesale – Cincinnati, OH
- WW. Purdue Pharma Manufacturing L.P. – Durham, NC
- XX. Purdue Pharmaceuticals L.P. – Wilson, NC
- YY. Retrophin, Inc. – San Diego, CA
- ZZ. RxPak – Memphis, TN
- AAA. UpWell Health Products, LLC – Murray, UT
- BBB. Verastem Oncology – Needham, MA
- CCC. WES Pharma Inc. – Westminster, MD

### Applications for Out-of-State Medical, Devices, Equipment and Gases – Non Appearance

- DDD. Abova Health, LLC – Minneapolis, MN
- EEE. Abova Health, LLC – Minneapolis, MN
- FFF. Advanced Medical Supply LLC – Largo, FL
- GGG. Allegro Enterprise Inc. – Bolingbrook, NY
- HHH. Apex Medical USA Corp. – Brea, CA
- III. Bard Medical Division of C.R. Bard, Inc. – Covington, GA
- JJJ. Brasseler U.S.A. Dental LLC – Savannah, GA
- KKK. Brasseler U.S.A. Medical LLC – Ventura, CA



LLL. Canoga Medical Supply, Inc. – Canoga Park, CA  
 MMM. Certified Medical Supply, Inc. – Port Washington, WA  
 NNN. Community Medical Rental and Supply – Fredericksburg, TX  
 OOO. CP Medical, Inc. – Norcross, GA  
 PPP. DJO, LLC – Fort Worth, TX  
 QQQ. DHL Supply Chain (USA) – Lockbourne, OH  
 RRR. Greenleaf Medical Supply LLC – Winston-Salem, NC  
 SSS. Hygeia II Medical Group, Inc. – Carlsbad, CA  
 TTT. Limb Lab – Rochester, MN  
 UUU. RMS Healthcare Consulting Inc. – Kansas City, MO  
 VVV. Silony Medical Corp. – Doral, FL  
 WWW. Universal Medsupports – La Mesa, CA  
 XXX. United Medical Benefits LLC – Newark, DE

#### Applications for Nevada Pharmacy – Non Appearance

YYY. Ambulatory Surgical Center of Southern Nevada – Las Vegas, NV  
 ZZZ. Community Health Alliance Sparks Pharmacy – Sparks, NV  
 AAAA. Flying Diamond Pharmacy, LLC – Reno, NV  
 BBBB. Lovelock Pharmacy – Lovelock, NV  
 CCCC. Silver Stage Pharmacy – Silver Springs, NV

After discussion, the Board directed Board Staff to verify if Clinical Specialty Infusions of Dallas, LLC (Item 3 Z) plans to provide sterile compounding services.

#### Board Action:

Motion: Jason Penrod moved to approve the Consent Agenda with the exception of Item 3 Z.

Second: Robert Sullivan

Action: Passed unanimously

Mr. Pinson stated that Clinical Specialty Infusions of Dallas, LLC has completed the affidavit stating that they will not be shipping sterile compounded products into Nevada.

#### Board Action:

Motion: Jason Penrod moved to approve Item 3 Z.

Second: Melissa Shake

Action: Passed unanimously

#### 4. Discipline

A. Raymond Duro, R.Ph

(17-117-RPH-N)

Wayne Mitchell recused from participation in this matter due to his employment with Carson Tahoe Regional Medical Center.

Raymond Duro appeared and was sworn by President Basch prior to answering questions or offering testimony.

Hal Taylor was present as counsel representing Mr. Duro.

Mr. Kandt summarized the facts of the case where Mr. Duro disclosed on his Nevada pharmacist registration renewal application that since his last renewal, he had been the subject of an administrative action in California. Mr. Kandt stated that Mr. Duro appeared at the October 2017 Board Meeting requesting consideration for renewal of his pharmacist registration. The Board granted the renewal conditioned on further review by Board Staff to determine if a parallel action by the Nevada State Board of Pharmacy was warranted.

Mr. Kandt stated that Mr. Duro's California pharmacist license was revoked, the revocation was stayed and Mr. Duro's license was placed on probation for three years with terms and conditions.

Mr. Taylor stated that Mr. Duro is currently completing the ethics course and paid his fines required by his California Settlement Agreement.

Mr. Kandt moved to have Exhibits 1-2 admitted into the record.

President Basch admitted Exhibits 1-2 into the record.

Mr. Kandt presented Exhibits 1 and 2, Mr. Duro's Nevada pharmacist registration renewal application and Stipulated Settlement and Disciplinary Order from the California State Board of Pharmacy in Case No.5709.

Mr. Kandt stated that Mr. Duro's admission and the evidence presented show findings of guilt on all three Causes of Action.

Mr. Kandt requested modifications to paragraphs 6-8 of the Accusation to strike any references to NRS 639.210 (1) (not of good moral character) and NRS 639.2107.

Mr. Taylor had no objections.

Mr. Duro apologized for his error and described the steps he has taken to comply with his California Order.

Mr. Taylor moved to have Exhibits B and C admitted into the record.

President Basch admitted Exhibits B and C into the record.

Mr. Taylor presented Exhibits B and C, a letter from the California State Board of Pharmacy showing that Mr. Duro's fines had been paid and documentation showing Mr. Duro completed the required ethics course.

Board Action:

Motion: Jason Penrod moved that the Board make findings of fact that the evidence supports the factual allegations in the Notice of Intended Action and Accusations, with the modifications to the Accusation striking references to NRS 639.210(1) and NRS 639.2107, as requested by Board Staff.

Second: Melissa Shake

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved that as a matter of law the Board has jurisdiction over this matter to find Raymond Duro guilty of the First, Second and Third Causes of Action.

Second: Melissa Shake

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to place Raymond Duro's Nevada Pharmacist Registration on probation for a period of 3 years. Mr. Duro shall pay an administrative fee of \$1,500.00. Mr. Duro shall not be a managing pharmacist, shall not own a pharmacy, and shall remain in compliance with all terms of his California Order. Mr. Duro shall notify Board Staff within one business day if he falls out of compliance with his California Order, and is responsible to provide documentation to Board Staff when his probation status is lifted in California. Should Mr. Duro fall out of compliance with his California Order the Executive Secretary or the Deputy Executive Secretary may immediately suspend Mr. Duro's Nevada pharmacist registration.

Second: Robert Sullivan

Action: Passed unanimously

B. Cheryl Mussell, PT

(18-013-PT-N)

Wayne Mitchell disclosed that Ms. Mussell was a former employee, but stated that he could participate in this matter fairly and without bias.

Cheryl Mussell appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Kandt moved to have Exhibits 1 and 2 admitted into the record.

President Basch admitted Exhibits 1 and 2 into the record.

Mr. Kandt presented Exhibits 1 and 2, Default Decision and Order of Revocation from the California State Board of Pharmacy in Case No. 5709 and her 2014 Nevada Pharmaceutical Technician Renewal Application.

Mr. Kandt described the facts of the case where the California State Board of Pharmacy revoked Ms. Mussell's California pharmaceutical technician registration for unprofessional conduct (practicing pharmacy and representing herself to be a pharmacist without a pharmacist license). The California State Board of Pharmacy found Ms. Mussell guilty by default after she failed to respond to the California Accusation.

Ms. Mussell apologized for the errors and described the events that led to facts listed in the California Accusation. She explained that her employer at the time had let go of the pharmacist on staff. She stated that she was informed by her employer that the classification of her work area had changed to a drug room which would allow her to practice at that location without direct pharmacist supervision. Ms. Mussell stated that she did not purposefully represent herself as a pharmacist.

The Board questioned Ms. Mussell regarding why she did not respond to her California Accusation.

She explained that she had moved and did not notify the California State Board of Pharmacy of her current address.

#### Board Action:

Motion: Jason Penrod moved that the Board make findings of fact that the evidence supports the factual allegations in the Notice of Intended Action and Accusation.

Second: Kirk Wentworth

Action: Passed unanimously

#### Board Action:

Motion: Jason Penrod moved that as a matter of law the Nevada State Board of Pharmacy has jurisdiction over this matter.

Second: Kirk Wentworth

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to find as a matter of law that Cheryl Mussell is guilty of the First Cause of Action.

Second: Kirk Wentworth

Melissa Shake offered a friendly amendment to strike “(2) fraudulently held herself out as a pharmacist when she is not,” from the Accusation.

After discussion, Jason Penrod did not accept the friendly amendment.

Aye: Penrod, Wentworth, Mitchell, Sullivan

Nay: Shake

Action: Motion carried

Mr. Kandt stated that Board Staff recommends revocation of Ms. Mussell’s pharmaceutical technician registration.

Board Action:

Motion: Melissa Shake moved to revoke Cheryl Mussell’s pharmaceutical technician registration for a minimum of one year. Ms. Mussell shall pay an administrative fee of \$500.00 within 30 days.

Second: Jason Penrod

Action: Passed unanimously

C. David J. Adams, DO (17-095-CS-S)

This matter was continued to the July 2018 Board Meeting.

5. Rehearing pursuant to NRS 639.252 – Case No. 17-038-RPH-S – BOARD OF PHARMACY v. NAZALENE ZEBARI, RPH – Appearance

Melissa Shake recused from participation in this matter due to her personal relationship with Ms. Zebari.

Kirk Wentworth disclosed that he was not present during Ms. Zebari’s hearing during the April 2018 Board Meeting but stated that he would be able to participate in this matter fairly and without bias.

Nazalene Zebari appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Kandt explained that Ms. Zebari is requesting the Board reconsider the discipline imposed at the last Board meeting where Ms. Zebari's Nevada pharmacist registration was revoked.

Ms. Zebari moved to have Exhibit A admitted into the record.

President Basch admitted Exhibit A into the record.

Ms. Zebari thanked the Board for reconsidering her case. She presented past Board meeting minutes where the Board had opted not to revoke a Nevada pharmacist for various violations of Nevada Pharmacy Law.

Mr. Kandt stated that Ms. Zebari is not disputing the facts of the case and stated that Board Staff recommends that the Board stand by their original decision.

Board Action:

Motion: Jason Penrod moved to deny Ms. Zebari's request for reconsideration.

Second: Wayne Mitchell

Action: Passed unanimously

6. Request for Renewal of Pharmacist License:

Dina El-Sayed

Dina El-Sayed appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Pinson explained that while renewing her Nevada Pharmacist License Ms. El-Sayed disclosed that her California pharmacy registration was revoked, the revocation stayed and placed on probation for four years for diverting hydrocodone for personal use.

Ms. El-Sayed answered questions to the Board's satisfaction regarding her discipline in California, conditions of her California order and recovery. Ms. El-Sayed stated that she enrolled into a drug treatment program.

Ms. El-Sayed moved to have Exhibit A admitted into the record.

President Basch admitted Exhibit A into the record.

Ms. El-Sayed presented Exhibit A, letters of recommendation and rehabilitation evaluations.

Ms. El-Sayed answered questions to the Board's satisfaction.

Board Action:

Motion: Jason Penrod moved to approve Dina El-Sayed's Request for Renewal of Pharmacist License with conditions. Ms. El-Sayed's Nevada Pharmacist License shall be placed on probation for four years until her probation is lifted in California. Ms. El-Sayed shall notify Board Staff of any changes to her license status in California within one business day. Ms. El-Sayed must contact Board Staff to request removal of probation in Nevada. Ms. El-Sayed shall not work in Nevada without permission and PRN-PRN evaluation.

Second: Melissa Shake

Action: Passed unanimously

7. Request for Pharmaceutical Technician in Training License:

Danisha M. Miller

Danisha Miller and Janine Hearn, Instructor Sierra Nevada Job Corps, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Edwards stated that Ms. Miller had disclosed past discipline on her Pharmaceutical Technician in Training application.

The Board questioned Ms. Miller regarding her past discipline.

Ms. Miller summarized the facts of a case where she had embezzled money from her place of employment in 2013. She apologized for her mistakes and explained that she has learned from this experience.

Ms. Hearn testified that Ms. Miller has been forthright with Sierra Nevada Job Corp about her past discipline.

Board Action:

Motion: Jason Penrod moved to approve Danish Miller's Application for Pharmaceutical Technician in Training License.

Second: Melissa Shake

Action: Passed unanimously

8. Request for Intern License:

Derek L. Durrett

Derek Durrett appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Edwards stated that Mr. Durrett disclosed on his Intern Pharmacist application that he was arrested for suspicion of driving under the influence.

Mr. Durrett stated that he is applying to pharmacy school at Roseman University. He explained that his hearing is scheduled in July 2018, but he wanted to be proactive in seeing if the Board would grant his Intern Pharmacist registration.

Mr. Durrett answered the Board's questions regarding his arrest and pending hearing.

After discussion, the Board offered Mr. Durrett the option to table his application until after his hearing.

The Board tabled Mr. Durrett's application for Intern Pharmacist License at his request.

#### 9. Applications for Out-of-State Compounding Pharmacy – Appearance

##### A. Coram CVS/specialty infusion service #48090 – Centennial, CO

Sherry Heinrichs, managing pharmacist, appeared and was sworn by President Basch prior to answering questions or offering testimony.

The Board removed the affidavit not to ship sterile products into Nevada from the record at Ms. Heinrichs' request.

Ms. Heinrichs explained that Coram CVS is a retail pharmacy that provides sterile compounding and mail services. She stated that Coram CVS compounds sterile IV antibiotics and parenteral nutrition products.

Joe Dodge, Inspector Nevada State Board of Pharmacy, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Dodge questioned Ms. Heinrichs regarding Coram CVS' shipping procedures, accreditation and products provided.

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

#### Board Action:

Motion: Kirk Wentworth moved to approve Coram CVS/Specialty Infusion Service #48090's Application for Out-of-State Pharmacy License.

Second: Wayne Mitchell

Action: Passed unanimously

##### B. Farmakeio – Richardson, TX



Justin Graves, managing pharmacist and part-owner, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Graves stated that Farmakeio is a retail pharmacy that provides both sterile and non-sterile compounding services. He explained that Farmakeio will be shipping non-sterile compounded products to Nevada.

Mr. Dodge questioned Mr. Graves regarding Farmakeio's high-risk compounding procedures, product testing, sterilization method and training for compounding staff.

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

Board Action:

Motion: Jason Penrod moved to approve Farmakeio's Application for Out-of-State Pharmacy License pending receipt of Farmakeio's last inspection by the Texas State Board of Pharmacy and Farmakeio's response. The Executive Secretary is authorized to review and approve the application.

Second: Kirk Wentworth

Action: Passed unanimously

10. Applications for Out-of-State Pharmacy – Appearance

A. Lynchburg Drug Store – Lynchburg, TN

No representative from Lynchburg Drug Store was present.

B. Pharmacy Care Concepts – Stockton, CA

Van Duong, managing pharmacist, Davis Tran, Director of Operations, and Scott Hancock, COO, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Tran stated that Pharmacy Care Concepts is a long term care pharmacy that services assisted living and hospice care facilities.

Ms. Duong, Mr. Tran and Mr. Hancock answered questions to the Board's satisfaction regarding Pharmacy Care Concepts, past ownership, policies and procedures, delivery procedures and past discipline and probation status in California.

Board Action:

Motion: Kirk Wentworth moved to approve Pharmacy Care Concept's Application for Out-of-State Pharmacy License. Pharmacy Care Concepts shall notify Board Staff regarding the results of their request for early termination of probation in California.

Second: Jason Penrod

Action: Passed unanimously

# 11. Applications for Out-of-State Outsourcing Facility – Appearance

## A. Pentec Health, Inc. – Boothwyn, PA

Jean Bickel, managing pharmacist, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Ms. Bickel stated that she would provide Board Staff with a Letter of Authorization allowing her to speak on behalf of the company.

Ms. Bickel explained that Pentec Health, Inc. is an Out-of-State Outsourcing Facility that will provide high-risk sterile compounding services to hospitals.

The Board questioned Ms. Bickel regarding Pentec Health, Inc.'s past discipline in Colorado.

Ms. Bickel explained that Pentec Health, Inc. was fined for failure to report to the Colorado PDMP for a period of time. She testified that this error has been rectified.

Mr. Dodge appeared and questioned Ms. Bickel regarding Pentec Health, Inc.'s past FDA inspections, policies and procedures, product testing and high-risk sterile compounding procedures.

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

## Board Action:

Motion: Kirk Wentworth moved to approve Pentec Health, Inc.'s Application for Out-of-State Outsourcing Facility License pending receipt of a Letter of Authorization allowing Ms. Bickel to speak on behalf of the company.

Second: Wayne Mitchell

Action: Passed unanimously

## B. PharMEDium Services, LLC – Cleveland, MS

This matter was continued to a future meeting.

## C. PharMEDium Services, LLC – Dayton, NJ

This matter was continued to a future meeting.

## D. PharMEDium Services, LLC – Memphis, TN

This matter was continued to a future meeting.

E. PharMEDium Services, LLC – Sugar Land, TX

This matter was continued to a future meeting.

F. SCA Pharmaceuticals LLC – Little Rock, AR

Matthew White, managing pharmacist, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. White presented a Letter of Authorization allowing him to speak on behalf of the company.

Mr. White explained that SCA Pharmaceuticals LLC is a 503B Outsourcing facility that provides parenteral and sterile compounding services to hospitals.

Mr. Dodge appeared and questioned Mr. White regarding SCA Pharmaceuticals LLC's past FDA inspections, products provided and policies and procedures.

Mr. White answered questions to the Board's satisfaction. He described the changes SCA Pharmaceuticals LLC made to address the FDA's observations.

Board Action:

Motion: Jason Penrod moved to approve SCA Pharmaceuticals LLC's Application for Out-of-State Outsourcing Facility License.

Second: Melissa Shake

Action: Passed unanimously

G. Stokes Healthcare Inc. – Mt Laurel, NJ

Michael Tursi, part-owner, and Emmett McVey, managing pharmacist and part-owner, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Tursi explained that Stokes Healthcare Inc. is an outsourcing facility that provides sterile and non-sterile compounded products for veterinary use.

Mr. Dodge questioned Mr. Tursi and Mr. McVey regarding Stokes Healthcare Inc.'s past inspections, products provided and work experience.

After discussion, Mr. Dodge suggested Mr. Tursi and Mr. McVey provide Board Staff with a copy of FDA form 483.

Mr. Tursi and Mr. McVey answered questions to the Board's satisfaction.

Board Action:

Motion: Jason Penrod moved to approve Stokes Healthcare Inc.'s Application for Out-of-State Outsourcing Facility License pending receipt of Stokes Healthcare Inc.'s FDA form 483 from their last inspection. Board Staff is authorized to review and evaluate the documentation.

Second: Melissa Shake

Action: Passed unanimously

H. Wells Pharmacy Network, LLC – Dyersburg, TN

Chris Fishman appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Fishman presented a Letter of Authorization allowing him to speak on behalf of the company.

The Board questioned Mr. Fishman regarding Wells Pharmacy Network, LLC's facility layout and products provided.

Mr. Wuest and Mr. Dodge questioned Mr. Fishman regarding Wells Pharmacy Network, LLC's past FDA inspections.

After discussion, the Board expressed concern regarding the findings from the last FDA inspection.

The Board offered Mr. Fishman the opportunity to table Wells Pharmacy Network, LLC's application while Board Staff evaluated the most recent FDA inspection.

The Board tabled Wells Pharmacy Network, LLC's application at Mr. Fishman's request.

12. Application for Nevada Wholesaler – Appearance

Reichman Distribution Inc. – Las Vegas, NV

No representative from Reichman Distribution Inc. was present.

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

Ideal Health Care, LLC – Las Vegas, NV

Rakesh Jain, owner, appeared and was sworn by President Basch prior to answering questions or offering testimony.

The Board updated Ideal Health Care, LLC's application to indicate Raju Roy as the MDEG Administrator and remove Mr. Jain from the list of practitioner owners at Mr. Jain's request.

The Board stated that Mr. Roy would need to provide the MDEG Administrator application to Board Staff.

Mr. Jain stated that Ideal Health Care, LLC will provide prosthetic products.

Mr. Jain answered questions to the Board's satisfaction regarding Ideal Health Care, LLC's out-of-state facilities and Mr. Roy's work history.

The Board expressed concern that Ms. Jain had indicated on her personal history record that she had a criminal indictment, information or complaint returned against her. Mr. Jain testified that Ms. Jain had incorrectly answered the question.

Board Action:

Motion: Jason Penrod moved to approve Ideal Health Care, LLC's Application for Nevada MDEG License pending receipt of a completed MDEG Administrator Application and a positive inspection. Board Staff is authorized to review Ms. Jain's Personal History Record and verify the answer regarding the possible indictment.

Second: Melissa Shake

Action: Passed unanimously

14. Applications for Nevada Pharmacy – Appearance

A. AbacusRx Pharmacy – Henderson, NV

Chuck Benain, COO AbacusRx Pharmacy, and Steve Carlton, managing pharmacist, appeared and were sworn by President Basch prior to answering questions or offering testimony.

The Board modified AbacusRx Pharmacy's application to include sterile compounding into their services provided at Mr. Benain's request.

Mr. Benain stated that AbacusRx Pharmacy is requesting Board approval for their ownership change. He explained that AbacusRx Pharmacy will continue to provide services for long term care facilities.

Mr. Benain answered questions to the Board's satisfaction regarding AbacusRx Pharmacy's clean room specifications, products provided and policies and procedures.

Mr. Carlton answered questions to the Board's satisfaction regarding his work history and past discipline.

Board Action:

Motion: Jason Penrod moved to approve AbacusRx Pharmacy's Application for Nevada Pharmacy pending a positive inspection. AbacusRx Pharmacy will notify Board Staff prior to compounding any high-risk sterile compounded products and will be re-inspected by Board Staff.

Second: Melissa Shake

Action: Passed unanimously

B. Desert Hope Treatment Center – Las Vegas, NV

Nathen Connolly, managing pharmacist, and Brian Bulfer appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Bulfer stated that he would provide a Letter of Authorization allowing him to speak on behalf of the company to Board Staff.

Mr. Bulfer and Mr. Connolly explained that Desert Hope Treatment Center is a hospital pharmacy with 148 beds that service addiction recovery patients.

Mr. Bulfer and Mr. Connolly answered questions to the Board's satisfaction regarding Desert Hope Treatment Center's policies and procedures, software and ownership structure.

Board Action:

Motion: Jason Penrod moved to approve Desert Hope Treatment Center's Ownership Change Application for Nevada Pharmacy License pending a positive inspection.

Second: Wayne Mitchell

Action: Passed unanimously

Public Comment June 7, 2018 4:00 PM

There was no public comment.

C. Las Vegas AMG Specialty Hospital, LLC – Las Vegas, NV

Ken D'Amico and Lane Cheramie, managing pharmacist, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. D'Amico explained that he would provide Board Staff with a Letter of Authorization allowing him to speak on behalf of the company.

Mr. D'Amico stated that Las Vegas AMG Specialty Hospital, LLC is a hospital pharmacy with 24 beds.

Mr. D'Amico and Mr. Cheramie answered questions to the Board's satisfaction regarding the pharmacy's policies and procedures, proposed layout, accreditation and staff.

Board Action:

Motion: Jason Penrod moved to approve Las Vegas AMG Specialty Hospital, LLC pending a positive inspection and receipt of a Letter of Authorization allowing Mr. D'Amico and Mr. Cheramie to speak on behalf of the company.

Second: Melissa Shake

Action: Passed unanimously

D. Nimble Pharmacy – Las Vegas, NV

Kartikeya Jha, Director of Operations, and Richard Rowles, managing pharmacist, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Jha explained that Nimble Pharmacy is a retail pharmacy that will provide delivery services.

Mr. Jha stated that he would provide Board Staff with a Letter of Authorization allowing him and Mr. Rowles to speak on behalf of the business.

Mr. Rowles answered questions to the Board's satisfaction regarding his past work history and pharmacy experience.

Mr. Jha answered the Board's questions regarding Nimble Pharmacy's out-of-state locations.

Board Action:

Motion: Kirk Wentworth moved to approve Nimble Pharmacy's Application for Nevada Pharmacy pending receipt of a Letter of Authorization allowing Mr. Jha and Mr. Rowles to speak on behalf of the company and a positive inspection.

Melissa Shake offered a friendly amendment to have Board Staff review Nimble Pharmacy's out-of-state location in California.

Kirk Wentworth accepted the friendly amendment.

Second: Melissa Shake

Action: Passed unanimously

E. Silver State Pharmacy LLC – Las Vegas, NV

Lizet Torres-Leon, owner and Kyeong Kang, managing pharmacist, appeared and were sworn by President Basch prior to answering questions or offering testimony.

The Board updated Silver State Pharmacy LLC's application to reflect the business address as 1591 N. Buffalo Dr. #140 at Ms. Torres-Leon's request.

Ms. Torres-Leon explained that Silver State Pharmacy LLC, is a retail pharmacy that will provide delivery services in the North Las Vegas area.

Ms. Torres-Leon and Mr. Kang answered questions to the Board's satisfaction regarding the pharmacy's policies and procedures and services provided

Board Action:

Motion: Melissa Shake moved to approve Silver State Pharmacy LLC's Application for Nevada Pharmacy License pending a positive inspection.

Second: Kirk Wentworth

Action: Passed unanimously.

15. Personnel Review

A. Personnel Evaluation

Mr. Wuest commended Board Staff commenting on their hard work and efficiency.

B. Executive Secretary Evaluation

Mr. Wuest complimented Mr. Pinson's hard work and leadership.

The Board spoke positively of Board Staff's hard work as well as Mr. Pinson's and Mr. Wuest's leadership.

16. Election of Officers

This matter was rescheduled for the July 2018 Board Meeting.

17. Training Session on Board's Use of Meeting Materials in Electronic Format

Mr. Kandt presented the "IT Acceptable Use Agreement" for execution by each Board member.

Ms. Long explained to the Board the procedure for downloading and navigating the meeting materials in electronic format. She stated that Board Staff would be available for any questions and to assist them in using the new electronic Board Books.



18. Discussion and determination regarding a pharmacist administering an immunization on an order of the practitioner transcribed on a prescription NAC 639.297 to 639.2978.

President Basch provided background information regarding the prohibition of a prescription written by a prescriber ordering the pharmacist to give an immunization. He stated that the situation arises when an immunization is being ordered outside of a protocol or manufacturer recommendation.

Board discussion ensued regarding the current immunization statutes, regulations and vaccine storage requirements.

The Board determined that any changes to these policies would require a statutory change.

19. General Counsel Report

20. Executive Secretary Report:

- A. Financial Report:
  1. 2018-2019 Budget

Mr. Wuest provided a copy of the budget for the fiscal year 2018-2019 to the Board and reviewed it to the Board's satisfaction.

- B. Temporary Licenses

Four temporary licenses were issued since the last meeting.

- C. Staff Activities:
  1. Sunset Subcommittee Board Review by the Legislative Commission
  2. Meetings for Other Health Care Licensing Boards

Mr. Pinson stated that Board Staff has met with the other Health Care Boards to discuss education on AB 474.

3. Governor's Task Force on Opiates
  4. NABP Annual Meeting
  5. AB 474 Meeting and Continuing Education
  6. CORA Meeting
- D. Report to Board:
  1. BD Production Information & Recall
- E. Board Related News

Mr. Pinson and Ms. Long introduced Darla Zarley as the most recent grant employee. Ms. Zarley will be working with the Prescription Monitoring Program's (PMP) audit project to ensure the accuracy of the PMP data.

- F. Licensing Activities Report

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

**Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the prescribing or dispensing of controlled substance for the treatment of pain in conformance with Assembly Bill 474 from the 2017 Nevada Legislative Session;**

Mr. Wuest presented the proposed workshop language and a letter from the Nevada State Board of Medical Examiners.

Mr. Wuest stated that the proposed language further defines “controlled substance” as it relates to a “written informed consent” and “medication agreement” and clarifies the application of Section 55; where it says “require the patient to complete an assessment of the patient’s risk for abuse, dependency and addiction.”

President Basch opened the Public Comment.

Catherine O’Mara, NSMA, expressed support of the proposed language and Mr. Wuest’s testimony. She stated that the proposed language will help clarify AB 474 requirements for practitioners.

Board Action:

Motion: Jason Penrod moved to adopt the proposed amendments and move forward to Public Hearing.

Second: Robert Sullivan

Action: Passed unanimously

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

**A. Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the dispensing of drugs with prescription readers.**

Dave Wuest, Deputy Executive Secretary Nevada State Board of Pharmacy, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Wuest explained that the proposed amendments enact provisions of Senate Bill 131 requiring certain pharmacies to, upon request, provide a prescription reader or advice on obtaining a prescription reader.

Mr. Kandt and Mr. Edwards provided background information.

Mr. Edwards read a letter from Rick Kuhlmeier into the record. Mr. Kuhlmeier had expressed concern regarding the clarity of previous versions of the proposed language.

President Basch opened the Public Comment.

Liz MacMenamin, RAN, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Ms. MacMenamin expressed support of the proposed amendments as presented by Board Staff. She thanked the Board and Board Staff for their work on this matter.

Board Action:

Motion: Jason Penrod moved to adopt R131-17 as presented.

Second: Melissa Shake

Action: Passed unanimously

**B. Amendment of Nevada Administrative Code Chapter 453 to add a new section thereto relating to practitioner access to the Prescription Monitoring Program (PMP) database established pursuant to NRS 453.162.**

Mr. Kandt presented proposed revisions to LCB File No. R013-18.

He explained that proposed regulation as revised requires practitioners to enroll with the Board for internet access to the Prescription Monitoring Program (PMP) database, allows a practitioner to designate members of his or her staff to act as delegates for the purposes of accessing the PMP database, provides for the suspension or termination of access to the PMP database if the PMP database has been intentionally accessed by a person for a purpose not authorized by law, and sets forth certain requirements for disclosure of information from the database.

President Basch opened the Public Comment.

Catherine O'Mara, NSMA, appeared and expressed support of the proposed amendments presented by Board Staff.

Liz MacMenamin, RAN, appeared and expressed support of the proposed amendments presented by Board Staff.

Board Action:

Motion: Jason Penrod moved to adopt R013-18 with revisions as presented by Board Staff.

Second: Melissa Shake

Action: Passed unanimously

**C. Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the prescribing or dispensing of controlled substances for the treatment of pain in conformance with Assembly Bill 474 from the 2017 Nevada Legislative Session.**

Mr. Wuest explained that the proposed amendments further define “acute pain” and “course of treatment;” clarify “initial prescription” as defined in section 51 of AB 474; clarify “written informed consent” in sections 53 and 54 of AB 474 for practice groups; clarify “making a good faith effort to obtain and review the medical records of the patient” in paragraph (c) of subsection 1 of section 54 of AB 474; clarify the application of section 57 of AB 474 requiring a practitioner, other than a veterinarian, to consider certain factors before prescribing a controlled substance listed in schedule II, III or IV.

President Basch opened the Public Comment.

Catherine O’Mara, NSMA, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Ms. O’Mara expressed support for the proposed amendments and thanked the Board and Board Staff for their work in this matter.

John Goldstein, Comprehensive Cancer Centers of Nevada, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Goldstein expressed support of the proposed amendments.

Board Action:

Motion: Jason Penrod moved to adopt R047-18 as presented.

Second: Melissa Shake

Action: Passed unanimously

23. Date and Location of Next Scheduled Board Meeting:

July 18-19, 2018 – Las Vegas, Nevada

24. Public Comment June 7, 2018 1:00 PM

There was no public comment.

A

# 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: **PHD3697**)  
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 **LLC**  
☐ 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: East Ridge Rx LLC

Physical Address: 12176 South 1000 East Ste 2

Mailing Address: 12176 South 1000 East Ste 2

City: Draper State: UT Zip Code: 84020

Telephone: 801-355-5176 Fax: 801-606-7358

Toll Free Number: 877-252-4882 (Required per NAC 639.708)

E-mail: pharmacist@eastridgerx.com Website: www.eastridgeex.com (In Progress)

Managing Pharmacist: Angelee Dean License Number: 6647553-1701

### TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail  
☐ ☒ Hospital (# beds     )  
☐ ☒ Internet - **SEE ENCLOSED STATEMENT**  
☐ ☒ 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,**

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509

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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: Haltom Pharmacy

Physical Address: 5310 E. Belknap STE E

Mailing Address: \_\_\_\_\_

City: Haltom City State: Texas Zip Code: 76117

Telephone: 817-838-2500 Fax: 817-838-2510

Toll Free Number: 888-642-5613 (Required per NAC 639.708)

E-mail: haltompharm@gmail.com Website: N/A

Managing Pharmacist: Thanh Ngo License Number: 39963

### 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,

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# 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

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☒ 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: LEGACYRX PHARMACY

Physical Address: 16051 ADDISON RD, STE 305

Mailing Address: 16051 ADDISON RD, STE 305

City: ADDISON State: TX Zip Code: 75001

Telephone: (972) 485-4443 Fax: (214) 594-7454

Toll Free Number: (800) 991-4752 (Required per NAC 639.708)

E-mail: LEGACYRXPHARM@GMAIL.COM Website: NONE

Managing Pharmacist: LISA LEELEN KUEHNE License Number: 35635

### 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,

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# 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\_\_\_\_)  
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: MP Pharmacy II

Physical Address: 4434 Cerritos Ave., Los Alamitos, CA 90720

Mailing Address: 4434 Cerritos Ave

City: Los Alamitos State: CA Zip Code: 90720

Telephone: 714-733-2701 Fax: 714-733-3702

Toll Free Number: 800-674-8901 (Required per NAC 639.708)

E-mail: mppharmaceuticalsla@gmail.com Website: mpmedsII.com

Managing Pharmacist: Ronak Desai License Number: RPH55481

### 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

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

10/1/19



E

# 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 \_\_\_\_\_)  
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: PREFERRED PHARMACY INC

Physical Address: 3303 HARBOR BLVD H7

Mailing Address: 3303 HARBOR BLVD H7

City: COSTA MESA State: CA Zip Code: 92626

Telephone: 714-497-2778 Fax: 714-787-4966

Toll Free Number: 877-737-8477 (Required per NAC 639.708)

E-mail: FSG@PREFERRED RX.COM Website: WWW.PREFERRED RX.COM

Managing Pharmacist: TONY LA License Number: 73904

### 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,**

101344

# 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 \_\_\_\_\_)  
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: Roman Health Pharmacy LLC

Physical Address: 900 Broadway St. Suite 706

Mailing Address: 900 Broadway St. Suite 706

City: New York State: New York Zip Code: 10003

Telephone: 347-719-1438 Fax: NONE

Toll Free Number: 888-798-8686 (Required per NAC 639.708)

E-mail: ana@getroman.com Website: www.getroman.com

Managing Pharmacist: Ana Espinal License Number: 062874

### TYPE OF PHARMACY AND

### SERVICES PROVIDED

Yes/No

☐ ☒ Retail

☐ ☒ Hospital (# beds \_\_\_\_\_)

☒ ☐ Internet

☐ ☒ Nuclear

☐ ☐ Ambulatory Surgery Center

☐ ☒ Community

☒ ☐ Other: Telemedicine

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,

10/185

G

## 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

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☒ 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: Fresh RxPhysical Address: 565 Goddard AvenueMailing Address: P.O. Box 347City: Ignacio State: CO Zip Code: 81137Telephone: 970.442.6400 Fax: 970.563.4403Toll Free Number: 800-388-3135 (Required per NAC 639.708)E-mail: johnkutzko@freshrxllc.com Website: under constructionManaging Pharmacist: John D. Kutzko License Number: PHA. 0019440**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,

101261

# 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** \_\_\_\_\_)  
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: Total Care Rx, Inc.  
Physical Address: 57-37 Main Street Flushing, NY 11355  
Mailing Address: 57-37 Main Street  
City: Flushing State: NY Zip Code: 11355  
Telephone: 718.762.7111 Fax: 718.947.1079  
Toll Free Number: 866.868.2579 (Required per NAC 639.708)  
E-mail: AdminLevel2@TotalCareRx.com Website: www.TotalCareRx.Com  
Managing Pharmacist: William B. Donnelly License Number: 043826

### 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,**

101158

I

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

## 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: Animal Health International, Inc.

Physical Address: 804 Henrietta Creek Road

City: Roanoke State: TX Zip Code: 76262

Telephone Number: 970-584-5200 Fax Number: 970-584-5700

Toll Free Number: \_\_\_\_\_

E-mail: marcus.prochazka@animalhealthinternational.com Website: www.animalhealthinternational.com

Facility Manager: Brandon Cochran

Professional qualifications and experience of facility manager: 4 years of experience working for a prescription drug wholesale distributor.

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: \_\_\_\_\_

101348

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**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: Animal Health International, Inc.

Physical Address: 640 South Main Street

City: Spanish Fork State: UT Zip Code: 84660

Telephone Number: 801-798-7347 Fax Number: 970-584-5841

Toll Free Number: \_\_\_\_\_

E-mail: marcus.prochazka@animalhealthinternational.com Website: www.animalhealthinternational.com

Facility Manager: Swade Bartlett

Professional qualifications and experience of facility manager: 5.5 years of experience working for  
prescription drug wholesale distributor

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: \_\_\_\_\_

K

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**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

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☒ 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

Johnson & Johnson Health Care Systems Inc. is wholly owned by Johnson & Johnson, a publicly traded company. As advised by your office, because the parent company is publicly traded, the publicly traded pages of this application must be completed.

**GENERAL INFORMATION to be completed by all types of ownership**

Facility Name: Johnson & Johnson Health Care Systems Inc.

Physical Address: 1101 Synthes Avenue

City: Monument State: CO Zip Code: 80132

Telephone Number: 719-481-5300 Fax Number: N/A

Toll Free Number: N/A

E-mail: Calvara2@its.jnj.com Website: www.ijchs.com

Facility Manager: Conrad P. Alvarado

Professional qualifications and experience of facility manager: See Attachment B

**Types of licensed outlets or authorized persons firm will serve:**

☐ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers  
☒ Other: Veterinarians

**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: \_\_\_\_\_

101255

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**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: Jubilant HollisterStier LLC

Physical Address: 3525 North Regal Street

City: Spokane State: Washington Zip Code: 99207

Telephone Number: 509-489-5656 Fax Number: 509-484-4320

Toll Free Number: 1-800-992-1128

E-mail: madams@jhs.jubl.com Website: hsallergy.com

Facility Manager: Gina L. Truscott, Site Head Director, Regulatory Affairs

Professional qualifications and experience of facility manager: Regulatory Affairs Certification, United States and Europe. 21 + years experience

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: \_\_\_\_\_



M

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

## 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: Novadoz Pharmaceuticals, LLC

Physical Address: 20 Duke Road, Suite A

City: Piscataway State: NJ Zip Code: 08854

Telephone Number: 908-887-0679 Fax Number: 732-902-2113

Toll Free Number: N/A

E-mail: seshu.akula@novadozpharma.com Website: novadozpharma.com

Facility Manager: Seshu Akula

Professional qualifications and experience of facility manager: Resume 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: \_\_\_\_\_

N

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

## 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: Remedy Rx Wholesale

Physical Address: 1057 S. Sherman St. Ste 120

City: Richardson State: Tx Zip Code: 75081

Telephone Number: 888-638-6793 Fax Number: 972-692-6793

Toll Free Number: 888-638-6793

E-mail: remedyrxwholesale@gmail.com Website: \_\_\_\_\_

Facility Manager: Tony Tran

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: \_\_\_\_\_

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

### 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

<input checked="" type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4	<input type="checkbox"/> Partnership – Pages 1,2,3,7
<input type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Sole Owner – Pages 1,2,3,8

#### GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Sage Therapeutics, Inc.

Physical Address: 215 First Street

City: Cambridge State: MA Zip Code: 01242

Telephone Number: (617) 299-8380 Fax Number: (617) 299-8379

Toll Free Number: N/A

E-mail: Mike.Flanagan@sagerx.com Website: www.sagerx.com

Facility Manager: Kimi Iguchi

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 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: \_\_\_\_\_

P

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**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: Top Quality Manufacturing, Inc.

Physical Address: 13165 Sandoval St

City: Santa Fe Springs State: CA Zip Code: 90670

Telephone Number: 562-906-6100 Fax Number: 562-906-6161

Toll Free Number: 800-483-8559

E-mail: jon@topqualitygloves.com Website: www.topqualitygloves.com

Facility Manager: Jando Chow

Professional qualifications and experience of facility manager: Manages warehouse operations including, Shipping, Receiving, Inventory Management, Safe storage, Quality control & Record keeping of RX products. Licensed as a Designated Rep in the State of California. Ensures compliance with Local, State & Federal regulations.

**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: \_\_\_\_\_

Q

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane □ Reno, NV 89509 □ (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG 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.

<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: CP Bracing Supply, Inc.

Physical Address: 801 W Bay Drive Suite 505

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 801 W Bay Drive Suite 505

City: Largo State: FL Zip Code: 33770

Telephone: 727-314-4343 Fax: 1-877-270-7712

E-mail: info@cpbracingsupply.com Website: N/A

### 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: N/A to Sun: N/A to Holidays: N/A to

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Daniil Demidov

### 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>Off the shelf Orthotics</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: \_\_\_\_\_

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane Reno, NV 89509 (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG 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.

<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"/> 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: Custom Milling Center

Physical Address: 4680 Table Mountain Drive  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 4680 Table Mountain Drive

City: Golden State: Co. Zip Code: 80403

Telephone: 303 865-7755 Fax: 303 865-7757

E-mail: Mike.Valenzuela@henry Schein.com Website: WWW.Custom-Milling.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: Mike Valenzuela

### 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: \_\_\_\_\_

\*\*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

S

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**APPLICATION FOR OOS MDEG 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.

<input checked="" type="checkbox"/> New MDEG or <input type="checkbox"/> Ownership Change (Provide current license number if making changes: MD or MW _____) Check <u>box</u> below for type of ownership and complete all required forms.	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4 <input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5,6	<input type="checkbox"/> Partnership - Pages 1,2,3,7 <input type="checkbox"/> Sole Owner – Pages 1,2,3,8

**GENERAL INFORMATION to be completed by all types of ownership**

Facility Name: Devotion Medical Supply, Inc.  
 Physical Address: 101 Kenwood Road Suite 26  
 Mailing Address: same as above  
 City: Fayetteville State: GA Zip Code: 30214  
 Telephone Number: 678-817-4418 Fax Number: 678-817-4419  
 Toll Free Number: 877-910-5341  
 E-mail: sorobor@sbcglobal.net Website: \_\_\_\_\_

**MDEG Administrator Information (Person in charge on a daily basis.)**

Name: Simon Orobor

**Days and Hours that the Facility will be Regularly Operated:**

Mon: 9 to 5 Tue: 9 to 5 Wed: 9 to 5 Thu: 9 to 5  
 Fri: 9 to 5 Sat: 9 to 3 Sun: \_\_\_\_\_ to \_\_\_\_\_ Holidays: \_\_\_\_\_ to \_\_\_\_\_

**TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)**

- |   |  |
|---|--|
| <input type="checkbox"/> Medical Gases **             | <input checked="" 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"/> 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 a telephone number of a Nevada contact.

Name: \_\_\_\_\_ Telephone: \_\_\_\_\_

100906

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane □ Reno, NV 89509 □ (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG 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

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<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: Elite Medical Supply

Physical Address: 2167 Camino Del Rio South #315  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: \_\_\_\_\_

City: San Diego State: CA Zip Code: 92108

Telephone: 1-844-434-1140 Fax: 1-877-219-6962

E-mail: nnexateelmedicalsupplyhmc.com Website: \_\_\_\_\_

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8<sup>30</sup> to 3 Tue: 8<sup>30</sup> to 3 Wed: 8<sup>30</sup> to 3 Thu: 8<sup>30</sup> to 3

Fri: 8<sup>30</sup> to 3 Sat: N/A to N/A Sun: N/A to N/A Holidays: N/A to N/A

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Sheila Negat

### 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: Sheila Negat Telephone: 1-844-434-1140



## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG LICENSE

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<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: FedEx Supply Chain, Inc.

Physical Address: 9 Gateway Commerce Center Dr. E, Ste. 110, Edwardsville, IL 62025  
 (This must be a business address, we can not issue a license to a home address)

Mailing Address: Attn: Licensing, 700 Cranberry Woods Dr.

City: Cranberry Twp. State: PA Zip Code: 16066

Telephone: 800-677-3110 Fax: 724-776-3167

E-mail: FSC-pharmalicensing@fedex.com Website: supplychain.fedex.com

#### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 6a to 4p Tue: 7a to 3p Wed: 7a to 3p Thu: 7a to 3p  
 Fri: 6a to 4p Sat: 6a to 4p Sun: 6a to 4p Holidays: — to —

#### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Eric Keelin

#### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |  |   |
|--|---|
| <input type="checkbox"/> Medical Gases**<br><input type="checkbox"/> Respiratory Equipment**<br><input type="checkbox"/> Life-sustaining equipment**<br><input type="checkbox"/> Diabetic Supplies | <input type="checkbox"/> Assistive Equipment<br><input type="checkbox"/> Parenteral and Enteral Equipment**<br><input type="checkbox"/> Orthotics and Prosthesis<br><input checked="" type="checkbox"/> Other: <u>Feminine hygiene products</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: \_\_\_\_\_

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane □ Reno, NV 89509 □ (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG LICENSE

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<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: First Stop Medical Supply, Inc.

Physical Address: 8800 49th Street North #309

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 8800 49th Street North #309

City: Pinellas Park State: FL Zip Code: 33782

Telephone: 727-498-8573 Fax: 1-888-785-6609

E-mail: info@firststopmedicalsurgery.com Website: N/A

#### 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: N/A to Sun: N/A to Holidays: N/A to

#### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Daniil Demidov

#### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |  |  |
|--|--|
| <input type="checkbox"/> Medical Gases**<br><input type="checkbox"/> Respiratory Equipment**<br><input type="checkbox"/> Life-sustaining equipment**<br><input type="checkbox"/> Diabetic Supplies | <input type="checkbox"/> Assistive Equipment<br><input type="checkbox"/> Parenteral and Enteral Equipment**<br><input checked="" type="checkbox"/> Orthotics and Prosthesis<br>Other: <u>Off the shelf Orthotics</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: \_\_\_\_\_

10/179

W

**NEVADA STATE BOARD OF PHARMACY**

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

**APPLICATION FOR OUT-OF-STATE MDEG LICENSE**

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

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<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: BioResolutions LLC (DBA: Halo Wound Solutions)Physical Address: N64 W24801 Main Street Suite #106 Sussex, WI 53089

(This must be a business address, we can not issue a license to a home address)

Mailing Address: N64 W24801 Main Street Suite # 106City: Sussex State: WI Zip Code: 53089 Telephone: 262-820-0289Fax: 888-655-6244 E-mail: Lesslinger@halodme.comWebsite: [www.halodme.com](http://www.halodme.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 5Sat: closed Sun: closed Holidays: \_\_\_\_\_ to \_\_\_\_\_**MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis**Name: Luke Esslinger**TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)**

- |  |   |                                      |
|--|---|--------------------------------------|
| <input type="radio"/> Medical Gases**  | <input type="radio"/> Assistive Equipment         | <input type="radio"/> Parenteral and |
| <input type="radio"/> Enteral Equipment**  | <input type="radio"/> Respiratory Equipment**     | <input type="radio"/> Orthotics and  |
| <input type="radio"/> Prosthetics  | <input type="radio"/> Life-sustaining equipment** |                                      |
| <input type="radio"/> Diabetic Supplies  |   |                                      |
| <input checked="" type="radio"/> Other: <u>Wound Care Surgical Dressing Supplies</u> |   |                                      |

101136

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG LICENSE

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<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: Healogics Wound Care Supply, LLC

Physical Address: 5220 Belfort Road, Suite 150, Jacksonville, FL 32256  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: P. O. Box 551187

City: Jacksonville State: FL Zip Code: 32256

Telephone: 904-446-3464 Fax: 904-446-3376

E-mail: jarrod.henshaw@healogics.com Website: www.healogics.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: Closed Sun: Closed Holidays: See attachment

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Jarrod Henshaw

### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |  |   |
|--|---|
| <input type="checkbox"/> Medical Gases**<br><input type="checkbox"/> Respiratory Equipment**<br><input type="checkbox"/> Life-sustaining equipment**<br><input type="checkbox"/> Diabetic Supplies | <input type="checkbox"/> Assistive Equipment<br><input type="checkbox"/> Parenteral and Enteral Equipment**<br><input type="checkbox"/> Orthotics and Prosthesis<br>Other: <u>wound 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: N/A

Telephone: N/A

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane ☐ Reno, NV 89509 ☐ (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG LICENSE

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<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: Jackson Medical Supply, Inc.

Physical Address: 801 West Bay Drive, Suite 515, Largo FL 33770

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 801 West Bay Drive, 515

City: Largo State: FL Zip Code: 33770

Telephone: 727-754-3306 Fax: 727-754-3396

E-mail: info@jacksonmedsupplyinc.com Website: N/A

### 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: N/A to      Sun: N/A to      Holidays: N/A to     

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Daniil Demidov

### 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>Off the shelf Orthotics</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: \_\_\_\_\_

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane ☐ Reno, NV 89509 ☐ (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG LICENSE

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<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: Layne Medical Supply, Inc.

Physical Address: 39047 County Rd 54  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: \_\_\_\_\_

City: Zephyrhills State: FL Zip Code: 33542

Telephone: 813-702-6376 Fax: 813-702-6315

E-mail: Info@laynemedicalsupply.com Website: \_\_\_\_\_

### 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: \_\_\_\_\_ to \_\_\_\_\_ Sun: \_\_\_\_\_ to \_\_\_\_\_ Holidays: \_\_\_\_\_ to \_\_\_\_\_

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Kristina Wexler

### 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: \_\_\_\_\_ Telephone: Off the Shelf Orthotics

AA

**NEVADA STATE BOARD OF PHARMACY**

431 W Plumb Lane ☐ Reno, NV 89509 ☐ (775) 850-1440

**APPLICATION FOR OUT-OF-STATE MDEG LICENSE**

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

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<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: LJH Medical Solutions, Inc.Physical Address: 801 West Bay Drive, Suite 504 Largo, FL 33770  
(This must be a business address, we can not issue a license to a home address)Mailing Address: 801 West Bay Drive, Suite 504City: Largo State: FL Zip Code: 33770Telephone: 727-223-8878 Fax: 727-240-1247E-mail: info@ljhmedicalsolutions.com Website: \_\_\_\_\_**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: 9AM to 5PM Sat: \_\_\_\_\_ to \_\_\_\_\_ Sun: \_\_\_\_\_ to \_\_\_\_\_ Holidays: \_\_\_\_\_ to \_\_\_\_\_

**MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis**Name: Kristina Wexler**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>Off the shelf Orthotics</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: \_\_\_\_\_

101182

BB

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane ☐ Reno, NV 89509 ☐ (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG LICENSE

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<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"/> 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: Lucky Medical Supply, Inc.

Physical Address: 14004 Roosevelt Boulevard Suite 612  
 (This must be a business address, we can not issue a license to a home address)

Mailing Address: 14004 Roosevelt Boulevard Suite 612

City: Clearwater State: FL Zip Code: 33762

Telephone: 727-351-7948 Fax: 727-509-3801

E-mail: info@luckymedsupply.com Website: N/A

### 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: 9AM to 5PM Sat: N/A to Sun: N/A to Holidays: N/A to

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Jimmy Darling III

### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |  |  |
|--|--|
| <input type="checkbox"/> Medical Gases**<br><input type="checkbox"/> Respiratory Equipment**<br><input type="checkbox"/> Life-sustaining equipment**<br><input type="checkbox"/> Diabetic Supplies | <input type="checkbox"/> Assistive Equipment<br><input type="checkbox"/> Parenteral and Enteral Equipment**<br><input checked="" type="checkbox"/> Orthotics and Prosthesis<br>Other: <u>Off the shelf orthotics</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: \_\_\_\_\_



CC

**NEVADA STATE BOARD OF PHARMACY**

431 W Plumb Lane ☐ Reno, NV 89509 ☐ (775) 850-1440

**APPLICATION FOR OUT-OF-STATE MDEG LICENSE**

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<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: Medical Rehab Supply, Inc.Physical Address: 3636 Camino Del Rio N. Suite 150, San Diego, CA.  
(This must be a business address, we can not issue a license to a home address)Mailing Address: 3636 Camino Del Rio N. Ste. 150City: San Diego State: CA Zip Code: 92108Telephone: 844-285-1135 Fax: 800-693-5073E-mail: info@medicalrehabsupply.net Website: NA**DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING**Mon: 9am to 4pm Tue: 9am to 4pm Wed: 9am to 4pm Thu: 9am to 4pmFri: 9am to 4pm Sat:     to     Sun:     to     Holidays:     to    **MDEG ADMINISTRATOR INFORMATION:** Person in charge on a daily basisName: Leticia Engleman**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: \_\_\_\_\_ Telephone: \_\_\_\_\_

101181

# DD

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG 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.

<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: TESLA MEDICAL LLC

Physical Address: 8401 BENJAMIN ROAD, SUITE C, TAMPA, FL 33634-1203  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 8401 BENJAMIN ROAD, SUITE C

City: TAMPA State: FL Zip Code: 33634-1203

Telephone: (813) 243-4353 Fax: (813) 433-5691

E-mail: dphilion@teslamedusa.com Website: www.teslamedusa.com

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8<sup>30</sup> AM to 2<sup>30</sup> PM Tue: 8<sup>30</sup> AM to 2<sup>30</sup> PM Wed: 8<sup>30</sup> AM to 2<sup>30</sup> PM Thu: 8<sup>30</sup> AM to 2<sup>30</sup> PM  
Fri: 8<sup>30</sup> AM to 2<sup>30</sup> PM Sat: CLOSED Sun: CLOSED Holidays: CLOSED

### MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: DAVID PHILION

### 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: \_\_\_\_\_ Telephone: \_\_\_\_\_

EE

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (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)**

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☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: **PH00640**)  
 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: CVS/pharmacy # 8806

Physical Address: 1250 West 7th St

City: Reno State: NV Zip Code: 89503

Telephone: 775-747-6658 Fax: (775) 747-7249

Toll Free Number: N/A E-mail: N/A

Website: N/A

Managing Pharmacist: Ali Asghar M-TaFreshi License Number: 14852 ✓

**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: \_\_\_\_\_

FF

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (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)**

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- ☒ 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: Medical and Dental Center of Nevada

Physical Address: 4275 Burnham Ave. #101

City: Las Vegas State: NV Zip Code: 89119

Telephone: 702-489-3555 Fax: pending

Toll Free Number: N/A E-mail: \_\_\_\_\_

Website: N/A

Managing Pharmacist: Mary Grear, RPh License Number: 10087v

**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 Surgery  
☐ ☒ Mail Service  
☐ ☒ Long Term Care  
☐ ☒ Sterile Compounding  
☐ ☒ Non Sterile Compounding  
☐ ☒ Mail Service Sterile Compounding  
☐ ☒ Other Services: \_\_\_\_\_

GG

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (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

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- ☐ 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: SAFE Pharmacy Corporation

Physical Address: 737 North Main Street

City: Las Vegas State: NV Zip Code: 89101

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

Toll Free Number: 800-642-1652 E-mail: pharmacy@safehealth.me

Website: safehealth.me

Managing Pharmacist: Susan A. Rounds License Number: 13868 ✓

**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: \_\_\_\_\_

HH

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (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

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☒ 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.  
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☒ 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: Spring Valley Surgery Center, LLC

Physical Address: 8828 Meadow Street

City: Las Vegas State: NV Zip Code: 89139

Telephone: (702) 227-4440 Fax: (702) 880-4197

Toll Free Number: N/A E-mail: epence@vpimmedical.com

Website: www.lasvegaspaininstitutes.com

Managing Pharmacist: Douglas Cammann License Number: 13340 ✓

**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: \_\_\_\_\_



### 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
Administrative fee	\$495.00	\$495.00	\$495.00
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 will be added costs 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 August 2014

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
RPH HC during data entry selected propranolol rather than Protonix as prescribed then unintentionally deleted the prescription. The patient ingested the wrong medication for 20 days with alleged adverse effects. RPH AD was PIC at the time of the violations.	Fatigue and lightheadedness.	HC: letter of reprimand; \$2,750 fine; 4 additional hours of CE on error prevention and patient counseling AD: letter of reprimand and 4 additional hours of CE on pharmacy management.	\$1,000 fine; \$1,500 administrative fee; create training module for all NV CVS pharmacy personnel on the proper procedure to cancel or inactivate and not delete a prescription returned because of an error.
RPH MT verified as accurate Adderall XR 25 mg. capsules rather than the prescribed Adderall ER 20 mg. capsules. She failed to act upon the DUR alert which indicated the potential for duplicate therapy and failed to counsel. The patient ingested the wrong medication for 30 days.	None reported.	Letter of reprimand; \$2,750 fine; and 4 additional hours of CE on error prevention and patient counseling.	\$1,500 administrative fee.
RPH DR entered 500 mg. vials for injection, rather than the ampicillin 500 mg. capsules as prescribed. RPH MG verified, labeled and dispensed ampicillin 500 mg. vials for injection, rather than the ampicillin 500 mg. capsules prescribed. RPH EB failed to adequately provide counseling.	Non-ingested.	RPH DR: registration is suspended; the suspension is stayed and RPH registration placed on probation for three months; four additional CEs on error prevention; \$3,000 fine. RPH MG: letter of reprimand: \$1,000 fine. RPH EB: letter of reprimand: \$750 fine; 2 additional CEs on patient counseling.	\$1,500 administrative fee; create training module for all NV CVS pharmacy personnel on the proper procedure to cancel or inactivate and to not delete a prescription returned because of an error.
RPH JF created multiple fraudulent prescriptions for himself, family members and for technicians TB and IK.	N/A	RPH JF, technicians TB and IK registrations revoked.	N/A
RPH RE committed multiple compounding violations.	Non-ingested	RPH registration suspended; suspension stayed and registration placed on probation for 30 days; \$2,000 fine; \$1,500 administrative fee; no sterile	Develop policies and procedures.



FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
		compounding; no non-sterile compounding until pharmacy staff complete a Board-approved compounding course.	
RPH DB verified as accurate Phenobarbital <b>15 mg.</b> tablets with instructions to take 1 tablet twice daily; rather than the Phenobarbital <b>60 mg.</b> tablets as prescribed. The patient ingested the wrong medication for 6 days.	Increased seizure activity.	Fined \$1,000; two additional hours of CE on error prevention; and public letter of reprimand.	\$1,500 administrative fee.
RPH NZ created a fraudulent prescription for a dangerous drug (Singulair) for herself and billed that prescription to an insurance provider. Respondent then furnished the dangerous drug to another person without a legal prescription.	N/A	Revoked	N/A
PT KY diverted 50-100 carisoprodol tablets monthly from her employing pharmacy beginning June 2015 until October 2017.	N/A	Revoked	N/A
TDs TJ and RVM dispensed controlled substances and dangerous drugs to patients without the prescriber's handwritten signature on each prescription; falsified the prescriber's signature on prescriptions for controlled substances and dangerous drugs; accessed the prescriber's inventory of controlled substances and dangerous drugs and dispensed them when the prescriber was not on-site at his medical office; dispensed controlled substances and dangerous drugs to patients who were not present at the prescriber's medical office,	N/A	Technician dispensing registrations revoked.	N/A

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
including dispensing using the U.S. Mail and Federal Express; falsely documented patient initials and dates of service on patient informed consent labels.			
Action to parallel CA order which found RPH RD guilty of subverting or attempting to subvert an investigation of the CA board; aiding or abetting violations of pharmacy law; violation of the statutes regulating controlled substances.	N/A	Three year probation; cannot own NV pharmacy; notify Board Staff if he falls out of compliance with CA Order.	N/A
Action to parallel CA order which found PT CM guilty of engaging in the practice of pharmacy without being a registered pharmacist, (2) fraudulently holding herself out as a pharmacist when she is not, and (3) signing documents that falsely indicate that she is a pharmacist.	N/A	Revocation.	N/A

MAY 31 2018

NEVADA STATE BOARD  
OF PHARMACY

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	CASE NO. 16-077-RPH-A-S
	)	16-077-RPH-B-S
Petitioner,	)	16-077-PH-S
v.	)	
	)	
RICHARD ANDERSON, RPH	)	
Certificate of Registration No. 10763,	)	NOTICE OF INTENDED ACTION
	)	AND ACCUSATION
NED MONJE QUADRA, RPH	)	
Certificate of Registration No. 15235	)	
	)	
WALMART PHARMACY #10-1560	)	
Certificate of Registration No. PH00800	)	
	)	
Respondents.	/	

Larry L. Pinson, 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 639.241.

**JURISDICTION**

## I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the alleged events, Respondent Richard Anderson (Anderson), Certificate of Registration No. 10763, was a pharmacist registered by the Board, and Respondent Walmart Pharmacy #10-1560, Certificate of Registration No. PH00800 (Walmart), was a pharmacy registered by the Board.

**FACTUAL ALLEGATIONS**

## II.

On August 25, 2016, physician assistant B.S. prescribed medications to N.P. and her two daughters. N.P. received two (2) prescriptions, daughter A.P. received two (2) prescriptions and daughter A.T. received three (3) prescriptions.

## III.

N.P. tendered the seven (7) prescriptions to Walmart the day B.S. wrote them, where pharmaceutical technician Brenda Alferos (Alferos) entered the data for each prescription in Walmart's computer system.

## IV.

During data entry, Alferos mistakenly entered all seven prescriptions under N.P.'s name and patient profile. Walmart processed and filled four of the prescriptions that evening.

## V.

At the point of sale, Alferos realized that two of the filled prescriptions with N.P.'s name on the label were actually for N.P.'s daughter A.T. Alferos presented the two erred prescriptions to Anderson for correction.

## VI.

Alferos did not detect that another one of the four prescriptions filled and labeled under N.P.'s name, Prescription No. 7732906, was a medication prescribed to daughter A.P.

## VII.

N.P. picked up Prescription No. 7732906 that evening.

## VIII.

The erred medication dispensed to N.P. was Naproxen 375mg tablets with instructions to take one (1) tablet by mouth every twelve (12) hours as needed.

## IX.

N.P. ingested the medication for approximately two (2) days and began to experience severe stomach pains. N.P. discovered that Walmart dispensed the wrong medication to her.

## X.

Anderson was the verifying pharmacist for Prescription No. 7732906. Anderson failed to detect the error when he verified data entry and the final product as accurate.

## XI.

Anderson was also the counseling pharmacist. Walmart's computer patient counseling field documents that counseling was refused.

## XII.

Counseling was not offered.

**FIRST CAUSE OF ACTION**

(Respondent Anderson)

## XIII.

Nevada Administrative Code (NAC) 639.945(1)(d) defines unprofessional conduct to include the failure by a licensee to follow strictly the instructions of a prescriber when filling, labeling and dispensing a prescription. Unprofessional conduct also includes performing duties in an "incompetent, unskillful or negligent manner". *See* NAC 639.945(1)(i).

Respondent Anderson engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) by verifying Prescription No. 7732906 as accurate, when it was mislabeled with the wrong patient name. That conduct caused patient N.P. to ingest the wrong medication for approximately two (2) days.

**SECOND CAUSE OF ACTION**

(Respondent Anderson)

## XIV.

NRS 639.266 requires a pharmacist, on receipt of a prescription and after review of the patient's record, to communicate with the patient, or a person caring for the patient, matters that will enhance the patient's therapy through drugs. NAC 639.707(1) and (2) require that discussion to include, among other things, the name of the drug, dosage and administration instructions, the intended use of the drug, common side effects, and other information that is necessary for the safe and effective use of the drug. Further, NAC 639.945(1)(i) defines unprofessional conduct as performing duties in an "incompetent, unskillful or negligent manner".

Anderson violated NRS 639.266, NAC 639.707(1) and (2), and NAC 639.945(1)(i), when he failed to counsel N.P. regarding Prescription No. 7732906, which was a new prescription for N.P. That error, combined with other errors within the pharmacy, caused the pharmacy to dispense the medication to the wrong patient.

### **THIRD CAUSE OF ACTION**

(Respondent Quadra)

XV.

As the managing pharmacist/pharmacist in charge of Walmart Pharmacy #10-1560 at the time of each of the violations alleged herein, respondent Quadra is responsible for those violations, including those of his employees. See NRS 639.0087, NRS 639.210(15), NRS 639.220(3)(c), NAC 639.702 and NAC 639.910(2).

### **FOURTH CAUSE OF ACTION**

(Respondent Walmart #10-1560)

XVI.

As the pharmacy in which the violations alleged above occurred, Walmart Pharmacy #10-1560 is responsible for the actions of Respondent Anderson and pharmaceutical technician Alferos pursuant to NRS 639.230(5), NAC 639.945(2) and/or NAC 639.702.


XVII.

For the errors, misconduct and violations alleged above in the First, Second, Third, and Fourth Causes of Action, Respondents, and each of them, are subject to discipline pursuant NRS 639.210(4), and/or (12), as well as NRS 639.230(5) and/or NRS 639.255.

XVIII.

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 31<sup>st</sup> day of May 2018.

  
Larry L. Pinson, Pharm.D., 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 regarding your certificate of registration. To do so, you must mail to the Board within 20 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

<b>NEVADA STATE BOARD OF PHARMACY,</b>	)	<b>ANSWER AND</b>
	)	<b>NOTICE OF DEFENSE</b>
<b>Petitioner,</b>	)	
<b>v.</b>	)	
	)	
<b>RICHARD ANDERSON, RPH</b>	)	<b>CASE NO. 16-077-RPH-A-S</b>
<b>Certificate of Registration No. 10763</b>	)	
	)	
<b>Respondent.</b>	)	
	/	

---

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 June 2018.

---

RICHARD ANDERSON, R.PH.

FILED

JUN 21 2018

NEVADA STATE BOARD  
OF PHARMACY

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

) ANSWER AND  
) NOTICE OF DEFENSE

Petitioner,

v.

NED MONJE QUADRA, RPH

Certificate of Registration No. 15235

) CASE NO. 16-077-RPH-B-S

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").

Respondent objects to all charges against him specifically the third cause of action.

Respondent objects to the charges relating to violation of NRS 639.210(15), NAC 639.702 & NAC 639.910(2).

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

Respondent denies any and all allegations against him as stated in the Third cause of actions.

Respondent denies any violations by him relating to NRS 639.210(15), NAC 639.702 and NAC 639.910(2).

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 18 day of June 2018.



NED MONJE QUADRA, R.PH.

FILED

JUN 28 2018

NEVADA STATE BOARD  
OF PHARMACY

HAL TAYLOR, ESQ.

223 Marsh Avenue  
RENO, NV 89509

TEL. (775) 825-2223, FAX (775) 329-1113

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, CASE NO. 13-077- RPH - A-S

Petitioner,

16-077- RPH - B-S

16-077 - PH - S

v.

RICHARD ANDERSON, RPH  
Certificate of Registration No. 10763,NED MOJE QUADRA, RPH  
Certificate of Registration No. 15235WALMART PHARMACY #10-1560  
Certificate of Registration No.: PH00800,

Respondents.

RESPONDENT WALMART PHARMACY #10-1560's  
ANSWER AND NOTICE OF DEFENSE

Respondent, WALMART PHARMACY #10-1560 ("Walmart"), through its representative, Hal Taylor, Esq., in answer to the Notice of Intended Action and Accusation ("Notice") in this case, states as follows:

Jurisdiction

I.

Admitted.

FACTUAL ALLEGATIONS

II.

Admitted that the prescriptions submitted to Walmart are consistent with these allegations.

III.

Admitted that pharmaceutical technician Brenda Alferos ("Alferos") received the

HAL TAYLOR, ESQ.  
223 Marsh Avenue  
RENO, NV 89509  
TEL. (775) 825-2223, FAX (775) 329-1113

1 prescriptions tendered to Walmart by N.P. and entered the data for each prescription  
2 into Walmart's computer system. Entry of these prescriptions also including scanning  
3 each prescription so that its image appears on the screen for review and comparison  
4 during the filling process. From this point forward, the scanned image of each  
5 prescription was shown on the computer screen.

6 IV.

7 Admitted that, despite having the prescriptions tendered by N.P. in hand, that  
8 Alferos mistakenly entered all seven prescriptions under N.P.'s name and patient  
9 profile. Admitted that four of the prescriptions were filled the same evening.  
10 Respondent Richard Anderson ("Anderson") performed a 4-Point Check/Input  
11 Verification on all four of these prescriptions. During this process, Anderson had  
12 scanned images of each of the prescriptions available for review and comparison on  
13 the computer screen.

14 V.

15 Admitted that at the point of sale, N.P. mentioned three different patient names  
16 and dates of birth to Alferos. Admitted that upon reviewing the four filled prescriptions  
17 after receiving this information, that Alferos realized that two of the four filled  
18 prescriptions with N.P. identified as the patient were actually prescriptions for N.P.'s  
19 daughter, A.T. Admitted that Alferos presented to Respondent Anderson the two erred  
20 prescriptions for correction. Anderson corrected these two prescriptions.

21 VI.

22 Admitted that Alferos failed to detect that another one of the four filled  
23 prescriptions filled and labeled under N.P.'s name, Prescription No. 7732906, was  
24 medication that was actually prescribed to N.P.'s daughter, A.P.

25 VII.

26 Admitted that N.P. picked up Prescription No. 7732906 that evening.

27 VIII.

28 Admitted.

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IX.

Walmart has no direct knowledge of N.P.'s ingestion of the medication or its alleged physical consequences, and therefore cannot respond to these allegations. Admitted that Prescription No. 7732906 was wrongly dispensed to N.P.

X.

Admitted that Respondent Anderson was the verifying pharmacist for Prescription No. 7732906, and that he failed to detect the patient error when he verified data entry and final product as accurate as part of Walmart's 4-Point Check/Input Verification despite having the image of the prescription on the computer screen for review and comparison. Further answering, even after Alferos brought to Anderson's attention that two of the four filled prescriptions with N.P. identified as the patient were actually prescriptions for N.P.'s daughter, Anderson still failed to identify the patient identification error made on Prescription No. 7732906.

XI.

Admitted that Anderson was the counseling pharmacist. Walmart's patient counseling records indicate that counseling was "refused."

XII.

Walmart has no direct knowledge of whether counseling was offered or not to N.P. , nor whether it was refused or not. Respondent Anderson is no longer a pharmacist with Walmart.

Further answering, Respondent Anderson wrote a statement for submission to the Board that described details of his purported counseling of N.P. However, that statement is at odds with the counseling information that Anderson placed into Walmart's system regarding counseling of N.P. Because the prescription being filled for N.P. was a new prescription, Anderson was required to offer counseling on Prescription No. 7732906. If Anderson did not offer counseling, he did so in violation of Walmart's policies and procedures. Walmart pharmacists are required to accurately

and timely enter the results of offers to counsel into Walmart's counseling records.

**FIRST CAUSE OF ACTION**

(Respondent Anderson)

XIII.

These allegations do not require a response by Walmart.

**SECOND CAUSE OF ACTION**

(Respondent Anderson)

XIV.

These allegations do not require a response by Walmart.

**THIRD CAUSE OF ACTION**

(Respondent Quadra)

XV.

These allegations do not require a response by Walmart.

**FOURTH CAUSE OF ACTION**

(Respondent Walmart #10-1560)

XVI.

Walmart's computer system provides a scanned image of the prescription at each state of filling and checking, including Walmart's 4-Point Check/Input Verification process, for review and comparison. Walmart's investigation of the allegations in this case has confirmed that the pharmacy technician initially placed the wrong patient name on five of seven prescriptions, and that the pharmacist failed to note that three of four prescriptions reviewed in his 4-Point Check/Input Verification were for the wrong patient, including one prescription that he reviewed twice. The pharmacist also entered counseling information into the Walmart counseling records that is inconsistent with the statement that he filed with the Board.

Walmart #10-1560 denies that it should be held strictly responsible and subject

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1 to suspension or revocation in violation of NRS 639.230(5) under these facts for errors  
2 made by personnel in the pharmacy, absent any action by Walmart #10-1560 that  
3 contributed to the alleged violations.

4 Walmart #10-1560 denies that it should be held strictly responsible as the owner  
5 of the pharmacy in violation of NAC 639.945(2) under these facts for the acts of its  
6 personnel absent any action by Walmart #10-1560 that contributed to the alleged  
7 violations.

8 Walmart #10-1560 denies that it knew or should have known of the errors of  
9 pharmacy technician Alferos alleged in this Accusation, and therefore, Walmart #10-  
10 1560 denies that it violated NAC 639.702.

#### 11 XVII.

12 Walmart #10-1560 denies that under these facts that it should be held strictly  
13 responsible for any specific unprofessional conduct or conduct contrary to the public  
14 interest alleged in this Accusation in violation of NRS 639.210(4) that might subject it to  
15 suspension of revocation absent any action by Walmart #10-1560 that contributed to  
16 the alleged violations.

17 Walmart #10-1560 denies that it violated, attempted to violate, assisted or  
18 abetted in the violation of or conspired to violate any of the provisions of NRS Chapter  
19 639 or any law or regulation relating to drugs,...the practice of pharmacy, or *knowingly*  
20 permitted, allowed, condoned or failed to report a violation of any of the provisions of  
21 NRS Chapter 639, or any law or regulation relating to drugs,...or the practice of  
22 pharmacy committed by the holder of a certificate, license, or registration in violation of  
23 NRS 639.210(12). (Emphasis added.)

24 Walmart #10-1560 denies that it should be held strictly responsible and subject  
25 to suspension or revocation for any violation of any provision of NRS Chapter 639 by a  
26 managing pharmacist or by personnel of the pharmacy under the supervision of the  
27 managing pharmacist in violation of NRS 639.230(5) under these facts absent any act  
28 by Walmart #10-1560 that contributed to the violations alleged in this Accusation.



1 **AFFIRMATIVE DEFENSE**

2 Had Walmart's policies and procedures been followed, the errors alleged would  
3 not have occurred, or at least have been detected in the Walmart prescription review  
4 process, and corrected before the prescriptions were dispensed, and therefore Walmart  
5 should not be held responsible for any violations alleged herein.

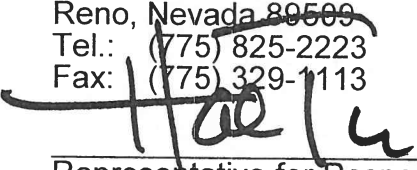
6 WHEREFORE, Respondent Walmart #10-1560, prays for dismissal of the  
7 accusations against it.

8 **AFFIRMATION PURSUANT TO NRS 239B.030**

9 By signature below, the undersigned affirms that the preceding document does  
10 not contain the social security number of any person.

11 Dated: June 28, 2018

12 Hal Taylor, Esq.  
13 233 Marsh Avenue  
14 Reno, Nevada 89509  
15 Tel.: (775) 825-2223  
16 Fax: (775) 329-1113

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18 \_\_\_\_\_  
19 Representative for Respondent  
20 Walmart Pharmacy #10-1560  
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HAL TAYLOR, ESQ.  
233 Marsh Avenue  
RENO, NV 89509  
TEL. (775) 825-2223, FAX (775) 329-1113

1 I hereby declare, under penalty of perjury, that the foregoing Respondent  
2 Walmart #10-1560's Answer and Notice of Defense, and all facts therein stated, are  
3 true and correct to the best of my knowledge.

4 Dated this \_\_\_\_ day of June 2018.

5 Walmart #10-1560

6 By:

*Deborah C Mack*  
7 Authorized Representative for  
8 Walmart Pharmacy #10-1560  
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HAL TAYLOR, ESQ.

223 Marsh Avenue

RENO, NV 89508

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On this date, the undersigned, an employee of Hal Taylor, Esq., delivered a copy of the attached Respondent Walmart Pharmacy #10-1560's Answer and Notice of Defense upon the following:

Nevada State Board of Pharmacy  
411 W. Plumb Ln.  
Reno, NV 89509

Attn: Larry L. Pinson  
Executive Secretary

Dated: June 28, 2018.

Hal Taylor, Esq.

MAY - 1 2018

NEVADA STATE BOARD  
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

<b>NEVADA STATE BOARD OF PHARMACY,</b>	)	<b>CASE NO. 17-101-CS-S</b>
	)	
<b>Petitioner,</b>	)	<b>NOTICE OF INTENDED ACTION</b>
<b>v.</b>	)	<b>AND ACCUSATION</b>
	)	
<b>IVAN GOLDSMITH, M.D.,</b>	)	
<b>Certificate of Registration No. CS20816, PD00413,</b>	)	
	)	
<b>Respondent.</b>	/	

Larry L. Pinson, 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 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, Ivan Goldsmith, M.D. (Goldsmith), had both a Controlled Substance Registration, Certificate No. CS20816, and a Practitioner Dispensing Registration, Certificate No. PD00413, issued by the Board.

**FACTUAL ALLEGATIONS****II.**

On December 9, 2013, the Board granted Goldsmith an account for Internet access to the Nevada Prescription Monitoring Program (PMP) for purposes authorized under federal and state law.

**III.**

Before receiving access, Goldsmith signed a Practitioner Certification Statement on December 6, 2013, stating that he understood and agreed under penalty of perjury that he was responsible for all patient information transmitted from his account, that he would treat PMP information as confidential, that he would protect any PMP information in his possession or control in accordance with federal and state laws governing health care information, and that he

would safeguard his password and not share his login credentials with any other person.

IV.

Stephen Paddock (Paddock) was the perpetrator of the October 1, 2017, Las Vegas mass shooting, and committed suicide immediately after the incident sometime before midnight.

V.

On or about October 2, 2017, Goldsmith verified through his office electronic medical records system (EMR) that Paddock was never his patient.

VI.

From October 2, 2017 at 9:25 a.m. to October 3, 2017 at 2:20 p.m., Goldsmith's PMP account was used to query the PMP database five separate times using different search parameters for each query, to access Paddock's confidential patient information, and to obtain patient utilization reports detailing Paddock's prescription-controlled substance utilization history.

VII.

The fourth search, conducted on October 3, 2017 at 10:18 a.m., yielded specific prescription information regarding two prescriptions for Paddock filled at Evergreens Drugs in Henderson, Nevada in 2016, and at a Walgreens pharmacy in Reno, Nevada in 2017.

VIII.

On October 3, 2017 at 9:00 p.m., the Las Vegas Review-Journal published an article written by reporter Paul Harasim. That article purported to include Paddock's confidential patient information, including information about the two prescriptions, which the reporter attributed to and obtained from the Nevada Prescription Monitoring Program (PMP).

IX.

The Las Vegas Review-Journal updated the article on October 4, 2017 at 10:00 a.m. to reference specific prescription data and prescriber information related to Paddock from June 7, 2016 and June 21, 2017.

## X.

On or about November 8, 2017, Goldsmith, through his counsel, filed an Amended Declaration with the Eighth Judicial District Court of Clark County Nevada in Case No. A-17-762877-W in which Goldsmith admits to directing his office staff to use his PMP account to query Paddock's confidential patient information and to obtain patient utilization reports on October 2, 2017, and again on October 3, 2017.

## XI.

In his Amended Declaration Goldsmith also admits to routinely allowing his staff to use his PMP account to query the PMP on his behalf.

**APPLICABLE LAW**

## XII.

The Board administers the Prescription Monitoring Program (PMP), which maintains a database of all transactions for schedule II, III, IV and V controlled substances prescribed and dispensed in Nevada. *See* NRS 453.162 through 453.165, *inclusive*.

## XIII.

At the time of the events alleged herein, NRS 639.23507(1) authorized a practitioner to obtain a patient utilization report from the PMP before prescribing a controlled substance to his patients under certain circumstances, to assess whether the prescription is medically necessary.<sup>1</sup>

## XIV.

Patient utilization reports and data in the PMP database constitute Protected Health Information (PHI) as defined in 45 C.F.R. § 160.103. They are protected from unauthorized access, use and disclosure under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). 45 C.F.R. Part 160 and Part 164, Subparts A and E (HIPPA Privacy Rule).

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<sup>1</sup> Assembly Bill (AB) 474, 79<sup>th</sup> Legislative Session (2017), amended NRS 639.23507(1). Those amendments became effective January 1, 2018 and are therefore immaterial to this action.

## XV.

Patient utilization reports and all data in the PMP database are also confidential and protected from unauthorized use or disclosure under state law. NRS 453.164(7).

## XVI.

Unauthorized access, use or disclosure of PHI carries civil and criminal penalties under federal law. Pub.L. 104-191, 42 U.S.C. § 1320d-5 and 6.

## XVII.

Unauthorized access, use or disclosure of information in the PMP database also constitutes a crime under state law. NRS 453.552(2).

**FIRST CAUSE OF ACTION**

## XVIII.

By accessing or directing his staff to access Paddock's confidential data in the PMP database when Paddock was deceased and never his patient and by obtaining Paddock's patient utilization report, Goldsmith performed his duties as the holder of a Nevada Controlled Substance Registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i). Goldsmith's Controlled Substance Registration, Certificate of Registration No. CS20816, and Practitioner Dispensing Registration, Certificate No. PD00413, are therefore subject to discipline pursuant to NRS 639.210(4) and NRS 639.255.

**SECOND CAUSE OF ACTION**

## XIX.

By accessing or directing his staff to access Paddock's confidential data in the PMP database when Paddock was deceased and never his patient and by obtaining Paddock's patient utilization report, Goldsmith violated the HIPAA Privacy Rule. His Controlled Substance Registration, Certificate of Registration No. CS20816, and Practitioner Dispensing Registration,

Certificate No. PD00413, are therefore subject to discipline pursuant to NRS 639.210(11) and NRS 639.255.

### **THIRD CAUSE OF ACTION**

XX.

By accessing or directing his staff to access Paddock's confidential data in the PMP database when Paddock was deceased and never his patient and by obtaining Paddock's patient utilization report, Goldsmith violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.164(7) and/or the HIPAA Privacy Rule. His Controlled Substance Registration, Certificate of Registration No. CS20816, and Practitioner Dispensing Registration, Certificate No. PD00413, are therefore subject to discipline pursuant to NRS 639.210(12) and NRS 639.255.

### **FOURTH CAUSE OF ACTION**

XXI.

By disclosing or allowing to be disclosed to the press—Las Vegas Review Journal and/or writer Paul Harasim—Paddock's confidential PMP data and patient utilization report, which were accessed only by Goldsmith's PMP account on October 2 and October 3, 2017, Goldsmith violated state and federal law, including the HIPAAA Privacy Rule and NRS 639.164(7). His Controlled Substance Registration, Certificate of Registration No. CS20816, and Practitioner Dispensing Registration, Certificate No. PD00413, are therefore subject to discipline pursuant to NRS 639.210(4), (11) and (12) as well as NRS 639.255.

### **FIFTH CAUSE OF ACTION**

XXII.

By accessing or directing his staff to access Paddock's confidential data in the PMP database when Paddock was deceased and never his patient and by obtaining Paddock's patient utilization report, Goldsmith committed an act that would render his Nevada Controlled Substance Registration inconsistent with the public interest pursuant to NRS 453.231, and is

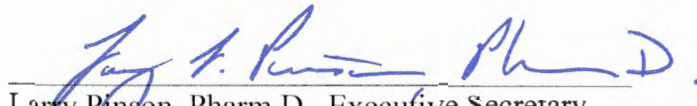


subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

XXIII.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the Controlled Substance Registration, Certificate No. CS20816, and Practitioner Dispensing Registration, Certificate No. PD00413 of Respondent Goldsmith.

Signed this 1<sup>st</sup> day of May 2018.

  
Larry Pinson, Pharm.D., 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 regarding your certificate of registration. To do so, you must mail to the Board within twenty (20) days of your receipt of the Notice of Intended Action and Accusation a written statement showing your compliance.

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

<b>NEVADA STATE BOARD OF PHARMACY,</b>	)	<b>CASE NO. 17-101-CS-S</b>
	)	
<b>Petitioner,</b>	)	
<b>v.</b>	)	<b>ANSWER AND NOTICE</b>
	)	<b>OF DEFENSE</b>
<b>IVAN GOLDSMITH, MD</b>	)	
<b>Certificate of Registration No. CS20816, PD00413,</b>	)	
	)	
<b>Respondent.</b>	)	
	/	

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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 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 May 2018.

---

IVAN GOLDSMITH, MD

FILED

APR 27 2018

NEVADA STATE BOARD  
OF PHARMACY

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

DAVID J. ADAMS, D.O., Certificate of  
Registration No. CS11506,

Respondent.

CASE NO. 17-095-CS-S

NOTICE OF INTENDED ACTION  
AND ACCUSATION

Larry L. Pinson, 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 639.241.

**JURISDICTION**

## I.

The Nevada State Board of Pharmacy ("Pharmacy Board") has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent David J. Adams, D.O., held a Nevada Controlled Substance Registration, Certificate No. CS11506, issued by the Pharmacy Board.

**FACTUAL ALLEGATIONS**

## II.

On April 10, 2018, the Nevada State Board of Osteopathic Medicine ("Osteopathic Board") approved and entered a Settlement Agreement and Order *In the Matter of: David J. Adams, D.O.*, Case No. AD1706001 (the "Order").

## III.

The "Pertinent Facts" as set forth in the Order include:

- a. David Adams, D.O. is licensed by the Board to practice osteopathic medicine in Nevada (License No. 1074). Dr. Adams is board certified in anesthesiology. Order, ¶

- 1.

- b. In February 2017, the Board's office received information upon which the Board's staff initiated an investigation relating to Dr. Adams' practice of medicine. The information indicated that Dr. Adams was engaged in the general practice of medicine in addition to his practice as an anesthesiologist in various institutional settings, and the information indicated concerns with Dr. Adams' practices as a general practitioner. Order, ¶ 2.
- c. The Board's investigation determined that Dr. Adams associated professionally with Ronald Foote, M.D. for over 15 years. On May 30, 2014, Dr. Foote and the Nevada State Board of Medical Examiners (BME) entered into a stipulated indefinite suspension of Dr. Foote's license on May 30, 2014 that was followed in July 2014 with the commencement of a disciplinary action by the BME against Dr. Foote. The disciplinary action was resolved and the indefinite suspension was modified by a Settlement Agreement and Order Lifting Suspension entered by the BME and Dr. Foote on June 3, 2016. As a result of the disciplinary actions by the BME against Dr. Foote, since May 30, 2014, Dr. Foote did not have a DEA registration or a Nevada Controlled Substances Registration, meaning that Dr. Foote was prohibited from prescribing, administering, possessing, or distributing controlled substances to his patients. Order, ¶ 3.
- d. When Dr. Foote's license was restored with conditions in June 2016, Dr. Adams assisted Dr. Foote with Dr. Foote's general practice from Dr. Foote's office at Las Vegas Pain and Wellness Center, 6773 W. Charleston Boulevard in Las Vegas, Nevada. The practices developed and implemented by Dr. Foote and Dr. Adams were that Dr. Foote would see a patient at his office, and when Dr. Foote determined that a patient would need medications, Dr. Foote would prescribe any

dangerous drugs himself and Dr. Adams would prescribe any controlled substances for the patient. When Dr. Adams prescribed controlled substances for Dr. Foote's patients, he did so on a prescription blank containing his name on top, along with Dr. Foote's name, and the address of the Las Vegas Pain and Wellness Center, indicating that he was doing so as a physician employed at or working from Dr. Foote's practice at the Las Vegas Pain and Wellness Center. Order, ¶ 4.

- e. The focus of the Board's investigation was prescriptions Dr. Adams wrote for Dr. Foote's patients for promethazine HCL and codeine phosphate syrup, a controlled substance in Schedule V. Regarding these prescriptions, Dr. Adams did not see, touch, or examine any of Dr. Foote's patients who received these prescriptions. Instead, Dr. Foote provided Dr. Adams' prescriptions to Dr. Foote's patients by filling in the patients' names in prescription blanks from Las Vegas Pain and Wellness Center on which Dr. Adams had pre-signed and pre-filled out the drug information, leaving the patient name blank. Dr. Adams provided such prescription blanks to Dr. Foote for Dr. Foote to complete and provide to Dr. Foote's patients. Dr. Adams would ratify the promethazine HCL and codeine phosphate syrup prescriptions filled out and issued by Dr. Foote after reviewing Dr. Foote's chart notes for the patients and after the prescriptions had been issued. Dr. Adams made no medical notes of his own regarding any of the patients to whom his pre-signed prescriptions were issued by Dr. Foote. Order, ¶ 5.
- f. On November 30, 2017, Dr. Foote's office was searched pursuant to a warrant by officers and agents from the federal Drug Enforcement Agency (DEA) Tactical Diversion Squad. Based upon the evidence seized and admissions made by Dr. Foote, Dr. Foote was arrested and was booked into the Clark County Detention

Center. Order, ¶ 6.

- g. As part of the investigation of Dr. Foote's medical practice, Dr. Foote was interviewed at length on November 30, 2017. Dr. Adams was interviewed on December 13, 2017. The interviews and evidence obtained pursuant to the DEA's investigation showed that Dr. Foote's examinations of his patients were cursory and inadequate, that based upon these examinations he would render a diagnosis that was merely pretextual, and then based upon the pretextual diagnosis he would issue prescriptions to the patients for promethazine HCL and codeine phosphate syrup using the pre-signed prescription blanks provided to him by Dr. Adams. Dr. Foote would then collect cash from the patient. Order, ¶ 7.
- h. The interviews and evidence obtained pursuant to the DEA's investigation included admissions by Dr. Adams that he knew of Dr. Foote's practices, that he knowingly provided pre-signed blank prescriptions from Las Vegas Pain and Wellness Center for Dr. Foote to facilitate his practice. The pre-signed prescriptions blanks would be prepared by Dr. Adams for promethazine HCL and codeine phosphate syrup 473 ml., and that Dr. Adams acknowledged that he did not know or understand the quantity measurement for 473 ml. or whether it was large or small. Order, ¶ 8.
- i. On February 14, 2018, a criminal complaint was filed in the Las Vegas Justice Court against Dr. Adams (Case No. 18F02513X), charging Dr. Adams with four counts of conspiracy to violate the controlled substances act (NRS 453.401(1)(a)) and four counts of possession of signed prescription blanks (NRS 453.331(1)(a)). All eight counts are felonies. Dr. Adams' initial appearance regarding the criminal complaint is scheduled for March 14, 2018. Order, ¶ 9.
- j. Based upon the above facts, on February 27, 2018, the IBM and the Board's

Executive Director issued an Order of Summary Suspension which was subsequently served on Dr. Adams. Order, ¶ 10.

#### IV.

The Order also includes the following acknowledgment: "Dr. Adams admits that the facts contained in the "Pertinent Facts" section constitute violations of NRS 633.131(1)(k) and NRS 633.511(1)(a)." Order, pg. 5, ll. 4-7.

NRS 633.131 provides:

1. "Unprofessional conduct" includes:

\* \* \* \*

(k) Knowingly or willfully disobeying regulations of the State Board of Health, the State Board of Pharmacy or the State Board of Osteopathic Medicine.

NRS 633.511 provides:

1. The grounds for initiating disciplinary action pursuant to this chapter are:
  - (a) Unprofessional conduct.

### **APPLICABLE LAW**

#### V.

A physician must be licensed to prescribe controlled substances. NRS 453.226; 21 CFR § 1306.03.

#### VI.

A physician may prescribe controlled substances only for a legitimate medical purpose and in the usual course of his professional practice. NRS 453.381(1); 21 CFR § 1306.04.

#### VII.

Each written prescription for a controlled substance must contain the handwritten signature of the prescribing practitioner. NRS 639.013(1)(a); NRS 639.2353(2); NAC 453.440(1)(c); 21 CFR § 1306.05.



## VIII.

“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).

## IX.

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).

## X.

“Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(j).

## XI.

“Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(o).

## XII.

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).

## XIII.

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).

## XIV.

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. NRS 639.210(11).

## XV.

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**

## XVI.

By providing pre-signed prescription blanks to Dr. Foote, who is not licensed to prescribe controlled substances, and facilitating the issuance of prescriptions for promethazine HCL and codeine phosphate syrup 473 ml., a Schedule V controlled substance, to patients with whom he does not have a bona fide therapeutic relationship, Dr. Adams performed his duties as the holder of a Nevada Controlled Substance Registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4) and NRS 639.255.

## **SECOND CAUSE OF ACTION**

### **XVII.**

By providing pre-signed prescription blanks to Dr. Foote, who is not licensed to prescribe controlled substances, and facilitating the issuance of prescriptions for a controlled substance to patients with whom he does not have a bona fide therapeutic relationship, Dr. Adams was a party to a fraudulent or deceitful practice or transaction and 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) and NRS 639.255.

## **THIRD CAUSE OF ACTION**

### **XVIII.**

By providing pre-signed prescription blanks to Dr. Foote, who is not licensed to prescribe controlled substances, and facilitating the issuance of prescriptions for a controlled substance to patients with whom he does not have a bona fide therapeutic relationship, Dr. Adams 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 pursuant to NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4) and NRS 639.255.

## **FOURTH CAUSE OF ACTION**

### **XIX.**

By prescribing a controlled substance for patients with whom he does not have a bona fide therapeutic relationship and outside the usual course of his professional practice as an anesthesiologist, Dr. Adams engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(o), and is subject to discipline pursuant to NRS 639.210(4) and NRS 639.255.

**FIFTH CAUSE OF ACTION**

XX.

By prescribing a controlled substance for patients with whom he does not have a bona fide therapeutic relationship and outside the usual course of his professional practice as an anesthesiologist, Dr. Adams violated 21 CFR § 1306.04. By providing pre-signed prescription blanks to Dr. Foote, who is not licensed to prescribe controlled substances, and facilitating the issuance of prescriptions for a controlled substance, Dr. Adams violated 21 CFR § 1306.03 and CFR § 1306.05. He is therefore subject to discipline pursuant to NRS 639.210(11) and NRS 639.255.

**SIXTH CAUSE OF ACTION**

XXI.

By providing pre-signed prescription blanks to Dr. Foote, who is not licensed to prescribe controlled substances, and facilitating the issuance of prescriptions for a controlled substance to patients with whom he does not have a bona fide therapeutic relationship, Dr. Adams violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.331(1)(a), NRS 453.381(1), NRS 453.401(1)(a), NRS 639.013(1)(a), NRS 639.2353(2), NAC 453.440(1)(c), 21 CFR § 1306.03, 21 CFR § 1306.04 and/or 21 CFR § 1306.05, and is subject to discipline pursuant to NRS 639.210(12) and NRS 639.255.

**SEVENTH CAUSE OF ACTION**

XXII.

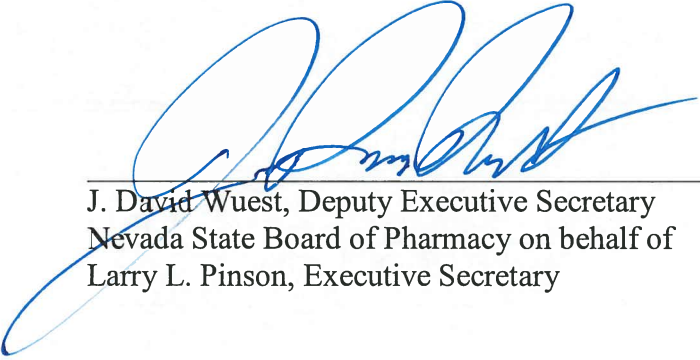
By providing pre-signed prescription blanks to Dr. Foote, who is not licensed to prescribe controlled substances, and facilitating the issuance of prescriptions for a controlled substance to patients with whom he does not have a bona fide therapeutic relationship, Dr. Adams committed an act that would render his Nevada 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).

XXIII.

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.

DATED this 27<sup>th</sup> day of April, 2018.



J. David Wuest, Deputy Executive Secretary  
Nevada State Board of Pharmacy on behalf of  
Larry L. Pinson, Executive Secretary

**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 regarding your certificate of registration. To do so, you must mail to the Board within twenty (20) days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

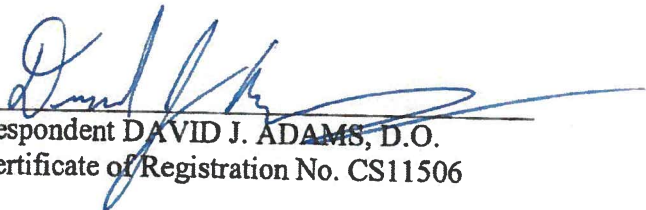


2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

See attached.

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 31 day of May, 2018.



Respondent DAVID J. ADAMS, D.O.  
Certificate of Registration No. CS11506

ADAMS, David  
Case no. 17-095-CS-S  
May 31, 2018

As you have a copy of my settlement agreement with the Osteopathic Board, I will dispense with responding to each Cause of Action in the Notice of Intended Action and Accusation. Instead, I submit this answer to express my remorse with regards to both my actions and my failure to recognize that my prescribing arrangement with Dr. Foote could violate state or federal law. I had no intention to violate the law or circumvent this Board's authority. At the time, I truly believed that I was supporting the physician I had agreed to supervise, and that my oversight of my cough syrup prescriptions left in the care of a licensed physician was sufficient in terms of compliance and patient safety. I acknowledge how misguided my reasoning was, and I plead with the Board to allow me to retain my controlled substances registration so that I may practice solely as an anesthesiologist, under prescribing restrictions already in place with the Nevada State Board of Osteopathic Medicine.

I have made several mistakes over the last few years, and I intend to spend the rest of my career regaining the reputation I had prior to working with Dr. Foote. While I had no intention of violating the law, I realize I should not have trusted the judgment of a physician who could not prescribe. I should have personally consulted the Pharmacy Board and the Osteopathic Board regarding the acceptability of clinic operations. I was present in the clinic typically three times per day, and closely monitored patient treatment by reviewing records on a daily basis, but I fully understand and accept that those controls were no replacement for my personal care of those patients.

As an anesthesiologist, a suspension or revocation of my CS registration would devastate my practice and my livelihood. I cannot maintain my hospital privileges, or perform my duties, without a CS registration. As the Board is aware, as part of my settlement with the Osteopathic Board, I agreed not to write any prescriptions whatsoever, or my medical license will be suspended. I agreed to practice only within facilities licensed under NRS Chapter 449. The Osteopathic Board basically allowed me to continue practicing as an anesthesiologist, and in no other area of medicine. As a result, without my CS registration to continue my anesthesia practice, I would effectively not be able to practice medicine at all and will lose my livelihood entirely.

With regards to my criminal case, I have come to a verbal agreement with the District Attorney whereby the felony charges against me will be reduced to a single misdemeanor. I expect a written Cooperation Agreement to that effect to be executed prior to my appearance scheduled for July 18, 2018 and I will provide the Board with a copy.

I have been practicing anesthesia for 16 years in both California and Nevada. Prior to this instance, I had never been disciplined by any licensure board, and I have never had any malpractice complaints. By all accounts, I am known as a good anesthesiologist.

I am also known as a man of good character, with deep love of my country and respect for its laws. I went to medical school relatively late in life, after serving as a C-130 navigator in the Air Force. I was commended for my eight years of military service, including three overseas tours and eight combat missions. I had intended to return to serve as an Air Force physician, however a motorcycle accident caused by a drunk driver left me with severe injuries requiring seven surgeries and



ADAMS, David  
Case no. 17-095-CS-S  
May 31, 2018

intensive rehabilitation. It was that experience, however, that triggered my interest in anesthesiology.

Respectfully, I beg the Board to allow me to retain the privilege of having a CS registration so that I may continue to practice anesthesia. I have already agreed not to write any prescriptions and I will be cooperating with the District Attorney's office in providing testimony regarding the operations of the clinic in which I had worked. I have learned that I have no place in an outpatient clinic setting, and I have no intention of practicing, if I am permitted to do so, in any environment other than a surgical suite. I have no history of complaints or discipline with regard to anesthesia, and my continued practice of anesthesia would not pose any harm to public safety or threat to the public interest. I have many contacts in professional sports who are willing to help me design and implement a community education program to deter prescription drug abuse in the midst of the opioid crisis. Please do not allow one mistake, related to a Schedule V substance, define and destroy my entire career and livelihood.

**FILED****JUN 15 2018****NEVADA STATE BOARD  
OF PHARMACY****BEFORE THE NEVADA STATE BOARD OF PHARMACY**

<b>NEVADA STATE BOARD OF PHARMACY,</b>	)	<b>CASE NOS. 16-013-PD-S</b>
	)	
<b>Petitioner,</b>	)	
<b>v.</b>	)	<b>NOTICE OF INTENDED ACTION</b>
	)	<b>AND ACCUSATION</b>
<b>ROBERT TOLEDO, D.O.,</b>	)	
<b>Certificate of Registration Nos. CS11019,</b>	)	
<b>CS17832,</b>	)	
<b>CS19754,</b>	)	
<b>CS23073,</b>	)	
<b>PD00063, and</b>	)	
<b>PD11019,</b>	)	
	)	
<b>Respondent.</b>	/	

Larry L. Pinson, 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 639.241.

**I.**

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent ROBERT ANTHONY TOLEDO, D.O. (Toledo) held active Controlled Substance Registrations, Certificate Nos. CS11019, CS17832, CS19754, and CS23073, issued by the Board. Toledo also held active Board-issued Practitioner Dispensing Registrations, Certificate Nos. PD00063 and PD11019.

**FACTUAL ALLEGATIONS****II.**

At the time of the events alleged herein, Toledo held an active license issued by the Nevada State Board of Osteopathic Medicine (D.O. Board) to practice osteopathic medicine in Nevada (License No. 1057), and owned and operated Henderson Wellness Medical Spa & Colonics (HWMS), located at 9895 Maryland Parkway, #C, Las Vegas, Nevada.

## III.

On March 30, 2016, investigators from the Board and the D.O. Board (collectively the “Investigators”) conducted a joint investigation of HWMS.

## IV.

When the Investigators arrived at HWMS, there was no one present there who was licensed to possess, access, order, prescribe or dispense dangerous drugs or controlled substances.

## V.

Toledo arrived at HWMS approximately thirty (30) minutes after the Investigators arrived and initiated their investigation.

## VI.

Prior to Toledo’s arrival on March 30, 2016, Toledo’s staff wrote and dispensed prescriptions for two (2) walk in patients without Toledo present at HWMS.

## VII.

Toledo’s HWMS staff assisted each of the two (2) patients to complete a Medical Weight Loss Program – Progress Note, and, in Toledo’s absence, signed the Medical Weight Loss Program – Progress Notes with a stamp of Toledo’s signature.

## VIII.

Without Toledo present, his HWMS staff created a prescription for each patient, prescription numbers 11211 for patient W.H., and 11212 for patient L.V., by stamping Phentermine 37.5 MG and instructions for use on a copied prescription blank bearing Toledo’s pre-signed signature.

## IX.

Toledo’s staff accessed HWMS’s inventory of controlled substances and dangerous drugs and dispensed Phentermine 37.5 MG tablets to each patient without Toledo present and without Toledo or any licensed practitioner examining the patient to establish a bona fide therapeutic relationship between Toledo and the patient.

## X.

Phentermine is a schedule IV-controlled substance.

## XI.

Toledo established a system at HWMS wherein he directed his staff to routinely possess, prescribe and dispense controlled substances and dangerous drugs to patients on his behalf and in his absence without a bona fide relationship between Toledo and the patient.

## XII.

HWMS had five (5) manila folders onsite that each contained copies of pre-signed prescription blanks which were pre-written for a dangerous drug and each bearing Toledo's copied signature. When a patient visited HWMS for a prescription, an unlicensed staff member wrote in the patient's name and information.

## XIII.

The copies of pre-signed prescriptions in the five manila folders at HWMS included:

- Latisse – 14 pre-signed copied prescription blanks.
- Obagi CRS – 11 pre-signed copied prescription blanks.
- Obagi Nuderm – 21 pre-signed copied prescription blanks.
- Obagi Clenziderm – 13 pre-signed copied prescription blanks.
- Rx Sheets – 17 pre-signed copied prescription blanks for use when staff wrote for Phentermine and other prescription medications other than the Latisse and Obagi products.

## XIV.

HWMS maintained a stock of controlled substances and dangerous drugs that were readily accessible to HWMS staff in Toledo's absence.

## XV.

The acts performed by Toledo's HWMS staff constituted the practice of medicine since they involved assessment, diagnosis, and treatment of HWMS's patients.

## XVI.

None of Toledo's HWMS staff were licensed to practice medicine as a physician, physician's assistant, or advanced practice registered nurse.

## XVII.

Toledo did not examine any of the patients of HWMS in any capacity and did not maintain medical charts on any patients of HWMS.

## XVIII.

Toledo's HWMS staff possessed the controlled substances and dangerous drugs they dispensed with Toledo's knowledge and consent and through the exercise of Toledo's authority to obtain and/or prescribe controlled substances and dangerous drugs.

## XIX.

In August 2016, Toledo entered into a Settlement Agreement and Order with the Nevada State Board of Osteopathic Medicine, Case No. AD1606001, wherein he admitted to the factual allegations that form the basis for the causes of action set forth below.

**APPLICABLE LAW**

## XX.

No person may possess a controlled substance or dangerous drug in Nevada except as authorized by law. NRS 453.336; NRS 453.338; NRS 453.373; NRS 454.213; NRS 454.316; NRS 454.321.

## XXI.

No person may prescribe and dispense controlled substances in Nevada except as authorized by law. NRS 453.226; NRS 453.375(1); NRS 453.377; NRS 639.235(1); NAC 639.742(1), (3) and (4); 21 CFR § 1301.11; 21 CFR § 1306.03.

## XXII.

A physician may prescribe and dispense controlled substances only for a legitimate medical purpose and in the usual course of his professional practice. NRS 453.381(1); 21 CFR § 1306.04.

## XXIII.

Each written prescription for a controlled substance must contain the handwritten signature of the prescribing practitioner. NRS 639.013(1)(a); NRS 639.2353(2); NAC 453.440(1)(c); 21 CFR § 1306.05.

## XXIV.

No person may prescribe and dispense dangerous drugs in Nevada except as authorized by law. NRS 454.213; NRS 454.215; NRS 639.235(1); NAC 639.742(1), (3) and (4).

## XXV.

Each written prescription for a dangerous drug must contain the handwritten signature of the prescribing practitioner. NRS 639.013(1)(a); NRS 639.2353(2); NRS 454.223; NAC 454.060(1).

## XXVI.

A dispensing practitioner must secure all controlled substances and dangerous drugs in his inventory in a locked storage area to which the dispensing practitioner has the only key or lock. NRS 453.375; NAC 453.400; NAC 453.410(1)(d); NAC 639.742(3)(c) and (4)(a); NAC 639.745(1)(c).

## XXVII.

A dispensing practitioner shall ensure that no prescription for a controlled substance or dangerous drug is dispensed to a patient unless the dispensing practitioner is on-site at the facility. NAC 639.742(3)(e).

## XXVIII.

“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).

## XXIX.

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).

## XXX.

“Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(j).

## XXXI.

“Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(o).

## XXXII.

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).

## XXXIII.

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).

## XXXIV.

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. NRS 639.210(11).

## XXXV.

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**

**(Aiding and Abetting the Unlawful Possession of Controlled Substances)**

## XXXVI.

By allowing his HWMS staff, none of whom were practitioners licensed to possess controlled substances, to use his authority to access and possess an inventory of controlled substances, Toledo aided and abetted his HWMS staff in the unlicensed practice of pharmacy in violation of NRS

453.338(1) and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(g), (h), (i), (j) and (k) and NRS 633.131(d). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (12) and (16), and NRS 639.255.

### **SECOND CAUSE OF ACTION**

#### **(Aiding and Abetting the Unlawful Possession of Dangerous Drugs)**

#### XXXVII.

By allowing his HWMS staff, none of whom were practitioners licensed to possess dangerous drugs, to use his authority to obtain and possess an inventory of dangerous drugs, Toledo aided and abetted his HWMS staff in the unlicensed practice of pharmacy in violation of NRS 454.213; NRS 454.311 and NRS 454.316 and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(g), (h), (i), (j) and (k) and NRS 633.131(d). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (12) and (16), and NRS 639.255.

### **THIRD CAUSE OF ACTION**

#### **(Aiding and Abetting the Unlawful Prescribing of Controlled Substances)**

#### XXXVIII.

By allowing his HWMS staff, none of whom were practitioners licensed to prescribe controlled substances, to issue prescriptions for controlled substances using pre-signed and copied prescription blanks or a stamp of Toledo's signature to patients with whom Toledo had no bona fide therapeutic relationship, Toledo violated and/or aided and abetted his HWMS staff in violating 21 CFR § 1306.03; 21 CFR § 1306.04; 21 CFR § 1306.05; NRS 453.321(1)(a); NRS 453.331(1)(b), (c), (d), (f) and (h), NRS 453.381(1); NRS 639.2813(1) and NAC 453.440(1)(c). Toledo has therefore engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(g), (h), (i), (k), (n) and (o) and NRS 633.131(d). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (11), (12) and (16), and NRS 639.255.



**FOURTH CAUSE OF ACTION**  
**(Aiding and Abetting the Unlawful Prescribing of Dangerous Drugs)**

XXXIX.

By allowing his HWMS staff, none of whom were practitioners licensed to prescribe dangerous drugs, to issue prescriptions for dangerous drugs using pre-signed and copied prescription blanks or a stamp of Toledo's signature to patients with whom Toledo had no bona fide therapeutic relationship, Toledo violated and/or aided and abetted HWMS's staff in violating NRS 454.221(1), NRS 454.223, NRS 454.311(1) and (2), NRS 454.316; NRS 639.2813(1); NAC 454.060(1) and NRS 639.235(1). Toledo has therefore engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(g), (h), (i), (k), (n) and (o) and NRS 633.131(1)(d). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (12) and (16), and NRS 639.255.

**FIFTH CAUSE OF ACTION**  
**(Aiding and Abetting the Unlawful Dispensing of Prescription Drugs)**

XL.

By allowing his HWMS staff, none of whom were practitioners licensed to prescribe dangerous drugs, to dispense controlled substances and/or dangerous drugs using pre-signed and copied prescription blanks or a stamped signature to patients with whom Toledo had no bona fide therapeutic relationship, Toledo violated and/or aided and abetted his HWMS staff in violating 21 CFR § 1306.03; 21 CFR § 1306.04; 21 CFR § 1306.05; NRS 639.235(1); NRS 639.284(2) and NRS 639.285. Toledo has therefore engaged in unprofessional conduct and conduct contrary to the public interest as defined in NRS 639.945(g), (h), (i), (j), (k), (n) and (o). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (11), (12) and (16), NRS 639.255 and NAC 639.7445.

**SIXTH CAUSE OF ACTION**  
**(Aiding and Abetting the Unlawful Dispensing of Controlled Substances)**

XLI.

By allowing his HWMS staff, none of whom were practitioners licensed to prescribe controlled substances, to possess and dispense controlled substances to patients with whom he had no

bona fide therapeutic relationship, Toledo aided and abetted HWMS's staff in violating 21 CFR § 1301.11; NRS 639.100(1); NRS 453.316(1); and NRS 453.331(1)(b), (c), (d), (f) and (h). Toledo has therefore engaged in unprofessional conduct and conduct contrary to the public interest as defined in NRS 639.945(g), (h), (i), (j), (k), (n) and (o). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (11), (12) and (16), NRS 639.255 and NAC 639.7445.

### **SEVENTH CAUSE OF ACTION**

#### **(Aiding and Abetting the Unlawful Dispensing of Dangerous Drugs)**

#### XLII.

By allowing his HWMS staff, none of whom were practitioners licensed to prescribe dangerous drugs, to possess and dispense dangerous drugs to patients with whom he had no bona fide therapeutic relationship, Toledo aided and abetted HWMS's staff in violating NRS 639.100(1); NRS 454.215 and NRS 454.321. Toledo has therefore engaged in unprofessional conduct and conduct contrary to the public interest as defined in NRS 639.945(g), (h), (i), (j), (k), (n) and (o). For that conduct, Toledo is subject to discipline pursuant to NRS 639.210(1), (4), (12) and (16), NRS 639.255 and NAC 639.7445.

### **EIGHTH CAUSE OF ACTION**

#### **(Fraudulent or Deceitful Practices and Transactions)**

#### XLIII.

By allowing his HWMS staff, none of whom were practitioners licensed to possess, prescribe and dispense controlled substances or dangerous drugs, to possess, prescribe and dispense controlled substances and dangerous drugs under his authority, Toledo performed and/or was a party to fraudulent and deceitful practices and transactions and 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) and NRS 639.255.

**NINTH CAUSE OF ACTION**  
**(Dispensing Controlled Substances Without A Practitioner's Signature)**

XLIV.

By dispensing, and/or by allowing his HWMS staff to dispense, controlled substances to patients without Toledo's valid handwritten signature on each written prescription, Toledo acted in violation of 21 CFR § 1306.05; NRS 639.2353(2); NAC 453.440(1)(c); and NAC 453.410(1)(b)(8), and is subject to discipline pursuant to NRS 639.210(1), (4), (11), (12) and (16), NRS 639.255 and NAC 639.7445.

**TENTH CAUSE OF ACTION**  
**(Dispensing Dangerous Drugs Without A Practitioner's Signature)**

XLV.

By dispensing, and/or by allowing his HWMS staff to dispense, dangerous drugs to patients without Toledo's valid handwritten signature on each written prescription, Toledo acted in violation of NRS 454.223(2)(a); NRS 639.2353(2); and NAC 454.060(1), and is subject to discipline pursuant to NRS 639.210(1), (4), (12) and (16), NRS 639.255 and NAC 639.7445.

**ELEVENTH CAUSE OF ACTION**  
**(Failure to Adequately Secure Drugs)**

XLVI.

By allowing his HWMS staff access to his inventory of controlled substances and dangerous drugs when he was not on site at his facility, Toledo violated NRS 453.375; NAC 453.400; NAC 453.410(1)(d); NAC 639.742(3)(c) and (4)(a), and NAC 639.745(1)(c), and is subject to discipline under NRS 639.210(11) and (12), NRS 639.255 and NAC 639.7445.

**TWELFTH CAUSE OF ACTION**  
**(Dispensing When Practitioner Off-Site)**

XLVII.

By allowing his HWMS staff to dispense controlled substances and dangerous drugs to patients when he was not on-site at his facility, Toledo violated and/or aided and abetted his HWMS

staff in violating 21 CFR § 1301.11 and NAC 639.742(3)(e), and is subject to discipline pursuant to NRS 639.210(11) and (12), NRS 639.255 and NAC 639.7445.

**THIRTEENTH CAUSE OF ACTION**  
**(Dispensing Without Dispensing Practitioner Verification)**

XLVIII.

By allowing his HWMS staff to dispense prescriptions for controlled substances and dangerous drugs without Toledo first personally checking the medications and initialing them before they were dispensed, Toledo violated 21 CFR § 1306.05 and NAC 639.743(2)(a) and/or (b). Toledo is therefore subject to discipline pursuant to NRS 639.210(11) and (12), NRS 639.255 and NAC 639.7445.

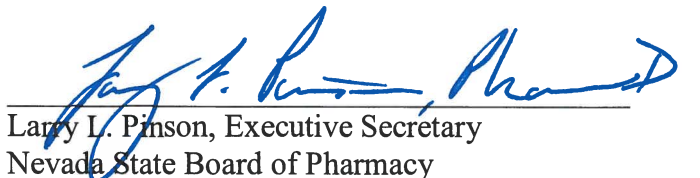
**FOURTEENTH CAUSE OF ACTION**  
**(Conduct Inconsistent with Public Interest)**

XLIX.

By providing pre-signed prescription blanks and/or a stamp of his signature to his HWMS staff, none of whom were practitioners licensed to prescribe controlled substances, and by facilitating the issuance of prescriptions for controlled substances to patients with whom Toledo does not have a bona fide therapeutic relationship, Toledo committed an act that would render his Nevada 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).

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 <sup>12</sup>15 day of June 2018.

  
 \_\_\_\_\_  
 Larry L. Pinson, 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 regarding your certificate of registration. To do so, you must mail to the Board within 20 (twenty) days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

**FILED****JUL 03 2018****NEVADA STATE BOARD  
OF PHARMACY**

**ANS**  
**JOHN H. COTTON, ESQ.**  
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 Las Vegas, Nevada 89117  
 Telephone: 702/832-5909  
 Facsimile: 702/832-5910

*Attorneys for Robert Toledo, D.O., Respondent*

**BEFORE THE NEVADA STATE**

\* \* \*

**BOARD OF PHARMACY**

**Nevada State Board of Pharmacy,**

**Petitioner,**

**v.**

**Robert Toledo, D.O.,**  
**Certificate of Registration Nos. CS1109,**  
**CS17832,**  
**CS19754,**  
**CS23073,**  
**PD00063, and**  
**PD11019**

**Respondent.**

**Case No.: 16-013-PD-S**

**ANSWER TO NOTICE OF INTENDED  
ACTION AND ACCUSATION**

Comes now Respondent, ROBERT TOLEDO, D.O. ("Respondent"), by and through his  
 attorneys of record, the law firm of JOHN H. COTTON & ASSOCIATES, and answers the  
 Notice of Intended Action and Accusations filed by the Nevada State Board of Pharmacy as  
 follows:

...

...

**I.**

Respondent admits the allegations contained in Paragraph I of the Notice of Intended Action and Accusation.

**FACTUAL ALLEGATIONS****II.**

Respondent admits the allegations contained in Paragraph II of the Notice of Intended Action and Accusation.

**III.**

Respondent admits the allegations contained in Paragraph III of the Notice of Intended Action and Accusation.

**IV.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**V.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**VI.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**VII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**VIII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**IX.**

Respondent generally denies each and every allegation of malpractice and each and every

1 statutory violation that is set forth in the Notice of Intended Action and Accusation.

2 **X.**

3 The statements herein speak for themselves. No further response is indicated.

4 **XI.**

5 Respondent generally denies each and every allegation of malpractice and each and every  
6 statutory violation that is set forth in the Notice of Intended Action and Accusation.

7 **XII.**

8 Respondent generally denies each and every allegation of malpractice and each and every  
9 statutory violation that is set forth in the Notice of Intended Action and Accusation.

10 **XIII.**

11 Respondent generally denies each and every allegation of malpractice and each and every  
12 statutory violation that is set forth in the Notice of Intended Action and Accusation.

13 **XIV.**

14 Respondent generally denies each and every allegation of malpractice and each and every  
15 statutory violation that is set forth in the Notice of Intended Action and Accusation.

16 **XV.**

17 Respondent generally denies each and every allegation of malpractice and each and every  
18 statutory violation that is set forth in the Notice of Intended Action and Accusation.

19 **XVI.**

20 Respondent generally denies each and every allegation of malpractice and each and every  
21 statutory violation that is set forth in the Notice of Intended Action and Accusation.

22 **XVII.**

23 Respondent generally denies each and every allegation of malpractice and each and every  
24 statutory violation that is set forth in the Notice of Intended Action and Accusation.

25 **XIX.**

26 Respondent admits that in August 2016, he entered into a Settlement Agreement and  
27 Order with the Nevada State Board of Osteopathic Medicine, Case No. AD1606001.  
28 Defendant denies that, when entering into the Settlement Agreement, that he admitted to



1 the factual allegations that thereby form the basis for the causes of the action set forth in  
2 the Notice of Intended Action and Accusation.

3 **APPLICABLE LAW**

4 **XX.**

5 The cited Nevada Revised Statutes speak for themselves. No further response is  
6 indicated.

7 **XXI.**

8 The cited Nevada Revised Statutes speak for themselves. No further response is  
9 indicated.

10 **XXII.**

11 The cited Nevada Revised Statutes and Code of Federal Regulations speak for  
12 themselves. No further response is indicated

13 **XXIII.**

14 The cited Nevada Revised Statutes and Code of Federal Regulations speak for  
15 themselves. No further response is indicated

16 **XXIV.**

17 The cited Nevada Revised Statutes and Nevada Administrative Codes speak for  
18 themselves. No further response is indicated.

19 **XXV.**

20 The cited Nevada Revised Statutes and Nevada Administrative Codes speak for  
21 themselves. No further response is indicated.

22 **XXVI.**

23 The cited Nevada Revised Statutes and Nevada Administrative Codes speak for  
24 themselves. No further response is indicated.

25 **XXVII.**

26 The cited Nevada Administrative Codes speak for themselves. No further response is  
27 indicated.

**XXVIII.**

The cited Nevada Administrative Codes speak for themselves. No further response is indicated.

**XXIX.**

The cited Nevada Administrative Codes speak for themselves. No further response is indicated.

**XXX.**

The cited Nevada Administrative Codes speak for themselves. No further response is indicated.

**XXXI.**

The cited Nevada Administrative Codes speak for themselves. No further response is indicated.

**XXXII.**

The cited Nevada Revised Statutes speak for themselves. No further response is indicated.

**XXXIII.**

The cited Nevada Revised Statutes speak for themselves. No further response is indicated.

**XXXIV.**

The cited Nevada Revised Statutes speak for themselves. No further response is indicated.

**XXXV.**

The cited Nevada Revised Statutes speak for themselves. No further response is indicated.

...

...

...

...

**FIRST CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Possession of Controlled Substances)**

**XXXVI.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**SECOND CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Possession of Dangerous Drugs)**

**XXXVII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**THIRD CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Prescribing of Controlled Substances)**

**XXXVIII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**FOURTH CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Prescribing of Dangerous Drugs)**

**XXXIX.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**FIFTH CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Dispensing of Prescription Drugs)**

**XL.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

...

...

...

**SIXTH CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Dispensing of Controlled Substances)**

**XLI.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**SEVENTH CAUSE OF ACTION**

**(Aiding and Abetting the Unlawful Dispensing of Dangerous Drugs)**

**XLII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**EIGHTH CAUSE OF ACTION**

**(Fraudulent or Deceitful Practices and Transactions)**

**XLIII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**NINTH CAUSE OF ACTION**

**(Dispensing Controlled Substances Without A Practitioner's Signature)**

**XLIV.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**TENTH CAUSE OF ACTION**

**(Dispensing Dangerous Drugs Without a Practitioner's Signature)**

**XLV.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

...

...

...

**ELEVENTH CAUSE OF ACTION**

**(Failure to Adequately Secure Drugs)**

**XLVI.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**TWELFTH CAUSE OF ACTION**

**(Dispensing When Practitioner Off-Site)**

**XLVII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**THIRTEENTH CAUSE OF ACTION**

**(Dispensing Without Dispensing Practitioner Verification)**

**XLVIII.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**FOURTEENTH CAUSE OF ACTION**

**(Conduct Inconsistent with Public Interest)**

**XLIX.**

Respondent generally denies each and every allegation of malpractice and each and every statutory violation that is set forth in the Notice of Intended Action and Accusation.

**AFFIRMATIVE DEFENSES**

Having Answered the Board's Notice of Intended Action and Accusation, Respondent avails himself to all available Affirmative Defenses, including but not limited to

The Notice of Intended Action and Accusation is legally insufficient.

The Notice of Intended Action and Accusation should be barred by the Doctrine of Laches and Prejudicial Delay in bringing the Accusation against Respondent.

...

1 The Notice of Intended Action and Accusation is barred by the applicable statute of  
2 limitations.

3 The Notice of Intended Action and Accusation and related proceedings deny and impinge  
4 upon the procedural and substantive due process rights of the Respondent.

5 The Notice of Intended Action and Accusation and related proceedings violate the  
6 Respondent's Double Jeopardy rights, amounting to duplicative and successive prosecutions and  
7 disciplines by the same sovereign, namely, the State of Nevada, based on the same alleged  
8 actions and offense.

9 Respondent reserves the right to amend this Answer to allege additional affirmative  
10 defenses if subsequent investigation warrants.

11 **WHEREFORE**, Respondent prays:

12 1. That the Board find that the Notice of Intended Action and Accusation and any  
13 facts obtained during discovery do not support issuance of any discipline against Respondent;

14 2. That the Board find that Respondent did not violate any provisions of the NRS,  
15 NAC or CFR; and

16 3. That this matter be stayed and then dismissed, pending ongoing compliance with  
17 and completion of the Stipulated Settlement Agreement entered into between the Respondent and  
18 the State of Nevada, Board of Osteopathic Medicine, arising out of the same set of alleged facts  
19 asserted by the State of Nevada, Board of Pharmacy, Notice of Intended Action and Accusation.

20 4. That the Board provide further relief as the Board deems just and proper.

21 **DATED** this 2d day of July 2018.

22 **JOHN H. COTTON & ASSOCIATES**

23 */s/ Katherine L. Turpen*

24 

---

JOHN H. COTTON, ESQ.  
25 Nevada Bar No. 005268  
26 KATHERINE L. TURPEN, ESQ.  
27 Nevada Bar No. 008911  
28 *Attorneys for Respondent*

FILED

FEB 27 2018

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD  
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	CASE NOS. 17-066-CS-S
	)	17-066-TD-A-S
Petitioner,	)	17-066-TD-B-S
v.	)	
	)	
CRAIG WEINGROW, M.D.,	)	NOTICE OF INTENDED ACTION
Certificate of Registration Nos. CS20272	)	AND ACCUSATION
PD00502,	)	
	)	
TERESA JAFFER, T.D.,	)	
Certificate of Registration No. TD01408,	)	
	)	
and	)	
	)	
MARECXY RUBIO-VERONICA, T.D.,	)	
Certificate of Registration No. TD01461,	)	
	)	
Respondents.	/	

Larry L. Pinson, 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 639.241.

## I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Craig Weingrow, MD (Weingrow) had both a Controlled Substance Registration, Certificate No. CS20272 and a Practitioner Dispensing Registration, Certificate No. PD00502, with the Board. Respondents Teresa Jaffer (Jaffer), Certificate of Registration No. TD01408, and Marecxy Rubio-Veronica (Rubio-Veronica), Certificate of Registration No. TD01461, each held Technician Dispensing Registrations with the Board.

## **FACTUAL ALLEGATIONS**

### **II.**

On November 1, 2017, investigators from the Board, the Nevada State Board of Medical Examiners (BME) and the Drug Enforcement Administration (DEA) conducted a joint investigation at Respondent Weingrow's medical office.

### **III.**

The investigators found evidence of misconduct and violations involving prescription records and the unlawful dispensing of controlled substances at Wiengrow's medical office. The misconduct and the violations the investigators observed and documented at Weingrow's medical office include:

1. Investigators obtained a sample of five hundred and eighty (580) prescriptions for controlled substances and dangerous drugs that Wiengrow's medical office dispensed to patients between October 14, 2017 and October 31, 2017. Of those 580 prescriptions, not one was signed by Weingrow personally.
2. Weingrow knowingly permitted Respondents Jaffer, Rubio-Veronica and three unlicensed office staff members, namely, two receptionists and one medical assistant/receptionist (collectively "Office Staff"), to falsify his signature or initials on his prescriptions.
3. Weingrow typically signs his full name when he signs prescriptions and other documents personally.
4. Weingrow trained and/or permitted Jaffer, Rubio-Veronica and Office Staff to write a "C" followed by a wavy line to falsify his signature to his prescriptions.
5. Jaffer, Rubio-Veronica, and Office Staff falsely documented patient initials and dates of service on patient's informed consent labels.
6. Weingrow allowed Jaffer, Rubio-Veronica and Office Staff access to his inventory of controlled substances and dangerous drugs to dispense to his patients when he was not present in the office.



7. Weingrow, Jaffer, Ruboio-Veronica and Office Staff mailed controlled substances to patients who lived out-of-town.

8. Weingrow allowed Jaffer to transport controlled substances to a United States Post Office for mailing.

9. Weingrow, Jaffer, Rubio-Veronica and Office Staff also used Federal Express to ship medications to patients.

10. As examples of Weingrow's unlawful activities, the investigators found evidence that Weingrow vacationed outside of the country in October 2016, and again in July 2017. The following is a summary of the controlled substances Jaffer, Rubio-Veronica and Office Staff wrote for and/or dispensed to Weingrow's patients during those periods while Weingrow was absent.

**October 18, 2016 to October 28, 2016**

Weingrow's medical office:

- Issued 18 prescriptions with Weingrow's signature on them to 14 patients.
- Dispensed 6 medications at Weingrow's office.
- Dispensed 4 medications to patients by mail.

**July 1, 2017 to July 9, 2017**

Weingrow's medical office:

- Issued 4 prescriptions with Weingrow's signature on them to 3 patients.
- Dispensed 1 medication at Weingrow's office.

11. The "Medical Weight Loss" shipping log at Wiengrow's medical office for the time period between August 26, 2016, through October 31, 2017, indicates that his staff shipped approximately 166 shipments containing controlled substances to Weingrow's patients.

## IV.

Weingrow and Jaffer each signed a statement admitting that Jaffer, Rubio-Veronica and Office Staff:

- Signed Weingrow's name on prescriptions for controlled substances and dangerous drugs;
- Falsely documented patient initials on informed consent forms;
- Dispensed controlled substances to patients by U.S. Mail and Federal Express; and
- Dispensed medications for controlled substances and dangerous drugs without Weingrow's signature on the prescriptions.

**APPLICABLE LAW**

## V.

Each written prescription for a controlled substance and each written prescription for a dangerous drug must contain the handwritten signature of the prescribing practitioner. *See* Nevada Revised Statutes (NRS) 453.128(1)(a), NRS 454.00961(1)(a), NRS 454.223(2)(a), NRS 639.013(1)(a) and NRS 639.2353(2); *see also* Nevada Administrative Code (NAC) 453.440(1)(c), NAC 453.410(1)(b)(8) and NAC 454.060(1).

## VI.

"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." Nevada Administrative Code (NAC) 639.945(1)(h).

## VII.

A licensee "[p]erforming 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" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(i).

## VIII.

A person must be a *licensed practitioner* in order to lawfully write a prescription. See NRS 453.226, NRS 453.231, and NRS 639.100.

## IX.

“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(k).

## X.

NAC 639.742 states in relevant part:

1. A practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs.

....

3. Except as otherwise provided in NRS 639.23277 and NAC 639.395, the dispensing practitioner and, if applicable, the owner or owners of the facility, shall ensure that:

- (a) All drugs are ordered by the dispensing practitioner;
- (b) All drugs are received and accounted for by the dispensing practitioner;
- (c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;
- (d) All drugs are dispensed in accordance with NAC 639.745;
- (e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility;
- (f) All drugs are dispensed only to the patient personally at the facility;

....

4. With regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:

- (a) Enter the room or cabinet in which drugs are stored;
- (b) Remove drugs from stock;
- (c) Count, pour or reconstitute drugs;
- (d) Place drugs into containers;
- (e) Produce and affix appropriate labels to containers that contain or will contain drugs;
- (f) Fill containers for later use in dispensing drugs; or
- (g) Package or repackage drugs.

## XI.

NAC 639.743 states:

1. Except as otherwise provided in NRS 639.23277 and NAC 639.395, a person to whom a dispensing practitioner is providing training and experience pursuant to subsection 4 of NAC 639.7425 must not be allowed access to the room or cabinet in which drugs are stored unless accompanied by the dispensing practitioner. After the person has completed his or her training and experience and the Board has received an affidavit from the dispensing practitioner pursuant to subsection 5 of NAC 639.7425:

(a) The person may access the room or cabinet in which drugs are stored without being accompanied by the dispensing practitioner, so long as the dispensing practitioner is on-site at the facility; and

(b) The dispensing practitioner is not required to observe the work of the person.

2. A dispensing practitioner who allows a dispensing technician to perform any function described in subsection 4 or 5 of NAC 639.742 is responsible for the performance of that function by the dispensing technician. All such functions performed by a dispensing technician must be performed at the express direction and delegation of the dispensing practitioner. Each prescription with respect to which a dispensing technician performed such a function:

(a) Must be checked by the dispensing practitioner, and the dispensing practitioner shall indicate on the label of the prescription and in his or her record regarding the prescription that the dispensing practitioner has checked the work performed by the dispensing technician; and

(b) Must not be dispensed to the patient without the initials of the dispensing practitioner thereon. A prescription which has been so initialed must be handed to the patient only by the dispensing practitioner or an employee authorized by the dispensing practitioner.

## XII.

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.

Nevada Revised Statute (NRS) 639.210(4).

**FIRST CAUSE OF ACTION**

**Dispensing Without A Practitioner's Signature**  
(Respondents Weingrow, Jaffer, and Rubio-Veronica)

## XIII.

By dispensing, and/or by allowing to be dispensed, controlled substances and dangerous

drugs to patients without Weingrow's handwritten signature on each written prescription, Respondents Weingrow, Jaffer and Rubio-Veronica each acted in violation of NRS 454.223(2)(a), NRS 639.2353(2), NAC 453.440(1)(c), NAC 453.410(1)(b)(8) and NAC 454.060(1).

## **SECOND CAUSE OF ACTION**

### **Falsifying Signatures**

(Respondents Weingrow, Jaffer, and Rubio-Veronica)

#### XIV.

By falsifying Weingrow's signature on written prescriptions for controlled substances and/or dangerous drugs that Weingrow's medical office dispensed, and/or by allowing Jaffer, Rubio-Veronica and Office Staff to falsify Weingrow's signature on prescriptions for controlled substances and/or dangerous drugs that Weingrow's medical office dispensed, Respondents, and each of them, engaged in fraudulent and/or deceitful transactions. Those actions constitute unprofessional conduct and conduct contrary to the public interest per NAC 639.945(1)(h).

## **THIRD CAUSE OF ACTION**

### **Unlicensed Practice of Medicine**

(Respondents Weingrow, Jaffer, and Rubio-Veronica)

#### XV.

By signing prescriptions as if they were authorized practitioners, and/or by allowing Jaffer, Rubio-Veronica and Office Staff to sign prescriptions as if they were authorized practitioners, Respondents, and each of them, "performed acts, tasks or operations for which licensure, certification or registration is required without the required license, certificate or registration, or knowingly allowed such conduct to occur." Those actions constitute unprofessional conduct and conduct contrary to the public interest per NAC 639.945(k).

**FOURTH CAUSE OF ACTION**  
**Failure to Adequately Secure Drugs**  
 (Respondent Weingrow)

XVI.

A dispensing practitioner must secure all controlled substances and dangerous drugs in his inventory in a locked storage area to which the dispensing practitioner has the only key or lock. *See* NAC 639.742(3)(c) and (4)(a), *see also* NAC 639.745(1)(c). Respondent Weingrow violated those regulations by allowing Jaffer, Rubio-Veronica and Office Staff access to his inventory of controlled substances and dangerous drugs when he was not onsite at his facility.

**FIFTH CAUSE OF ACTION**  
**Unlawful Access to Drugs**  
 (Respondents Weingrow, Jaffer and Rubio-Veronica)

XVII.

A dispensing technician may not access the room or cabinet in which controlled substances and/or dangerous drugs are stored unless the dispensing practitioner is on-site at the facility. *See* NAC 639.743. Respondents Jaffer and Rubio-Veronica accessed controlled substances and dangerous drugs when Weingrow was not onsite at the office, which conduct Weingrow allowed. By doing so, Respondents, and each of them, violated NAC 639.743.

**SIXTH CAUSE OF ACTION**  
**Dispensing When Practitioner Off-Site**  
 (Respondent Weingrow)

XVIII.

A dispensing practitioner may not allow his staff to dispense any controlled substance or dangerous drug when he is not on-site at his facility. *See* NAC 639.742(3)(e). By allowing Jaffer, Rubio-Veronica and/or Office Staff to dispense controlled substances and dangerous drugs to patients when he was not on-site at his medical facility, Weingrow violated NAC 639.742(3)(e).

**SEVENTH CAUSE OF ACTION**  
**Dispensing When Practitioner Off-Site**  
 (Respondents Jaffer and Rubio-Veronica)

XIX.

No person may dispense any controlled substance or dangerous drug from a dispensing practitioner's office when the dispensing practitioner is not on-site at his facility. *See* NAC 639.742(3)(e). Jaffer and Rubio-Veronica dispensed medications to patients while Weingrow was not on-site at his facility. By doing so Jaffer and Rubio-Veronica violated NAC 639.742(3)(e).

**EIGHTH CAUSE OF ACTION**  
**Dispensing to Off-Site Patients**  
 (Respondents Weingrow, Jaffer, and Rubio-Veronica)

XX.

A dispensing practitioner is required to ensure that "[a]ll drugs are dispensed only to the patient personally at the [dispensing practitioner's] facility." *See* NAC 639.742(3)(f). Weingrow allowed Jaffer, Rubio-Veronica and Office Staff to dispense to patients who were not at Weingrow's facility, including dispensing by U.S. Mail and Federal Express. By doing so, Weingrow, Jaffer and Rubio-Veronica violated NAC 639.742(3)(f).

**NINTH CAUSE OF ACTION**  
**Dispensing Without Dispensing Practitioner Verification**  
 (Respondents Weingrow, Jaffer, and Rubio-Veronica)

XXI.

By dispensing prescriptions for controlled substances and dangerous drugs that were not first checked and initialed by Weingrow – when Weingrow was not at the facility – and by allowing his staff to dispense prescriptions without personally checking the medications before they were dispensed, Respondents, and each of them, violated NAC 639.743(2)(a) and/or (b).

**TENTH CAUSE OF ACTION**

**Falsifying Patient Records**

(Respondents Weingrow, Jaffer, and Rubio-Veronica)

XXII.

By falsely documenting patient initials and dates of service on patient informed consent labels, and by allowing his staff to falsely document that information, Jaffer, Rubio-Veronica and Weingrow are each guilty of “unprofessional conduct and conduct contrary to the public interest”, as defined at NAC 639.945(1)(h).


XXIII.

For the misconduct and violations described in each of the Causes of Action above, Respondents, and each of them, are subject to discipline per NRS 639.210(1), (4), (11) and/or (12), and NRS 639.255, as well as NAC 639.7445.

XXIV.

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 27<sup>th</sup> day of February, 2018.

  
\_\_\_\_\_  
Larry Pinson, Pharm.D., 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 regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.



ORIGINAL

FILED

MAR 23 2018

NEVADA STATE BOARD  
OF PHARMACY

Jason G. Weiner, Esq.  
Nevada Bar No. 7555  
Gregory V. Cortese, Esq.  
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Attorneys for Respondent  
Craig Weingrow, M.D.

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF  
PHARMACY,

Petitioner,

v.

CRAIG WEINGROW, M.D.,  
Certificate of Registration Nos. CS20272  
PD00502,

TERESA JAFFER, T.D.  
Certificate of Registration No. TD01408,

and

MARECXY RUBIO-VERONICA, T.D.,  
Certificate of Registration No. TD01461

Respondents.

CASE NOS. 17-066-CS-S  
17-066-TD-A-S  
17-066-TD-B-S

ANSWER AND NOTICE OF DEFENSE  
OF CRAIG WEINGROW, M.D.

Respondent CRAIG WEINGROW, M.D., 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.

WEINER LAW GROUP, LLC  
2820 W. Charleston Blvd. #35  
Las Vegas, Nevada 89102  
Tel: (702) 202-0500 Fax: (702) 202-4999

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

Respondent CRAIG WEINGROW, M.D., admits the following allegations: I, III (3), III (7), III (8), III (9), IV, V, VI, VII, VIII, IX, X, XI, XII

Respondent CRAIG WEINGROW, M.D., denies the following allegations: III (1), III (2), III (4), III (5), III (6), III (10), XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX, XXI, XXII, XXIII, XXIV

Respondent CRAIG WEINGROW, M.D., is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraphs: II, III (11),


Any paragraph not explicitly admitted or denied is hereby denied.

Therefore, Respondent CRAIG WEINGROW, M.D., respectfully requests:

1. That the Board deny the requested relief in the Complaint; and
2. For such other relief as the Board finds to be just and proper.

DATED this 22 day of March, 2018.

WEINER LAW GROUP, LLC

  
 Jason G. Weiner, Esq.  
 Nevada Bar No. 7555  
 Gregory V. Cortese, Esq.  
 Nevada Bar No. 6610  
 2820 W. Charleston Blvd., Ste. 35  
 Las Vegas, NV 89102  
 Attorneys for Respondent  
 Craig Weingrow, M.D.

WEINER LAW GROUP, LLC  
2820 W. Charleston Blvd. #35  
Las Vegas, Nevada 89102  
Tel: (702) 202-0500 Fax: (702) 202-4999

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 22<sup>nd</sup> day of March, 2018, I served a true and correct copy of the aforementioned **ANSWER AND NOTICE OF DEFENSE OF CRAIG WEINGROW, M/D.** by facsimile and by U.S. Mail addressed to the following:

Larry Pinson, Pharm.D  
Executive Secretary  
Nevada State Board of Pharmacy  
431 W. Plumb Lane  
Reno, NV 89509  
FaX: (775) 850-1444

  
An Employee of the Weiner Law Group, LLC



NEVADA STATE BOARD OF PHARMACY  
**OFFICE OF THE GENERAL COUNSEL**

WRITER'S DIRECT DIAL: (775) 850-1440 • E-MAIL: PEDWARDS@PHARMACY.NV.GOV • FAX: (775) 850-1444

April 17, 2018

**CERTIFIED U.S. MAIL**

Chelsea Rene Flores  
 4880 E. Charleston Blvd. #10  
 Las Vegas, Nevada 89104

**RE: Notice of Denial of Pharmaceutical Technician in Training Application**

Dear Ms. Flores:

On April 11, 2018, the Nevada State Board of Pharmacy ("Board") considered and denied your *Pharmaceutical Technician in Training Application* ("Application"). This letter shall serve as written notice of the Board's decision.

The Board's primary reason for denying your application is your unlawful use of marijuana, which you admit occurred while you were on a break at your pharmaceutical technician school. The Board provided you the opportunity to appear before it on April 11 to discuss the matter, but you failed to appear. With your admissions, and absent your presentation of any mitigating factors, the Board denied your application out of concern for safety and the public interest.

Nevada law, NRS 639.210, states that "[t]he Board may . . . deny the application of any person for a certificate, license, registration or permit, if the holder or applicant":

- "[i]s not of good moral character;"
- "[is] guilty of unprofessional conduct or conduct contrary to the public interest;"

or

- "[h]as violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs." Each of those factors apply to the circumstances put before the Board with your application.

You have the right under NRS 639.139 to petition the Board for reconsideration of your Application. The statute provides in relevant part:

NRS 639.139 Denial of application: Procedure for reconsideration.

1. At any time within *30 days after receipt of the notice of denial* of an application, the applicant may petition the Board for reconsideration of the application. The petition *must set forth a denial, in whole or in part, of the violations alleged* and a statement that the applicant is prepared to submit evidence in support of the denial of the allegations.

....

(Emphasis added.)

If you opt to exercise your right to petition the Board for reconsideration, please submit that petition and all supporting evidence you wish to present to the Board's offices at 431 W. Plumb Lane, Reno, Nevada 89509, within thirty (30) days of receipt of this notice.

Please feel free to contact me if you have questions.

Best regards,

A handwritten signature in black ink, appearing to read "S. Paul Edwards". The signature is fluid and cursive, with the first name "S. Paul" and last name "Edwards" clearly distinguishable.

S. Paul Edwards  
General Counsel  
Nevada State Board of Pharmacy

Cc: Larry Pinson, Executive Secretary of the Nevada Board of Pharmacy

PT20618

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane ~ Reno, NV 89509

## PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION

Registration Fee: \$40.00 - (non-refundable money order only, no cash)

Complete Name (no abbreviations):

First: Chelsea Middle: Rene Last: FloresHome Address: E-Charleston Apt #: 10City: Las Vegas State: NV Zip Code: 89104Telephone: 702-251-1234 Social Security Number: 123-45-6789Date of Birth: 11/11/1995 Place of Birth: Las Vegas, NV Sex: ☐ M or ☒ FE-mail Address: chelsear.flores@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: NORTHWEST CAREER COLLEGE Store #: \_\_\_\_\_Address: 7398 SMOKE RANCH ROADCity: LAS VEGAS State: NV Zip Code: 89128Signature of Managing Pharmacist: [Signature] Lic #: PT07935 Date: \_\_\_\_\_

(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 type="checkbox"/>	<input checked="" 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 &amp; provide an explanation &amp; documentation:

Board Administrative Action:	State	Date:	Case #:
		/ /	
Criminal Action:	State	Date:	Case #:
		/ /	
		County	Court

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: Chelsea Rene Flores Date: Jan 30, 2018

Board Use Only Date Processed: 2/15/18 Amount: \$40.00



## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane ~ Reno, NV 89509

## PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION

Registration Fee: \$40.00 - (non-refundable money order only, no cash)

Complete Name (no abbreviations):

First: Eugene Middle: Troy Last: MillerHome Address: Losee Rd. Apt #: \_\_\_\_\_City: N. Las Vegas State: NV Zip Code: 89086

Telephone: \_\_\_\_\_ Social Security Number: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Place of Birth: California 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: 21/A

## I am requesting registration at the following pharmacy:

Pharmacy: Encompass Care Store #: \_\_\_\_\_Address: 1424 Losee Rd #100City: North Las Vegas State: NV Zip Code: 89086Signature of Managing Pharmacist: \_\_\_\_\_ Lic #: PD00633 Date: 4/19/18

(Without the signature of the managing pharmacist, the application will be returned.)

- |  |   |
|--|---|
| 1. Are you 18 years of age or older?                 | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| 2. Are you a high school graduate or the equivalent? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
- (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 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: Info Attached: Want like to say that the incident was almost

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
	<u>NV</u>	<u>6/18/2009</u>	<u>09C256244</u>	<u>CLARK</u>	<u>Eighth Judicial District Court</u>

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 <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| IF you marked YES to the question, above are you in compliance with the court order?..... | Yes <input type="checkbox"/> No <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 \_\_\_\_\_ Date: 4-10-2018

Board Use Only Date Processed: \_\_\_\_\_ Amount: \_\_\_\_\_

## Case Information

09C256244 | The State of Nevada vs Eugene T Miller

Case Number

09C256244

File Date

07/16/2009

Court

Department 8

Case Type

Felony/Gross

Misdemeanor

Judicial Officer

Smith, Douglas E.

Case Status

Closed

## Party

Plaintiff

State of Nevada

Active Attorneys ▼

Attorney

Jorgenson, Eric G.

Attorney

O'Brien, Glen

Attorney

Iscan, Ercan E

Attorney

Morton, Carrie A.

Attorney

Ferreira, Amy L.

Attorney

Martinez, Samuel

Lead Attorney

Wolfson, Steven B



Defendant  
Miller, Eugene T

Active Attorneys ▼  
Attorney  
Gardner, Robert M.  
Retained

Attorney  
Jorgenson, Craig F.  
Retained

Lead Attorney  
Public Defender  
Retained

## Charge

Charges  
Miller, Eugene T

	Description	Statute	Level	Date
1	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
1	MURDER.	200.010	Felony	01/01/1900
1	DEGREES OF MURDER	200.030	Felony	01/01/1900
1	USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME.	193.165	Felony	01/01/1900
2	MURDER.	200.010	Felony	01/01/1900
2	DEGREES OF MURDER	200.030	Felony	01/01/1900

	Description	Statute	Level	Date
2	USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME.	193.165	Felony	01/01/1900
2	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
3	DISCHARGE OF FIREARM OUT OF MOTOR VEHICLE	202.287	Felony	01/01/1900
3	MURDER.	200.010	Felony	01/01/1900
3	DEGREES OF MURDER	200.030	Felony	01/01/1900
3	USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME.	193.165	Felony	01/01/1900
4	ATTEMPT.	193.330	Felony	01/01/1900
4	MURDER.	200.010	Felony	01/01/1900
4	DEGREES OF MURDER	200.030	Felony	01/01/1900
4	USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME.	193.165	Felony	01/01/1900
5	ATTEMPT.	193.330	Felony	01/01/1900
5	MURDER.	200.010	Felony	01/01/1900
5	DEGREES OF MURDER	200.030	Felony	01/01/1900
5	USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME.	193.165	Felony	01/01/1900
6	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
7	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
8	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
9	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900

	Description	Statute	Level	Date
10	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
11	DISCHARGE OF FIREARM OUT OF MOTOR VEHICLE	202.287	Felony	01/01/1900
12	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
13	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
14	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
15	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
16	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900
17	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	202.285	Felony	01/01/1900

## Disposition Events

09/23/2009 Plea ▼

Judicial Officer  
Smith, Douglas E.

1	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Guilty
2	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Guilty
3	DISCHARGE OF FIREARM OUT OF MOTOR VEHICLE	Guilty

09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

1 MURDER. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

1 DEGREES OF MURDER Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

1 USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME. Charges Amended/Dropped

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12/16/2009 Disposition ▼

Judicial Officer  
Smith, Douglas E.

1	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Guilty
2	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Guilty
3	DISCHARGE OF FIREARM OUT OF MOTOR VEHICLE	Guilty

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

2 MURDER. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

2 DEGREES OF MURDER Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

2 USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

3 MURDER. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

3 DEGREES OF MURDER Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

3 USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

4 ATTEMPT. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

4 MURDER. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

4 DEGREES OF MURDER Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

4 USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

5 ATTEMPT. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

5 MURDER. Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

5 DEGREES OF MURDER Charges Amended/Dropped

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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

- 5 USE OF A DEADLY WEAPON OR TEAR GAS IN COMMISSION OF A CRIME. Charges Amended/Dropped
- 

09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

- 6 DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR Charges Amended/Dropped
- 

09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

- 7 DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR Charges Amended/Dropped
- 

09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

- 8 DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR Charges Amended/Dropped
- 

09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

- 9 DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR Charges Amended/Dropped
- 

09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

10	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

11	DISCHARGE OF FIREARM OUT OF MOTOR VEHICLE	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

12	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

13	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

14	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer  
User, Conversion

15	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer

User, Conversion

16	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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09/23/2009 Disposition ▼

Judicial Officer

User, Conversion

17	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Charges Amended/Dropped
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12/16/2009 Adult Adjudication ▼

3	DISCHARGE OF FIREARM OUT OF MOTOR VEHICLE	Adult Adjudication
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Sentenced to Nevada Dept of Corrections

Term: Minimum: 24 Months Maximum: 60 Months

Consecutive: Charge 1 and 2

Credit for Time Served: 180 Days

Comments \$25 ADM Fee; 150 DNA Fee

Other Fees

1. , \$500

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12/16/2009 Adult Adjudication ▼

2	DISCHARGING FIREARM AT OR INTO STRUCTURE, VEHICLE, AIRCRAFT OR	Adult Adjudication
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Sentenced to Nevada Dept of Corrections

Term: Minimum: 14 Months Maximum: 36 Months

Concurrent: Charge 1

12/16/2009 Adult Adjudication ▼

1 DISCHARGING FIREARM AT OR INTO Adult Adjudication  
STRUCTURE, VEHICLE, AIRCRAFT OR

Sentenced to Nevada Dept of Corrections

Term: Minimum: 14 Months Maximum: 36 Months

## Events and Hearings

07/16/2009 Criminal Bindover ▼

Comment

CRIMINAL BINDOVER Fee \$0.00

07/16/2009 Hearing ▼

Comment

INITIAL ARRAIGNMENT

07/22/2009 Information ▼

Comment

INFORMATION

07/27/2009 Initial Arraignment ▼

Hearing Time

1:30 PM

Result

Matter Heard

## Comment

INITIAL ARRAIGNMENT Court Clerk: Phyllis Irby/pi Reporter/Recorder:  
Debra Winn Heard By: EUGENE MARTIN

## Parties Present ▲

## Plaintiff

Attorney: Jorgenson, Eric G.

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

## 08/04/2009 Motion ▼

## Comment

DEFT'S O.R. RELEASE/BAIL REDUCTION /4

## 08/06/2009 Reporters Transcript ▼

## Comment

REPORTER'S TRANSCRIPT OF PRELIMINARY HEARING  
PROCEEDINGS - HEARD 07-13-09

## 08/07/2009 Opposition ▼

## Comment

STATES OPPOSITION TO DEFTS MTN FOR AN OWN  
RECOGNIZANCE RELEASE OR A REDUCTION IN BAIL IN BAIL

## 08/10/2009 Motion for Own Recognizance Release/Setting Reasonable Bail ▼

## Hearing Time

8:30 AM

## Result

Denied

## Comment

DEFT'S O.R. RELEASE/BAIL REDUCTION /4 Court Clerk: Katherine  
Streuber/ks Relief Clerk: Melissa Benson Reporter/Recorder: Jill Jacoby  
Heard By: Doug Smith

## Parties Present ▲

## Plaintiff

Attorney: Iscan, Ercan E

Defendant: Miller, Eugene T

Attorney: Jorgenson, Craig F.

Attorney: Public Defender

## 08/10/2009 Opposition ▼

Comment  
 STATES OPPOSITION TO DEFTS MTN FOR AN OWN  
 RECOGNIZANCE RELEASE OR A REDUCTION IN BAIL IN BAIL

08/14/2009 Petition ▼

Comment  
 PTN FOR WRIT OF HABEAS CORPUS

08/19/2009 Motion ▼

Comment  
 DEFT'S MTN FOR DISCOVERY/06

08/25/2009 Writ ▼

Comment  
 RETURN TO WRIT OF HABEAS CORPUS

08/26/2009 Calendar Call ▼

Hearing Time  
 8:30 AM

Result  
 Matter Heard

Comment  
 CALENDAR CALL Heard By: Doug Smith

08/26/2009 Petition for Writ of Habeas Corpus ▼

Hearing Time  
 8:30 AM

Result  
 Matter Continued

Comment  
 PTN FOR WRIT OF HABEAS CORPUS

08/26/2009 Motion for Discovery ▼

Hearing Time  
 8:30 AM

Result  
 Granted

Comment  
 DEFT'S MTN FOR DISCOVERY/06 Heard By: Doug Smith

08/26/2009 All Pending Motions ▼

Hearing Time

8:30 AM

Result

Matter Heard

Comment

ALL PENDING MOTIONS (08/26/09) Court Clerk: Katherine Streuber/ks

Relief Clerk: Melissa Benson Reporter/Recorder: Jill Jacoby Heard By:

Doug Smith

Parties Present ▲

Plaintiff

Attorney: Martinez, Samuel

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

08/26/2009 Motion ▼

Comment

ALL PENDING MOTIONS (08/26/09)

08/26/2009 Hearing ▼

Comment

STATUS CHECK: WRIT RESPONSE/NEGOTIATIONS

08/28/2009 Order ▼

Comment

ORDER

08/31/2009 Jury Trial ▼

Hearing Time

10:00 AM

Cancel Reason

Vacated

Result

Vacate

09/03/2009 Order ▼

Comment

ORDER

09/03/2009 Writ ▼

Comment

WRIT OF HABEAS CORPUS

09/09/2009 Petition for Writ of Habeas Corpus ▼

Hearing Time

8:30 AM

Result

Matter Continued

Comment

PTN FOR WRIT OF HABEAS CORPUS

09/09/2009 Status Check ▼

Hearing Time

8:30 AM

Result

Matter Continued

Comment

STATUS CHECK: WRIT RESPONSE/NEGOTIATIONS

09/09/2009 All Pending Motions ▼

Hearing Time

8:30 AM

Result

Matter Heard

Comment

ALL PENDING MOTIONS (9/9/09) Court Clerk: Katherine Streuber Relief Clerk: Melissa Benson/mb Reporter/Recorder: Jill Jacoby Heard By: Doug Smith

Parties Present ▲

Plaintiff

Attorney: Morton, Carrie A.

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

09/09/2009 Motion ▼

Comment

ALL PENDING MOTIONS (9/9/09)

09/16/2009 Petition for Writ of Habeas Corpus ▼

Hearing Time

8:30 AM

Result

Matter Continued

Comment

PTN FOR WRIT OF HABEAS CORPUS

09/16/2009 Status Check ▼

Hearing Time

8:30 AM

Result

Matter Continued

Comment

STATUS CHECK: WRIT RESPONSE/NEGOTIATIONS

09/16/2009 All Pending Motions ▼

Hearing Time

8:30 AM

Result

Matter Heard

Comment

ALL PENDING MOTIONS (9/16/09) Court Clerk: Katherine Streuber/ks  
Relief Clerk: Melissa Benson Reporter/Recorder: Patti Slattery Heard By:  
Doug Smith

Parties Present ▲

Plaintiff

Attorney: Ferreira, Amy L.

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

09/16/2009 Motion ▼

Comment

ALL PENDING MOTIONS (9/16/09)

09/23/2009 Petition for Writ of Habeas Corpus ▼

Hearing Time

8:30 AM

Comment

PTN FOR WRIT OF HABEAS CORPUS

09/23/2009 Status Check ▼

Hearing Time

8:30 AM

Comment

STATUS CHECK: WRIT RESPONSE/NEGOTIATIONS

09/23/2009 All Pending Motions ▼

Hearing Time

8:30 AM

Result

Matter Heard

Comment

ALL PENDING MOTIONS (09/23/09) Court Clerk: Katherine Streuber/ks

Relief Clerk: Melissa Benson Reporter/Recorder: Jill Jacoby Heard By:

Doug Smith

Parties Present ▲

Plaintiff

Attorney: O'Brien, Glen

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

09/23/2009 Motion ▼

Comment

ALL PENDING MOTIONS (09/23/09)

09/23/2009 Conversion Case Event Type ▼

Comment

SENTENCING - COUNTS 1, 2 & 3

09/23/2009 Motion ▼

Comment

DEFT'S O.R. RELEASE/BAIL REDUCTION /13

09/23/2009 Memorandum ▼

Comment

GUILTY PLEA MEMORANDUM/AGREEMENT

09/23/2009 Information ▼

Comment

AMENDED INFORMATION



09/28/2009 Motion for Own Recognizance Release/Setting Reasonable

Bail ▼

Hearing Time

8:30 AM

Result

Denied

Comment

DEFT'S O.R. RELEASE/BAIL REDUCTION /13 Court Clerk: Katherine Streuber Relief Clerk: Melissa Benson/mb Reporter/Recorder: Jill Jacoby Heard By: Doug Smith

Parties Present ▲

Plaintiff

Attorney: Martinez, Samuel

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

11/04/2009 Sentencing ▼

Hearing Time

8:30 AM

Result

Matter Continued

Comment

SENTENCING - COUNTS 1, 2 & 3 Court Clerk: Katherine Streuber Reporter/Recorder: Jill Jacoby Heard By: Smith, Doug

Parties Present ▲

Plaintiff

Attorney: Martinez, Samuel

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

12/16/2009 Sentencing ▼

Hearing Time

8:30 AM

Result

Defendant Sentenced

Comment

SENTENCING - COUNTS 1, 2 & 3 Court Clerk: Katherine Streuber Reporter/Recorder: Jill Jacoby Heard By: Doug Smith

Parties Present ▲

**Plaintiff**

Attorney: Iscan, Ercan E

Defendant: Miller, Eugene T

Attorney: Gardner, Robert M.

Attorney: Public Defender

12/21/2009 Judgment ▼

Comment

JUDGMENT OF CONVICTION/ADMIN ASSESSMENT

12/21/2009 Judgment ▼

Comment

JUDGMENT OF CONVICTION/GENETIC TESTING

12/21/2009 Judgment ▼

Comment

JUDGMENT OF CONVICTION/RESTITUTION

03/03/2010 Judgment ▼

Comment

AMENDED JUDGMENT OF CONVICTION

06/03/2010 Ex Parte Order ▼

Comment

EX PARTE ORDER FOR TRANSCRIPT

06/04/2010 Reporters Transcript ▼

Comment

REPORTER'S TRANSCRIPT OF PROCEEDINGS - SENTENCING -  
HEARD 12-16-09**Financial**

Miller, Eugene T

Total Financial Assessment

\$175.00

Total Payments and Credits

\$0.00

3/18/2010

Transaction Assessment

\$175.00



.....DO NOT FOLD OR STAPLE ABOVE THIS LINE.....

## Nevada State Board of Pharmacy – Renewal Application - PHARMACIST

431 W Plumb Lane • Reno, NV 89509 • bop.nv.gov

For the period of November 1, 2015 to October 31, 2017

**Money Order ONLY** (NO BUSINESS or PERSONAL CHECKS, NO CASH)

\$180.00 (postmarked on or before 10/31/2015) **OR** \$320.00 (postmarked after 10/31/2015)

**LICENSE: 13105**

**Phic Kaing Lim**

LUCRETIA AVE,  
Los Angeles, CA 90026

Please make any changes to name or address next to the old information

*Must be postmarked no later than*  
**NOV 06 2015**  
*or late fees will apply!*

### RENEW BY MAIL

1. Complete **ALL** sections on this form
2. Sign and date this form
3. Send **MO** with this form (do **NOT** staple)
4. Mail **original** form/payment to address above
5. **NO COPIES**
6. **NO SIGNATURE STAMPS ACCEPTED**

<OR>

### RENEW ONLINE

1. Go to <http://bop.nv.gov>
2. Click "Applications" then, "License Renewal", FOLLOW instructions
3. Use: **USER ID:**  
**PASSWORD: \*\*\*\*\***  
*\*New Users: once logged in, when asked for OLD password, use the above password, then change*

**Section 1:** Since your last renewal or recent licensure have you: (Please fill in completely) 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?.....** ☐ ☒

1. Been charged, arrested or convicted of a felony or misdemeanor in any state?..... ☒ ☐
2. Been the subject of a board citation or an administrative action whether completed or pending in any state?..... ☒ ☐
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?..... ☐ ☒

**If you marked YES to any of the numbered questions (1-3) above, include the following information & letter of explanation:**

Board Administrative Action:	State	Date:	Case #:
CA	CA	4/17/2014	4873
		9/17/2014	4966
Criminal Action:	State	Date:	Case #:
CA	CA	October 12011	CR11-1075 SJ
			Los Angeles
			US Court Central District

**Section 2:** 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?.....** ☐ ☒

### Section 3: (Fees apply to either status) (see colored insert for details)

By signing below, you certify that you have completed **ALL** required CE Hours due for the 15/17 Renewal period.  
 (Dated from Nov. 1, 13 – Oct. 31, 15; 1.25hrs per mo.). The exemption period is 2yrs after graduation only.

**OR you may check the box for Inactive if you did NOT complete CE.**

**Inactive** - ☐ By checking this box you certify that you are **NOT** practicing in NV and do not wish to comply with the CE requirements of NV and would like your license changed to **inactive** status. Before re-activating your license it will be necessary to submit an application and to become compliant with current CE requirements (NAC 639.219). See reverse of insert for more information.

### Section 4: NON-DISCIPLINARY STATE-MANDATED QUESTIONS

1. Though it is **NOT** required to have, SB21 requires the Board to ask if you have a Nevada State Business license and if you do, please provide the #: \_\_\_\_\_ Leave blank if non-applicable

2. Have you ever served in the military, either active, reserve or retired? Yes ☐ No ☒ Branch: \_\_\_\_\_

Military Occupation/Specialty: \_\_\_\_\_ Dates of Service: \_\_\_\_\_

**Section 5:** 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 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: Phic Kaing Lim Date: 10/19/2015

11/5/15

## Explanation

Administration hearing cases # 4873 and 4906 involve excessive dispensing controlled medications without due diligence. The cases are still pending hearing in December 2015.

Case CR 11-1075-SJO involve Medi-Cal and Medicare fraud since November 2011. The case is still pending.

Phic Lim,





## Related Licenses/Registrations/Permits

[http://www2.dca.ca.gov/pls/wllpub/WLLQRYNA\\$LCEV2.QueryView?P\\_LICENSE\\_NUM...](http://www2.dca.ca.gov/pls/wllpub/WLLQRYNA$LCEV2.QueryView?P_LICENSE_NUM...) 7/3/2018

99632 GEMMEL PHARMACY OF ONTARIO LICENSED STERILE  
COMPOUNDING

CANCELLED

## Public Disclosure

### Administrative Disciplinary Actions

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.*

Case Number: AC201300490600  
Description of Action: THESE PROCEEDINGS ARE CONCLUDED WITHOUT THE IMPOSITION OF DISCIPLINE.  
Effective Date of Action: May 02, 2018

Public documents relating to this action are available here:  
<http://www.pharmacy.ca.gov/enforcement/afy1314/ac134906>

Case Number: AC201300487300  
Description of Action: THROUGH A DISCIPLINARY ACTION OF THE BOARD, THE LICENSE IS REVOKED, THE REVOCATION IS STAYED, AND THE LICENSEE IS PLACED ON PROBATION FOR THREE YEARS SUBJECT TO THE TERMS AND CONDITIONS IN THE DECISION.  
Effective Date of Action: May 02, 2018

Public documents relating to this action are available here:  
<http://www.pharmacy.ca.gov/enforcement/fy1314/ac134873>

**This information is updated Monday through Friday - Last updated: JUL-02-2018**

### Disclaimer

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 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. 4873

12 **GEMMEL PHARMACY INC., DBA B & B**  
 13 **PHARMACY; PHIC LIM; STANLEY**  
 14 **MARC SCHWARTZ**  
 10244 Rosecrans Ave.  
 Bellflower, CA 90706

**A C C U S A T I O N**

15 Pharmacy Permit No. PHY 49825,

16 **PHIC LIM**  
 17 **1107 Fair Oaks Avenue, #148**  
 18 **South Pasadena, CA 91030**

19 Pharmacist License No. RPH 49175,

20 and

21 **STANLEY MARC SCHWARTZ**  
 22 **4656 Adagio Lane**  
 23 **Cypress, CA 90630**

24 Pharmacist License No. RPH 32928

Respondents.

25 ///

26 ///

27 ///

28 ///

1 Complainant alleges:

2 PARTIES

3 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity  
4 as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs

5 2. On or about March 23, 2009, the Board issued Pharmacy Permit Number PHY 49825  
6 to Gemmel Pharmacy Inc., dba B & B Pharmacy; Phic Lim<sup>1</sup>; Stanley Marc Schwartz<sup>2</sup>  
7 (Respondent Pharmacy). The Pharmacy Permit expired on March 1, 2012, and has not been  
8 renewed.

9 3. On or about October 22, 1996, the Board issued Pharmacist License Number RPH  
10 49175 to Phic Lim (Respondent Lim). The Pharmacist License was in full force and effect at all  
11 times relevant to the charges brought herein and will expire on December 31, 2015, if not  
12 renewed.

13 4. On or about August 9, 1979, the Board issued Pharmacist License Number RPH  
14 32928 to Stanley Marc Schwartz (Respondent Schwartz). The Pharmacist License was in full  
15 force and effect at all times relevant to the charges brought herein and will expire on June 30,  
16 2015, unless renewed.

17 JURISDICTION

18 5. This Accusation is brought before the Board the authority of the following laws. All  
19 section references are to the Business and Professions Code ("Code") unless otherwise indicated.

20 6. Section 4300 of the Code states, in pertinent part:

21 "(a) Every license issued may be suspended or revoked."

22 7. Section 4300.1 of the Code states:

23 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by  
24 operation of law or by order or decision of the board or a court of law, the placement of a license

25 <sup>1</sup> Phic Lim was the Secretary from March 23, 2009 to December 23, 2011, and the  
26 Pharmacist-in-Charge from March 23, 2009 to February 28, 2010.

27 <sup>2</sup> Stanley Schwarz was the Pharmacist-in-Charge from March 1, 2010 to December 23,  
28 2011.

on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

#### **STATUTORY PROVISIONS**

8. Section 4301 of the Code states:

"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:

....

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

"(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

....

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

....

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

9. 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:

1       "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without  
2       prescription," "Rx only," or words of similar import.

3       "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale  
4       by or on the order of a \_\_\_\_\_," "Rx only," or words of similar import, the blank to be filled  
5       in with the designation of the practitioner licensed to use or order use of the device.

6       "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on  
7       prescription or furnished pursuant to Section 4006."

8       10. Section 4081 of the Code provides:

9       "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs  
10       or dangerous devices shall be at all times during business hours open to inspection by authorized  
11       officers of the law, and shall be preserved for at least three years from the date of making. A  
12       current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-  
13       animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,  
14       institution, or establishment holding a currently valid and unrevoked certificate, license, permit,  
15       registration, or exemption under Division 2 (commencing with Section 1200) of the Health and  
16       Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and  
17       Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

18       "(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal  
19       drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated  
20       representative-in charge, for maintaining the records and inventory described in this section."

21       11. Section 4105 of the Code provides:

22       "(a) All records or other documentation of the acquisition and disposition of dangerous  
23       drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed  
24       premises in a readily retrievable form.

25       "(b) The licensee may remove the original records or documentation from the licensed  
26       premises on a temporary basis for license-related purposes. However, a duplicate set of those  
27       records or other documentation shall be retained on the licensed premises.

28       ///

1       “(c) The records required by this section shall be retained on the licensed premises for a  
2 period of three years from the date of making.

3       “(d) Any records that are maintained electronically shall be maintained so that the  
4 pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the  
5 case of a veterinary food-animal drug retailer or wholesaler, the designated representative on  
6 duty, shall, at all times during which the licensed premises are open for business, be able to  
7 produce a hard copy and electronic copy of all records of acquisition or disposition or other drug  
8 or dispensing-related records maintained electronically.”

9       12. Health and Safety Code section 11153 provides:

10       “(a) A prescription for a controlled substance shall only be issued for a legitimate medical  
11 purpose by an individual practitioner acting in the usual course of his or her professional practice.  
12 The responsibility for the proper prescribing and dispensing of controlled substances is upon the  
13 prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the  
14 prescription. Except as authorized by this division, the following are not legal prescriptions: (1)  
15 an order purporting to be a prescription which is issued not in the usual course of professional  
16 treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of  
17 controlled substances, which is issued not in the course of professional treatment or as part of an  
18 authorized narcotic treatment program, for the purpose of providing the user with controlled  
19 substances, sufficient to keep him or her comfortable by maintaining customary use.”

#### 20       REGULATORY PROVISIONS

21       13. California Code of Regulations, title 16 (“Regulations”), section 1761 provides:

22       “(a) No pharmacist shall compound or dispense any prescription which contains any  
23 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any  
24 such prescription, the pharmacist shall contact the prescriber to obtain the information needed to  
25 validate the prescription.

26       “(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense  
27 a controlled substance prescription where the pharmacist knows or has objective reason to know  
28 that said prescription was not issued for a legitimate medical purpose.”

**COST RECOVERY PROVISION**

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licensee 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.

**DRUG CLASSIFICATIONS**

15. Dilaudid, brand name for hydromorphone, is a controlled substance as defined under Health and Safety Code section 11055, section (b)(1)(J), and a dangerous drug pursuant to Business and Professions Code section 4022. It is used for the relief of pain.

16. Oxycontin, brand name for oxycodone, is a controlled substance as defined under Health and Safety Code section 11055, section (b)(1)(M), and a dangerous drug pursuant to Business and Professions Code section 4022. It is used for the relief of pain.

17. Vicodin ES, brand name for hydrocodone/acetaminophen, is a controlled substance as defined under Health and Safety Code section 11056, section (e)(4), and a dangerous drug pursuant to Business and Professions Code section 4022. It is used for the relief of pain.

**BOARD INVESTIGATION**

18. On or about March 7, 2011, pursuant to a referral from the Department of Health Care Services, Board Inspectors investigated Respondent Pharmacy to gather prescriptions and other data. The investigation revealed that from about July 1, 2009 to about January 6, 2011, Respondent Pharmacy dispensed a total of about 2438 prescriptions for Oxycontin 80mg for a total of about 215,434 dosage units, of which 1503 (or 61.64%) prescription for total dosage units of 133,854 were from Dr. S.S., Dr. H.G. and Physician Assistant A.G. of Compton Pain Center ("CPC") in Compton. One of the common combinations prescribed by these three practitioners was Oxycontin 80mg with Dilaudid 4mg.

19. A review of the Controlled Substance Utilization Review ("CURES") data for Respondent Pharmacy reveals the following:

///

///

1 a. Physician Assistant A.G. wrote a total of 6,240 controlled substance prescriptions  
2 from July 1, 2009 to January 6, 2011, of which 2,504 (40.13%-largest) were dispensed at  
3 Respondent Pharmacy.

4 b. Dr. S.S. wrote a total of 1,037 controlled substance prescriptions from July 1, 2009 to  
5 January 6, 2011, of which 269 (25.94%-largest) were dispensed at Respondent Pharmacy.

6 c. Dr. H.G. wrote a total of 1,772 controlled substance prescriptions from July 1, 2009  
7 to January 6, 2011, of which 328 (18.51%-largest) were dispensed at Respondent Pharmacy.

8 20. The following are the prescriptions written from CPC and dispensed by Respondent  
9 Pharmacy between March 23, 2009 and December 23, 2011:

10 a. Patient HH received Oxycontin 80mg above the recommended dosing interval of  
11 twice daily, along with Dilaudid 4mg, 1 tab every 6 hours as needed #100.

12 b. Patient KH received Oxycontin 80mg above the recommended dosing interval of  
13 twice daily, along with Dilaudid 4mg, 1 tab every 6 hours as needed #100. KH lived in Los  
14 Angeles, traveled approximately 18 miles to CPC, and drove additional miles to Respondent  
15 Pharmacy to receive her prescriptions.

16 c. Patient JT received a combination of Oxycontin 80mg and hydromorphone 4mg.  
17 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. JT  
18 lived in Los Angeles, traveled approximately 18 miles to CPC, and drove additional miles to  
19 Respondent Pharmacy to receive her prescriptions. Respondent Pharmacy also dispensed 2  
20 prescriptions for Oxycontin 80mg on July 13, 2009.

21 d. Patient JW received a combination of Oxycontin 80mg and hydromorphone 4mg.  
22 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. JW  
23 lived in Los Angeles, traveled approximately 22 miles to CPC, and drove additional miles to  
24 Respondent Pharmacy to receive his prescriptions. JW paid cash for these drugs when they were  
25 not covered by insurance.

26 ///

27 ///

28 ///

1 e. Patient DU received a combination of Oxycontin 80mg and hydromorphone 4mg.  
2 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. DU  
3 lived in Los Angeles, traveled approximately 23 miles to CPC, and drove additional miles to  
4 Respondent Pharmacy to receive his prescriptions.

5 f. Patient AS received a combination of Oxycontin 80mg and hydromorphone 4mg.  
6 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. AS  
7 lived in Los Angeles, traveled approximately 12 miles to CPC, and drove additional miles to  
8 Respondent Pharmacy to receive his prescriptions.

9 g. Patient JJ received a combination of Oxycontin 80mg and hydromorphone 4mg.  
10 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. JJ  
11 lived in Los Angeles, traveled approximately 18 miles to CPC, and drove additional miles to  
12 Respondent Pharmacy to receive his prescriptions.

13 h. Patient FJ received a combination of Oxycontin 80mg and hydromorphone 4mg.  
14 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. FJ  
15 lived in Los Angeles, traveled approximately 10 miles to CPC, and drove additional miles to  
16 Respondent Pharmacy to receive his prescriptions.

17 i. Patient MC received a combination of Oxycontin 80mg and hydromorphone 4mg.  
18 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. MC  
19 lived in Los Angeles, traveled approximately 16 miles to CPC, and drove additional miles to  
20 Respondent Pharmacy to receive his prescriptions. Respondent Pharmacy's printed CURES  
21 report for MC shows that on June 16, 2010, July 14, 2010 and August 13, 2010, MC used  
22 multiple physicians and pharmacies to obtain his pain medications. MC also paid cash for his  
23 pain medications when they were not covered by his insurance.

24 j. Patient LM received a combination of Oxycontin 80mg and hydromorphone 4mg.  
25 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100. LM  
26 lived in Long Beach, traveled approximately 3 miles to CPC, and drove additional miles to  
27 Respondent Pharmacy to receive his prescriptions.

28 ///



1 k. Patient EA received hydrocodone/acetaminophen 7.5/750mg, above the  
2 recommended dose of 4000mg/day of acetaminophen. Respondent Pharmacy dispensed  
3 4500mg/day to EA who lived in Moreno Valley, traveled approximately 50 miles to visit his  
4 physician, and drove additional miles to Respondent Pharmacy to receive his prescriptions.

5 l. Patient RA received hydrocodone/acetaminophen 7.5/750mg, above the  
6 recommended dose of 4000mg/day of acetaminophen. Respondent Pharmacy dispensed 3000-  
7 4500 mg/day to RA.

8 m. Patient KB received hydrocodone/acetaminophen 7.5/750mg, above the  
9 recommended dose of 4000mg/day of acetaminophen. Respondent Pharmacy dispensed 3000-  
10 4500mg/day to KB. KB lived in Highland, traveled approximately 6 miles to visit his physician  
11 in San Bernardino, and drove an additional 67 miles to Respondent Pharmacy to receive his  
12 prescriptions.

13 n. Patient JH received hydrocodone/acetaminophen 7.5/750mg, above the recommended  
14 dose of 4000mg/day of acetaminophen. Respondent Pharmacy dispensed 3000-4500mg/day to  
15 JH. JH lived in Pomona, traveled approximately 40 miles to visit his physician in Beverly Hills,  
16 and drove additional miles to Respondent Pharmacy to receive his prescriptions.

17 o. Patient BH received hydrocodone/acetaminophen 7.5/750mg, 4500mg/day above the  
18 recommended dose of 4000mg/day of acetaminophen. Respondent Pharmacy dispensed  
19 4500mg/day to BH.

20 p. Patient NM received hydrocodone/acetaminophen 7.5/750mg, above the  
21 recommended dose of 4000mg/day of acetaminophen. Respondent Pharmacy dispensed 3000-  
22 4500mg/day to NM. NM lived in Anaheim, traveled approximately 17 miles to visit her physician  
23 in Pico Rivera, and drove additional miles to Respondent Pharmacy to receive her prescriptions.

24 q. Patient KA received a combination of Oxycontin 80mg and hydromorphone 4mg.  
25 Oxycontin 80mg – 2 tabs am, 1 pm #90; Dilaudid 4mg, 1 tab every 6 hours as needed #100.

26 r. Patient EM received Oxycontin 80mg above the recommended dosing interval of  
27 twice daily. EM was also prescribed Dilaudid 4mg, 1 tab every 6 hours as needed #90. EM lived  
28 in Los Angeles, traveled approximately 18 miles CPC, and drove additional miles to Respondent

1 Pharmacy to receive his prescriptions. Respondent Pharmacy's printed Controlled Substance  
 2 Utilization Review ("CURES") report for EM shows that on June 9, 2010, EM used multiple  
 3 physicians to obtain his pain medications.

#### 4 **FIRST CAUSE FOR DISCIPLINE**

##### 5 **(Failure to Assume Co-Responsibility to Validate Legitimacy of Prescription)**

6 21. Respondents Pharmacy, Lim and Schwartz are subject to disciplinary action under  
 7 Code section 4301, subdivisions (d) and (j) for violating Health and Safety Code section 11153,  
 8 subdivision (a), and Code section 4301, subdivision (o), for violating Regulations sections 1761,  
 9 in that between March 23, 2009 to December 23, 2011, Respondents failed to assume  
 10 corresponding responsibility by failing to validate the legitimacy of the prescriptions and/or  
 11 reviewing the patients' drug therapy, by dispensing prescriptions to physician shoppers, and/or by  
 12 dispensing erroneous/uncertain prescriptions. Complainant refers to and incorporates all the  
 13 allegations contained in paragraphs 18-20, as though set forth fully.

#### 14 **SECOND CAUSE FOR DISCIPLINE**

##### 15 **(Failure to Maintain Records)**

16 22. Respondents Pharmacy and Lim are subject to disciplinary action under Code section  
 17 4301, subdivision (o) for violating Code sections 4081 and 4105, in that during the Board  
 18 investigation on March 7, 2011, Respondents could not produce prescription hardcopies for RX  
 19 ## 1574617, 1578157, 1556336, 1578979, 1558050, 1558030, 1560968 and 1562161 for the  
 20 period between March 23, 2009 and February 28, 2010.

#### 21 **DISCIPLINE CONSIDERATIONS**

22 23. To determine the degree of discipline, if any, to be imposed on Respondent Lim,  
 23 Complainant alleges that on or about April 27, 2011, the Board of Pharmacy issued Citation  
 24 Number CI 2010 48039 to Respondent Lim for violations of Regulations section 1751.3,  
 25 subdivision (b), 1751.7, subdivision (a), and 1716.2. Respondent Lim was ordered to pay a fine  
 26 of \$1,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

27 ///

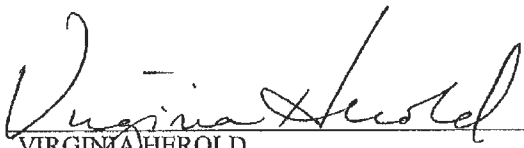
28 ///

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 Pharmacy Permit Number PHY 49825, issued to Gemmel Pharmacy Inc., dba B & B Pharmacy; Phic Lim; Stanley Marc Schwartz;
2. **Revoking or suspending** Pharmacist License Number RPH 49175, issued to Phic Lim;
3. Revoking or suspending Pharmacist License Number RPH 32928, issued to Stanley Marc Schwartz;
4. Ordering Gemmel Pharmacy Inc., dba B & B Pharmacy, Phic Lim and Stanley Marc Schwartz to jointly and severally 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;
5. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/14

  
VIRGINIA HEROLD  
Executive Officer  
Board of Pharmacy  
Department of Consumer Affairs  
State of California  
*Complainant*

LA2013509961  
51485506.doc

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 Supervising Deputy Attorney General  
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 6 (213) 897-7446

7 *Attorneys for Complainant*

8 **BEFORE THE**  
**BOARD OF PHARMACY**  
 9 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

12 **P S ENTERPRISE, INC.,**  
**d.b.a. HUNTINGTON PHARMACY;**  
 13 **PHIC LIM, President, Pharmacist-In-**  
**Charge**

14 2300 Huntington Dr.  
 San Marino, CA 91108

15 **Pharmacy Permit No. PHY 45238,**

16 and

17 **PHIC LIM**  
 18 1553 Lucretia Ave.  
 Los Angeles, CA 90026

19 **Pharmacist License No. RPH 49175,**

20 Respondents.

Case No. 4906

OAH No. 2014080925 [Consolidated]

**FIRST AMENDED ACCUSATION**

22 Complainant alleges:

23 **PARTIES**

24 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity  
 25 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

26 2. On May 29, 2001, the Board of Pharmacy issued Pharmacy Permit Number PHY  
 27 45238 to Respondent P S Enterprise, Inc., doing business as Huntington Pharmacy; with Phic Lim  
 28 as the President since May 29, 2001 and Pharmacist-in-Charge since March 10, 2010 (Respondent

1 Pharmacy). The Pharmacy Permit expired on May 1, 2012, and has not been renewed.

2 3. On October 22, 1996, the Board of Pharmacy issued Pharmacist License Number  
3 RPH 49175 to Phic Lim (Respondent Phic Lim). The Pharmacist License was in full force and  
4 effect at all times relevant to the charges brought herein and will expire on December 31, 2017  
5 unless it is renewed.

### 6 **JURISDICTION**

7 4. This Accusation is brought before the Board under the authority of the following  
8 laws. All section references are to the Business and Professions Code unless otherwise indicated.

9 5. Section 4300 of the Code states in relevant part that “[e]very license issued may be  
10 suspended or revoked.”

11 6. Section 4300.1 of the Code states:

12 The expiration, cancellation, forfeiture, or suspension of a board-issued license  
13 by operation of law or by order or decision of the board or a court of law, the  
14 placement of a license on a retired status, or the voluntary surrender of a license by a  
15 licensee shall not deprive the board of jurisdiction to commence or proceed with any  
16 investigation of, or action or disciplinary proceeding against, the licensee or to render a  
17 decision suspending or revoking the license.

### 16 **STATUTES**

17 7. Section 490 of the Code states in relevant part:

18 (a) In addition to any other action that a board is permitted to take against a  
19 licensee, a board may suspend or revoke a license on the ground that the licensee has  
20 been convicted of a crime, if the crime is substantially related to the qualifications,  
21 functions, or duties of the business or profession for which the license was issued.

22 (b) Notwithstanding any other provision of law, a board may exercise any  
23 authority to discipline a licensee for conviction of a crime that is independent of the  
24 authority granted under subdivision (a) only if the crime is substantially related to the  
25 qualifications, functions, or duties of the business or profession for which the licensee's  
26 license was issued.

27 (c) A conviction within the meaning of this section means a plea or verdict of  
28 guilty or a conviction following a plea of nolo contendere. An action that a board is  
permitted to take following the establishment of a conviction may be taken when the  
time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal,  
or when an order granting probation is made suspending the imposition of sentence,  
irrespective of a subsequent order under Section 1203.4 of the Penal Code.

1       8.     Section 4022 of the Code states:

2               "Dangerous drug" or "dangerous device" means any drug or device unsafe for  
3 self-use in humans or animals, and includes the following:

4               (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing  
5 without prescription," "Rx only," or words of similar import.

6               (b) Any device that bears the statement: "Caution: federal law restricts this device  
7 to sale by or on the order of a \_\_\_\_\_," "Rx only," or words of similar import, the blank  
8 to be filled in with the designation of the practitioner licensed to use or order use of the  
9 device.

10              (c) Any other drug or device that by federal or state law can be lawfully  
11 dispensed only on prescription or furnished pursuant to Section 4006.

12       9.     Section 4081 of the Code states in relevant part:

13              (a) All records of manufacture and of sale, acquisition, receipt, shipment, or  
14 disposition of dangerous drugs or dangerous devices shall be at all times during  
15 business hours open to inspection by authorized officers of the law, and shall be  
16 preserved for at least three years from the date of making. A current inventory shall be  
17 kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy,  
18 veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist,  
19 veterinarian, laboratory, clinic, hospital, institution, or establishment holding a  
20 currently valid and unrevoked certificate, license, permit, registration, or exemption  
21 under Division 2 (commencing with Section 1200) of the Health and Safety Code or  
22 under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and  
23 Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

24              (b) The owner, officer, and partner of a pharmacy, wholesaler, third-party  
25 logistics provider, or veterinary food-animal drug retailer shall be jointly responsible,  
26 with the pharmacist-in-charge, responsible manager, or designated representative-in-  
27 charge, for maintaining the records and inventory described in this section.

28       10.    Section 4301 of the Code states:

              The board shall take action against any holder of a license who is guilty of  
unprofessional conduct or whose license has been issued by mistake. Unprofessional  
conduct shall include, but is not limited to, any of the following:

...

(d) The clearly excessive furnishing of controlled substances in violation of  
subdivision (a) of Section 11153 of the Health and Safety Code.

...

(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.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

# 11. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or

1 knowingly participated in any conduct for which the license was denied, revoked,  
2 suspended, or placed on probation, shall be prohibited from serving as a manager,  
3 administrator, owner, member, officer, director, associate, partner, or in any other  
4 position with management or control of a licensee as follows:

5 (1) Where a probationary license is issued or where an existing license is placed  
6 on probation, this prohibition shall remain in effect for a period not to exceed five  
7 years.

8 (2) Where the license is denied or revoked, the prohibition shall continue until  
9 the license is issued or reinstated.

10 (b) "Manager, administrator, owner, member, officer, director, associate, partner,  
11 or any other person with management or control of a license" as used in this section  
12 and Section 4308, may refer to a pharmacist or to any other person who serves in such  
13 capacity in or for a licensee.

14 (c) The provisions of subdivision (a) may be alleged in any pleading filed  
15 pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the  
16 Government Code. However, no order may be issued in that case except as to a person  
17 who is named in the caption, as to whom the pleading alleges the applicability of this  
18 section, and where the person has been given notice of the proceeding as required by  
19 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government  
20 Code. The authority to proceed as provided by this subdivision shall be in addition to  
21 the board's authority to proceed under Section 4339 or any other provision of law.

22 12. Section 4332 of the Code states in relevant part:

23 Any person who fails, neglects, or refuses to maintain the records required by  
24 Section 4081 or who, when called upon by an authorized officer or a member of the  
25 board, fails, neglects, or refuses to produce or provide the records within a reasonable  
26 time, or who willfully produces or furnishes records that are false, is guilty of a  
27 misdemeanor.

28 13. Health and Safety Code section 11153 states in relevant part:

(a) A prescription for a controlled substance shall only be issued for a legitimate  
medical purpose by an individual practitioner acting in the usual course of his or her  
professional practice. The responsibility for the proper prescribing and dispensing of  
controlled substances is upon the prescribing practitioner, but a corresponding  
responsibility rests with the pharmacist who fills the prescription. Except as authorized  
by this division, the following are not legal prescriptions: (1) an order purporting to be  
a prescription which is issued not in the usual course of professional treatment or in  
legitimate and authorized research; or (2) an order for an addict or habitual user of  
controlled substances, which is issued not in the course of professional treatment or as  
part of an authorized narcotic treatment program, for the purpose of providing the user  
with controlled substances, sufficient to keep him or her comfortable by maintaining  
customary use.

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14. Health and Safety Code section 11200 states:

(a) No person shall dispense or refill a controlled substance prescription more than six months after the date thereof.

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

(c) No prescription for a Schedule II substance may be refilled.

### **REGULATIONS**

15. California Code of Regulations, title 16, section 1718, states:

“Current Inventory” as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

16. California Code of Regulations, title 16, section 1761, states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

17. California Code of Regulations, title 16, section 1770, states:

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

### **COST RECOVERY**

18. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licensee 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.

**DRUG CLASSIFICATIONS**

19. Dilaudid is a brand name for hydromorphone. Dilaudid is a Schedule II controlled substance and a dangerous drug. (Health & Saf. Code, § 11055, subd. (b)(1)(J); Bus. & Prof. Code, § 4022.) Dilaudid is indicated for severe pain.

20. OxyContin is a brand name for oxycodone. OxyContin is a Schedule II controlled substance and a dangerous drug. (Health & Saf. Code, § 11055, subd. (b)(1)(M); Bus. & Prof. Code, § 4022.) OxyContin is indicated for moderate to severe pain.

21. Lyrica is a brand name for pregabalin. Lyrica is a Schedule V controlled substance and a dangerous drug. (Code Fed. Regs., tit. 21, § 1308.15, subd. (e)(13); Bus. & Prof. Code, § 4022.) Lyrica is indicated for fibromyalgia, diabetic nerve pain, spinal cord injury nerve pain, pain after shingles, and partial onset seizures in adults with epilepsy.

**BOARD INVESTIGATION**

22. From 2011 to 2013, the Board conducted a series of investigations of Respondent Pharmacy. Respondent Pharmacy's controlled substance log, prescription copies, Patient Activity Reports (PARs) and other documents, revealed violations of the Pharmacy Law.

**FIRST CAUSE FOR DISCIPLINE**

**(Conviction of a Substantially Related Crime)**

**(As to Respondent Phic Lim)**

23. Respondent Phic Lim is subject to disciplinary action under sections 490 and 4301, subdivision (I), in conjunction with California Code of Regulations, title 16, section 1770, in that Respondent Phic Lim was convicted of a crime that is substantially related to the qualifications, functions, and duties of a registered pharmacist.

24. On or about December 11, 2015, Respondent Phic Lim pleaded guilty to one felony count of structuring of currency transactions (31 U.S.C. § 5324(a)(3).) On or about February 8, 2016, Respondent was sentenced to 12 months and one day in a federal penitentiary and ordered to pay a fine of \$15,000 and a special assessment of \$100. Following release from imprisonment, Respondent was placed on supervised release for three years upon terms and conditions that, in relevant part, require him to obtain prior written approval from his probation officer before being

1 employed in any position that requires licensing and/or certification by a local, state, or federal  
2 agency. (*United States of America v. Phic Lim* (C.D.Cal. 2016) No. CR-11-1075-SJO-5).)

3 25. The circumstances of the conviction are that beginning not earlier than July 2009,  
4 Respondent and his wife, a co-defendant, engaged in a pattern of knowingly and intentionally  
5 depositing cash proceeds in structured amounts (that is, in individual transactions less than  
6 \$10,000), resulting in combined deposits per day of more than \$10,000, and using multiple bank  
7 accounts.

8 26. In total, Respondent and his wife made structured deposits of at least \$105,826 in  
9 such cash proceeds. Respondent made those structured deposits knowing that the relevant  
10 financial institutions had a legal obligation to report currency transactions in excess of \$10,000,  
11 and Respondent acted for the purpose of evading that reporting obligation.

12 27. As an example of the structuring in which Respondent was engaged, on August 4,  
13 2009, Respondent and his wife made two cash deposits in the amounts of \$1,662 and \$9,000 into  
14 a Chase Bank account ending in numbers 0725.

## 15 **SECOND CAUSE FOR DISCIPLINE**

### 16 **(Commission of Act of Dishonesty, Fraud, Deceit, Corruption)**

#### 17 **(As to Respondent Phic Lim)**

18 28. Respondent Phic Lim is subject to disciplinary action under Code section 4301,  
19 subdivision (f), in conjunction with California Code of Regulations, title 16, section 1770, in that  
20 Respondent Phic Lim committed an act involving moral turpitude, dishonesty, fraud, deceit or  
21 corruption. Complainant realleges paragraphs 21–26.

## 22 **THIRD CAUSE FOR DISCIPLINE**

### 23 **(Failure to Validate Legitimacy of Prescriptions)**

#### 24 **(As to All Respondents)**

25 29. Respondents are subject to disciplinary action under Code section 4301, subdivisions  
26 (d) and (j) for violating Health and Safety Code section 11153, subdivision (a), and Code section  
27 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1761,  
28 subdivisions (a) and (b), in that between 2009 and 2011, Respondents failed to assume

corresponding responsibility by failing to validate the legitimacy of the prescriptions they dispensed; by failing to review the patients' drug therapy; by dispensing prescriptions to physician shoppers or habitual users; and/or by dispensing erroneous or uncertain prescriptions. The circumstances are as follows:

**A. Patient E.H. Received Prescriptions From Other Pharmacies While Receiving Lyrica 300 mg from Respondents**

30. On or about February 5, 2010, Respondents dispensed prescription number 699247 to Patient E.H. The prescription consisted of 60 tablets of Lyrica 300 mg, a 30-day supply.

31. Respondents refilled the prescription five times between March and December, 2017.

32. Respondents knew or should have known that Patient E.H. obtained prescriptions from five other pharmacies and seven doctors during the time that he received prescriptions from Respondents.

**B. Patient P.G. Received an Excessive Amount of OxyContin 80 mg**

33. On or about November 25, 2009, Respondents dispensed prescription number 693275 to Patient P.G. The prescription consisted of 90 pills of OxyContin 80 mg, a 30-day supply.

34. On or about December 1, 2009, Respondents dispensed a 30-day supply of Patient P.G.'s prescription.

35. On or about December 24, 2009, Respondents dispensed another 30-day supply to Patient P.G. 30 days early.

36. Respondents knew or should have known that Patient P.G. received prescriptions from two different doctors while receiving his prescriptions from Respondents.

**C. Patient S.A. Received an Excessive Amount of Hydrocodone/APAP 10/325**

37. On or about June 22, 2010, Respondents dispensed prescription number 711850 to Patient S.A. The prescription consisted of 120 pills of hydrocodone/APAP 10 mg /325 mg, a 30-day supply.

38. On or about July 6, 2010, Respondents dispensed a refill 16 days early.

39. On or about July 21, 2010 Respondents dispensed a refill 15 days early.

40. Respondents knew or should have known that Patient S.A. obtained 120

hydrocodone/APAP 10 mg/325 mg from four other pharmacies during the period in which she obtained the prescriptions from Respondents.

41. Respondents knew or should have known that Respondent lived in Palmdale and traveled to San Dimas and Azusa for her prescriptions.

**D. Patient Y.B. Received an Excessive Amount of Hydrocodone/APAP 10/325**

42. On or about January 21, 2011, Respondents dispensed prescription number 724719 to Patient Y.B. The prescription consisted of 45 pills of hydrocodone/APAP 10 mg/325 mg, an 11-day supply.

43. On or about January 26, 2011, Respondents dispensed a refill six days early.

44. On or about February 3, 2011, Respondents dispensed a refill eight days early.

45. On or about February 8, 2011, Respondents dispensed a refill six days early.

46. On or about February 21, 2011, Respondents dispensed a refill.

47. On or about February 25, 2011, Respondents dispensed a refill seven days early.

48. On or about March 4, 2011, Respondents ran a CURES report on Patient Y.B.

A CURES report is a report generated from California's Controlled Substance Utilization Review and Evaluation System. All prescription drug history information is maintained in CURES, a database which contains about 86 million records. The database includes information about the drug dispensed, drug quantity and strength, patient name, address, prescriber name, and authorization number, including DEA number and prescription number.

49. By virtue of the information conveyed in the CURES report, Respondents knew or should have known that during the period in which Patient Y.B. obtained prescriptions from Respondents, she also obtained prescriptions from 16 other pharmacies and 13 doctors.

50. Respondents knew or should have known that Patient Y.B. lived in San Gabriel and traveled to Glendora and Norwalk for her prescriptions.

**E. Daily Logs Reveal Questionable Prescribing and Dispensing Patterns**

51. The daily logs for Respondent Pharmacy reveal prescribing and dispensing patterns from which Respondents knew or should have known that the prescriptions they filled were not issued for a lawful medical purpose. Specifically, the daily logs show that out-of-area patients

received a combined 123 prescriptions for pain killers, including OxyContin 80 mg, morphine sulphate, and hydromorphone/Dilaudid 4 mg between January 4, 2010 and February 6, 2010, as follows:

	Date	Rx No.	Count	Drug
<b>January 4, 2010</b>				
1	1/4/2010	696115	90	OxyContin 80 mg
2	1/4/2010	696137	90	OxyContin 80 mg
3	1/4/2010	696141	90	OxyContin 80 mg
4	1/4/2010	696145	90	OxyContin 80 mg
5	1/4/2010	696150	90	OxyContin 80 mg
6	1/4/2010	696155	90	OxyContin 80 mg
7	1/4/2010	696161	90	OxyContin 80 mg
8	1/4/2010	696169	90	OxyContin 80 mg
<b>January 5, 2010</b>				
9	1/5/2010	696270	90	OxyContin 80 mg
10	1/5/2010	696274	90	OxyContin 80 mg
11	1/5/2010	696278	90	OxyContin 80 mg
12	1/5/2010	696282	90	OxyContin 80 mg
13	1/5/2010	696286	90	OxyContin 80 mg
14	1/5/2010	696291	90	OxyContin 80 mg
15	1/5/2010	696295	90	OxyContin 80 mg
<b>January 7, 2010</b>				
16	1/7/2010	696489	90	OxyContin 80 mg
17	1/7/2010	696493	90	OxyContin 80 mg
18	1/7/2010	696500	90	OxyContin 80 mg
19	1/7/2010	696504	90	OxyContin 80 mg
20	1/7/2010	696505	60	Hydromorphone 4 mg

	Date	Rx No.	Count	Drug
21	1/7/2010	696510	90	OxyContin 80 mg
22	1/7/2010	696514	90	OxyContin 80 mg
23	1/7/2010	696518	90	OxyContin 80 mg
<b>January 8, 2010</b>				
24	1/8/2010	696600	90	OxyContin 80 mg
25	1/8/2010	696604	90	OxyContin 80 mg
26	1/8/2010	696608	90	OxyContin 80 mg
27	1/8/2010	696613	90	OxyContin 80 mg
28	1/8/2010	696617	90	OxyContin 80 mg
29	1/8/2010	696621	90	OxyContin 80 mg
<b>January 9, 2010</b>				
30	1/9/2010	696717	90	OxyContin 80 mg
31	1/9/2010	696718	60	Morphine sulphate 50 mg
32	1/9/2010	696722	90	OxyContin 80 mg
33	1/9/2010	696727	90	OxyContin 80 mg
34	1/9/2010	696730	90	OxyContin 80 mg
35	1/9/2010	696734	90	OxyContin 80 mg
36	1/9/2010	696735	60	Hydromorphone 4 mg
37	1/9/2010	696740	90	OxyContin 80 mg
38	1/9/2010	696748	90	OxyContin 80 mg
39	1/9/2010	696752	90	OxyContin 80 mg
40	1/9/2010	696756	90	OxyContin 80 mg
41	1/9/2010	696760	90	OxyContin 80 mg
<b>January 11, 2010</b>				
42	1/11/2010	696788	90	OxyContin 80 mg
43	1/11/2010	696796	60	Morphine sulphate 50 mg

	Date	Rx No.	Count	Drug
44	1/11/2010	696801	90	OxyContin 80 mg
45	1/11/2010	696805	90	OxyContin 80 mg
46	1/11/2010	696809	90	OxyContin 80 mg
47	1/11/2010	696813	90	OxyContin 80 mg
48	1/11/2010	696815	60	Hydromorphone 4 mg
49	1/11/2010	696831	90	OxyContin 80 mg
50	1/11/2010	696832	100	Dilaudid 4 mg
51	1/11/2010	696835	90	OxyContin 80 mg
52	1/11/2010	696836	100	Dilaudid 4 mg
<b>January 12, 2010</b>				
53	1/12/2010	696924	90	OxyContin 80 mg
54	1/12/2010	696928	90	OxyContin 80 mg
55	1/12/2010	696932	90	OxyContin 80 mg
56	1/12/2010	696937	90	OxyContin 80 mg
57	1/12/2010	696941	90	OxyContin 80 mg
58	1/12/2010	696942	60	Hydromorphone 4 mg
59	1/12/2010	696943	90	OxyContin 80 mg
60	1/12/2010	696949	90	OxyContin 80 mg
61	1/12/2010	696953	90	OxyContin 80 mg
62	1/12/2010	696972	90	OxyContin 80 mg
<b>January 16, 2010</b>				
63	1/16/2010	697326	90	OxyContin 80 mg
64	1/16/2010	697330	90	OxyContin 80 mg
65	1/16/2010	697334	90	OxyContin 80 mg
66	1/16/2010	697343	90	OxyContin 80 mg
67	1/16/2010	697349	90	OxyContin 80 mg



	Date	Rx No.	Count	Drug
68	1/16/2010	697353	90	OxyContin 80 mg
69	1/16/2010	697357	90	OxyContin 80 mg
70	1/16/2010	697361	90	OxyContin 80 mg
71	1/16/2010	697365	90	OxyContin 80 mg
72	1/16/2010	697369	90	OxyContin 80 mg
<b>January 18, 2010</b>				
73	1/18/2010	697399	90	OxyContin 80 mg
74	1/18/2010	697409	90	OxyContin 80 mg
75	1/18/2010	697416	90	OxyContin 80 mg
76	1/18/2010	697422	90	OxyContin 80 mg
77	1/18/2010	697427	90	OxyContin 80 mg
78	1/18/2010	697436	90	OxyContin 80 mg
79	1/18/2010	697440	90	OxyContin 80 mg
80	1/18/2010	697444	90	OxyContin 80 mg
81	1/18/2010	697448	90	OxyContin 80 mg
82	1/18/2010	697454	90	OxyContin 80 mg
83	1/18/2010	697458	90	OxyContin 80 mg
84	1/18/2010	697462	90	OxyContin 80 mg
<b>January 23, 2010</b>				
85	1/23/2010	697925	90	OxyContin 80 mg
86	1/23/2010	697934	90	OxyContin 80 mg
87	1/23/2010	697938	90	OxyContin 80 mg
88	1/23/2010	697942	90	OxyContin 80 mg
89	1/23/2010	697946	90	OxyContin 80 mg
90	1/23/2010	697950	90	OxyContin 80 mg
91	1/23/2010	697955	90	OxyContin 80 mg

	Date	Rx No.	Count	Drug
92	1/23/2010	697960	90	OxyContin 80 mg
93	1/23/2010	697965	90	OxyContin 80 mg
94	1/23/2010	697969	90	OxyContin 80 mg
<b>January 25, 2010</b>				
95	1/25/2010	698017	90	OxyContin 80 mg
96	1/25/2010	698021	90	OxyContin 80 mg
97	1/25/2010	698025	90	OxyContin 80 mg
98	1/25/2010	698029	90	OxyContin 80 mg
99	1/25/2010	698033	90	OxyContin 80 mg
100	1/25/2010	698037	90	OxyContin 80 mg
101	1/25/2010	698069	90	OxyContin 80 mg
102	1/25/2010	698077	90	OxyContin 80 mg
103	1/25/2010	698080	90	OxyContin 80 mg
104	1/25/2010	698082	100	Dilaudid 4 mg
<b>January 30, 2010</b>				
105	1/30/2010	698644	90	OxyContin 80 mg
106	1/30/2010	698647	90	OxyContin 80 mg
107	1/30/2010	698652	90	OxyContin 80 mg
108	1/30/2010	698655	90	OxyContin 80 mg
109	1/30/2010	698658	90	OxyContin 80 mg
110	1/30/2010	698661	90	OxyContin 80 mg
111	1/30/2010	698664	90	OxyContin 80 mg
112	1/30/2010	698667	90	OxyContin 80 mg
113	1/30/2010	698679	90	OxyContin 80 mg
<b>February 6, 2010</b>				
114	2/6/2010	699317	90	OxyContin 80 mg

	Date	Rx No.	Count	Drug
115	2/6/2010	699320	90	OxyContin 80 mg
116	2/6/2010	699323	90	OxyContin 80 mg
117	2/6/2010	699326	90	OxyContin 80 mg
118	2/6/2010	699329	90	OxyContin 80 mg
119	2/6/2010	699334	90	OxyContin 80 mg
120	2/6/2010	699337	90	OxyContin 80 mg
121	2/6/2010	699340	90	OxyContin 80 mg
122	2/6/2010	699343	90	OxyContin 80 mg
123	2/6/2010	699346	90	OxyContin 80 mg

#### **FOURTH CAUSE FOR DISCIPLINE**

##### **(Unauthorized Dispensing of Controlled Substance Refill)**

##### **(As to All Respondents)**

52. Respondents are subject to disciplinary action under Code section 4301, subdivision (j), for violating Health and Safety Code section 11200, in that Respondents dispensed a controlled substance refill more than six months after the date of the original prescription. On or about February 5, 2010, Respondents dispensed prescription number 699247 to Patient E.H. The prescription consisted of 60 tablets of Lyrica 300 mg, a 30-day supply. Respondents dispensed a refill prescription on December 17, 2010, which was more than six months from the date of the original prescription.

#### **FIFTH CAUSE FOR DISCIPLINE**

##### **(Failure to Keep Complete Accountability)**

##### **(As to All Respondents)**

53. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating Code sections 4081, 4332, and California Code of Regulations, title 16, section 1718, in that, pursuant to an audit based on Respondent Pharmacy's records from March 25, 2010 to December 23, 2011, Respondents could not account for 142 tablets of Dilaudid 4 mg and 200

1 tablets of OxyContin 80 mg.

2 54. The Selected Data Audit Summary follows:

3 <b>Drug</b>	<b>Initial Amount</b>	<b>Amount Ordered</b>	<b>Total</b>	<b>Amount Dispensed</b>	<b>Amt. to Account</b>	<b>Stock On Hand</b>	<b>Short- age</b>
4 Dilaudid 4 mg	840	7,300	8,140	7,320	820	620	200
5 OxyCon- tin 80 mg	820	22,900	23,720	23,550	170	28	142

### 7 **DISCIPLINARY CONSIDERATIONS**

8 55. To determine the degree of discipline, if any, to be imposed on Respondent Phic Lim,  
9 Complainant alleges that on or about April 27, 2011, the Board issued Citation Number CI 2010  
10 48039 to Respondent Phic Lim for violations of California Code of Regulations, title 16, sections  
11 1751.3, subdivision (b), 1751.7, subdivision (a), and 1716.2. Respondent Phic Lim was ordered to  
12 pay a fine of \$1,500. That Citation is now final and is incorporated herein by reference as if set  
13 forth fully.

### 14 **OTHER MATTERS**

15 56. Pursuant to Business and Professions Code section 4307, if Pharmacy Permit Number  
16 PHY 45238 or Pharmacist License Number RPH 49175 is disciplined as part of the Board's  
17 Decision, then Phic Lim shall be prohibited from serving as a manager, administrator, owner,  
18 member, officer, director, associate, partner, or in any other position with management or control  
19 of a licensee for a period (1) not to exceed five years if either Pharmacy Permit Number PHY  
20 45238 or Pharmacist License Number RPH 49175 is placed on probation as part of the Board's  
21 decision, or (2) until said licenses are reinstated if they are revoked as part of the Board's  
22 decision.

23 ///

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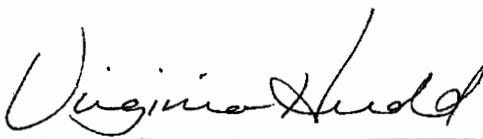
28 ///

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 Pharmacy Permit Number PHY 45238, issued to P S Enterprise, Inc., doing business as Huntington Pharmacy; with Phic Lim as the President and Pharmacist-in-Charge;
2. Revoking or suspending Pharmacist License Number RPH 49175, issued to Phic Lim;
3. Prohibiting Phic Lim, pursuant to Business and Professions Code section 4307, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee for a period (1) not to exceed five years if either Pharmacy Permit Number PHY 45238 or Pharmacist License Number RPH 49175 is placed on probation as part of the Board's decision, or (2) until said licenses are reinstated if they are revoked as part of the Board's decision;
4. Ordering P S Enterprise, Inc., d.b.a. Huntington Pharmacy and Phic Lim, jointly and severally, 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; and,
5. Taking such other and further action as deemed necessary and proper.

DATED: 2/17/17



VIRGINIA HEROLD  
Executive Officer  
Board of Pharmacy  
Department of Consumer Affairs  
State of California  
*Complainant*

LA2013510033 | 52385142\_3

# 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 \_\_\_\_\_)  
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: Axtells Rite Value Pharmacy Inc

Physical Address: 304 1/2 Charlie Street

Mailing Address: P O Box 9

City: Whitesboro State: TX Zip Code: 76273

Telephone: 903.564.3216 Fax: 903.564.7261

Toll Free Number: 855.203.3717 (Required per NAC 639.708)

E-mail: axtellaccounting@suddenlinkmail.com Website: axtellritevalue.com

Managing Pharmacist: James T Axtell Jr License Number: 19414

#### TYPE OF PHARMACY

AND

#### SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail  
☐ ☒ Hospital (# beds N/A)  
☐ ☒ 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: \_\_\_\_\_

**\*\*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

James T Axtell Jr

Print Name of Authorized Person

10-26-17  
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: TexasParent Company if any: N/AMailing Address: P O Box 9City: Whitesboro State: TX Zip: 76273Telephone: 903.564.3216 Fax: 903.564.7261

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) James T Axtell Jr 304 1/2 Charlie Street, Whitesboro, TX 76273  
Name Addressb) Gina R Axtell 1640 Roland Rd, Whitesboro, TX 76273  
Name Addressc) N/A  
Name Addressd) N/A  
Name Address2) Provide the number of shares issued by the corporation. 10003) What was the price paid per share? \$1.004) What date did the corporation actually receive the cash assets? 12/30/1997

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

List any physician shareholders and percentage of ownership.

Name: James T Axtell Jr %: 50Name: Gina R Axtell %: 50**Hours of Operation for the pharmacy:**Monday thru ~~Friday~~ Thursday 8:00 am 7:00 pm Friday 6:00 pm Saturday 8:00 am 1:00 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



**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 attached '*

STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

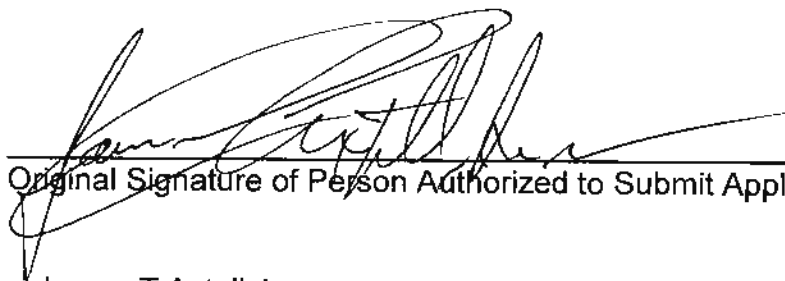
I, James T Axtell, Jr

Responsible Person of Axtells Rite Value Pharmacy 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

James T Axtell Jr

Print Name of Authorized Person

10-26-17

Date

Pharmacy	License Number	Registration Date	Expiration Date		
<b>AXTELL RITE-VALUE PHARMACY</b>	19414	02/22/1999	02/28/2019		

Pharmacist-in-Charge/President	License Number	Registration Date	Expiration Date	F/T	P/T
JAMES THOMAS AXTELL, JR	36160	08/02/1996	02/28/2019	40	

Pharmacists	License Number	Registration Date	Expiration Date	F/T	P/T
BEDOLLA, JOE	21162	01/30/1975	05/31/2019		20
MCLENDON, MICHAEL	30773	11/25/2008	07/31/2020		20
MERRILL, DAVID	35328	05/01/1995	02/28/2019	40	
HAGAN, PATRICK	54889	07/03/2014	12/31/2017	40	

Technicians	Cert#	Registration Date	Expiration Date	F/T	P/T
AHL, ASHLYNNE	210638	03/31/2014	03/31/2018	40	
BAGWELL, LAURA	114614	05/04/2004	12/31/2017	40	
DURHAM, STEPHANIE	110597	07/21/2001	10/31/2019	40	
JOHNSON, MARK	124425	09/16/2004	03/31/2019	40	
MOFFITT, NICOLE WINKLER	101495	05/20/2004	04/30/2018		20
LEVERETT, REBECCA	102131		05/31/2019	40	
LOWRY, JIEZEL	241517	03/09/2015	03/31/2018		20
MCKINNEY, TERESA	222654		09/30/2018	40	
PATTERSON, TONI	112803	05/04/2004	05/31/2018	40	
RICHARDSON, DONNA MEEKS	137292	10/30/2006	03/31/2019	40	
VANDERGRIFF, BREE	173260	03/07/2011	05/30/2018		20



**RITE-VALUE  
PHARMACY**

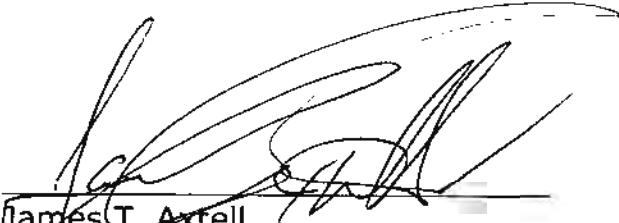
*and Compounding Center*

304 1/2 Charlie Drive Whitesboro, TX 76273  
903-564-3216 x210 Billing FAX: 903-564-7261  
Toll Free: 1-855-203-3717

Name: James T. Axtell Jr.  
DOB: 02/19/1969

Arrest: October 28, 2012  
Charge: Assault Family Violence  
Released on Bail: October 28, 2012  
Complaint Filed: January 14, 2013  
Dismissed: October 28, 2014

Attorney: Keith B. Brown  
124 S. Crockett St  
Sherman, TX 75090  
903.892.9131

  
James T. Axtell,  
President  
Axtells Rite Value Pharmacy Inc

10-26-17  
Date



## TEXAS STATE BOARD OF PHARMACY

**Re:** Axtell Rite-Value Pharmacy, Inc.  
**Address:** 304 1/2 Charlie Drive  
Whitesboro, Texas 76273  
**License No.:** 19414  
**Date Issued:** February 22, 1999  
**Licensure Status:** Active  
**Expiration Date:** February 28, 2019  
**Type of Pharmacy:** Community Sterile Compounding  
**Prior Disciplinary Orders:** Yes

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Axtell Rite-Value Pharmacy (Texas Pharmacy License #19414) has been subject to disciplinary action by the Texas State Board of Pharmacy (see attached).

Form Completed by:

Allison Vordenbaumen Benz, R.Ph., M.S.  
Director of Professional Services  
Texas State Board of Pharmacy

October 26, 2017  
Date



The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49<sup>th</sup> Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.



*Agreed Board Order #B-11-030*  
*Axtell Rite-Value Pharmacy Inc.*  
*Page 2*

An informal conference was held in the office of the Texas State Board of Pharmacy on September 5, 2012, with James Thomas Axtell, R.Ph., Pharmacist-in-Charge and Corporate President of Respondent; Gina Axtell, Corporate Vice President of Respondent; and Julie A. Nelson, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: W. Benjamin Fry, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Caroline K. Hotchkiss, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Respondent 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.

#### **ORDER OF THE BOARD**

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

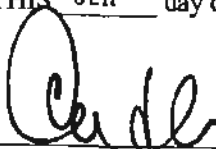
- (1) Respondent shall pay an administrative penalty of one thousand dollars (\$1,000) due ninety (90) days after the entry of this Order.
- (2) Respondent shall develop and implement policies and procedures to be used by pharmacy personnel to detect shortages and to prevent theft and loss of controlled substances. A written report of such policies and procedures shall be submitted to Board staff within ninety (90) days after the entry of this Order.
- (3) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.
- (4) 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 (2011), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012).

Agreed Board Order #B-11-030  
 Axtell Rite-Value Pharmacy Inc.  
 Page 3

And it is so ORDERED.

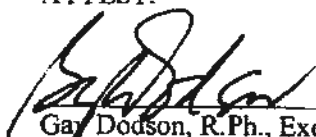
THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of November, 2012.



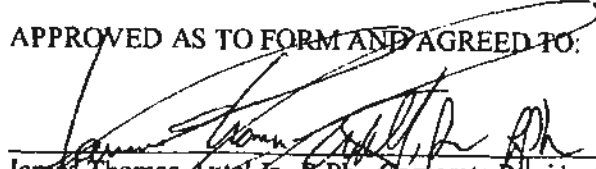
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

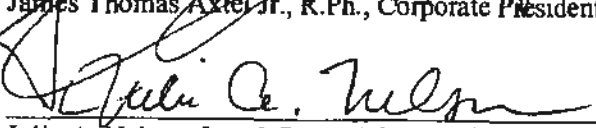


Gay Dodson, R.Ph., Executive Director/Secretary  
 Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

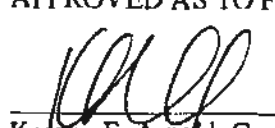


James Thomas Axtell Jr., R.Ph., Corporate President of Axtell Rite-Value Pharmacy Inc.



Julie A. Nelson, Legal Counsel for Axtell Rite-Value Pharmacy Inc.  
 Law Office of Julie Nelson, PLLC  
 1305 Crestwood Road  
 Austin, Texas 78722

APPROVED AS TO FORM:



Kersun E. Arnold, General Counsel  
 Texas State Board of Pharmacy



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Artel Rite Value Pharmacy  
Address 30412 Charlie City Whitesboro State TX  
Pharmacist License # 21610  
NAME OF PERSON RESPONSIBLE Spencer Axtell

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(d)(2)(D)(1)(VI)  
Explanation of violation Minimum product sterility testing when exceeding storage requirements of 25 days. Contacted AirScan, passed audit. Test cannot be used, may be needed.
2. Law/Rule 291.135(d)(14)(C)  
Explanation of violation Minimum record retention complete. 150 certification reports with rapid testing for 2 years. maintain all complete reports for 2 years.
3. Law/Rule 291.135(d)(14)(C)  
Explanation of violation Failure to maintain all balances with TSBP Register Balance for a total of 4 corrected.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/10/2018, disciplinary action may be instituted against your license.

Agent, Texas State Board of Pharmacy  
Date 1/10/2018

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [Signature]

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Artel Rite Value Pharmacy

- ② Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

- STERILE PRODUCTS ARE TESTED INHOUSE. AQUEOUS 2 TUBE MEDIA AND RANDOM 3rd DAY TESTING WILL CONTINUE
- CONTACTED AIRSCAN REQUESTED 2yr DOCUMENTATION OF COMPLETE REPORT FOR EACH 6 MONTH EVALUATION. WILL MAINTAIN REPORTS IN LAB FILING CABINET
- HAVE REGISTERED ALL BALANCES WITH TSBP WEB SITE

Additional comments:

Date 1/18/18

Signature of the person listed in the block titled "NAME OF PERSON RESPONSIBLE" must appear here.)

36/60  
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



## Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-500, Box 21

Austin, Texas 78701-3942

Phone: 512/305-8000

## WARNING NOTICE

Pharmacy License # 19414  
 Name of Facility Axtell Rite Value Pharmacy  
 Address 3411/2 Charles City Whitcomb Zip 78773  
 Pharmacist License # 36160  
 NAME OF PERSON RESPONSIBLE James Thomas Axtell Jr

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

## 1. Law/Rule

291.34 (a)

Explanation of violation Pharmacy maintains C-3 invoices & separates C-3 & C-2 invoices readily retrievable. 30 days of invoice retention & date of invoice. Separate C-3 invoices and maintain C-3 invoices readily retrievable.

## 2. Law/Rule

Pen to invoice, initial & date invoices

Explanation of violation

## 3. Law/Rule

291.34 (b)(1)(B)(i) & 291.34 (b)(1)(D)

Explanation of violation Pharmacy fails to control substance prescriptions issued by out-of-state nurse practitioners. Cease practice.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/10/2010, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Adrienne S. B...  
 Agent, Texas State Board of Pharmacy  
 Date 2/10/2010

Signed

## RESPONSE TO WARNING NOTICE

Pharmacy License #

Name of Facility

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

## Explanation of Correction:

1. FILES WILL BE KEPT IN LAB IN DESIGNATED FILE FOLDERS C-3-5 and C-2 SEPARATE FOR ALL BULK CHEMICALS

2. PHARMACIST ON DUTY WILL INITIAL ALL INVOICES PRIOR TO FILLING

3. PHARMACY WILL NO LONGER FILL AND SHIP TO OUT OF STATE NURSE MID-LEVEL PRACTITIONERS

Additional comments:

Date

01/18/10

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

License #

36160

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

### WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axell Rite Value Pharmacy  
Address 341 1/2 Charlie City Wichita Falls State Texas  
Pharmacist License # 36160  
NAME OF PERSON RESPONSIBLE James Axell

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 295.15 (c) & (g)  
Explanation of violation Failure to maintain documentation of RPH 20hr immunization course and CPR training. Failure to notify PCP of immunization maintenance 12 hr RPH
2. Law/Rule immunization training and document  
Explanation of violation CPR training. Notify patients PCP of immunization

3. Law/Rule 291.51 (d)(5)(C)(ii) & (iii)  
Explanation of violation Failure to maintain data beyond BUDs of non-sterile products. maintain valid scientific data when extending BUD beyond above referenced rules

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/20/2018 disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Adrianna Salas  
Agent, Texas State Board of Pharmacy  
Date 1/10/2018

Signed [Signature]

30 Day

### RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axell Rite Value Pharmacy

☒ Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected, DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

#### Explanation of Correction:

1. \_\_\_\_\_
2. PROOF OF IMMUNIZATION FORM SENT WITH ALL REQUIRED INFO FAXED TO PCP.
3. NON STERILE PRODUCTS WILL BE TESTED BY OUTSIDE SOURCE OF LITERATURE BACK UP BY COMPOUNDING TODAY OR OTHER SOURCES

#### Additional comments:

Date \_\_\_\_\_

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.) \_\_\_\_\_

License # \_\_\_\_\_

☒ Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Art's Rite Value Pharmacy  
Address 2412 Charles Columbus Spokane 78205  
Pharmacist License # 36160  
NAME OF PERSON RESPONSIBLE James A. Langer

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law Rule 291.33(c)(1)(B)(C)  
Explanation of violation Link Service: patient is denied new prescription pickup. Non-RPh pharmacist staff ask question of patients that limit understanding with RPh.
2. Law Rule 291.33(c)(1)(B)(iv)  
Explanation of violation Pharmacist must maintain accurate record of RPh providing computer with new prescriptions. Accurate document must also be provided to RPh providing discharge.
3. Law Rule \_\_\_\_\_  
Explanation of violation \_\_\_\_\_

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 1/11/12, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By James A. Langer  
Agent, Texas State Board of Pharmacy  
Date 1/9/12

Signed \_\_\_\_\_

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Art's Rite Value Pharmacy

- ② Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

1. All NEW RX'S will be counseled By PHARMACIST. FINGER PRINT
2. FINGER PRINT BIO IDENTIFIER was purchased 11/18, Received 1/11. Process Initiated 1/12
3. \_\_\_\_\_

Additional comments: \_\_\_\_\_

Date 1/11/12

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

License # 36160

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Rite-Value Pharmacy  
Address 412 Charlie D. Crutcher Dr. Waco, TX 76713  
Pharmacist License # 36160  
NAME OF PERSON RESPONSIBLE Jane Vandergriff, R.Ph.

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law Rule 291.133(C)(4)(L)(V)  
Explanation of violation Failure to conduct initial and annual fingerprint testing and document for all CSP staff & document.
2. Law Rule 291.133(C)(4)  
Explanation of violation Failure to maintain in-house OJT training for Jane Vandergriff, R.Ph. evaluation of a new fingerprinting and medication for Jazzel Lowrey, CNA and document.  
Explanation of violation Failure to maintain in-house OJT training for Jazzel Lowrey, CNA and document.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/9/2018, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [Signature]  
Agent, Texas State Board of Pharmacy  
Date 1/9/2018

Signed

[Signature]

11/00

30 day

# RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Rite-Value Pharmacy

☒ Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

## Explanation of Correction:

1. Bi-Annual Fingerprint test will continue along with a Red Initial test for All Acrylic Qualified Technicians
2. Bree Vandergriff OJT was found in another file and moved to OJT file Jazzel Lowrey will conduct Fingerprint Test. She has moved from Fulltime to Part Time Employees and all New Employees will be put on the same Bi-Annual Shadow, Fingerprint Test Dates and Signatures on

Additional comments:

Date 1/18/18

Signature (The person listed in the blank titled NAME OF PERSON RESPONSIBLE must sign here.)

36160  
License #

☒ Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



**Texas State Board of Pharmacy**  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

**WARNING NOTICE**

19414  
Only License #  
of Family 19414 KPH Value Premium  
as 2412 cash on hand  
agent License # 2412  
OF PERSON RESPONSIBLE James H. H. H. H.  
is hereby given that the above

is hereby given that you are not complying with the following laws and or rules  
governing the practice of pharmacy:

(29) 32(1)(3)  
Date of visitation  
In 10 minutes mounted a prof.  
per hater at all times 184 inches as a

Date: 29.12.22 (b)(3)  
 Place of violation: Public building, outside perimeter  
 Description: Public building, outside perimeter  
 Date: 29.12.22 (a)(1)(4)  
 Place of violation: Public building, outside perimeter  
 Description: Public building, outside perimeter

also hereby given that unless the conditions noted above are corrected and a written failing the corrections is submitted to the Executive Director/Secretary of the Texas Board of Pharmacy on or before 11/19/2018 disciplinary action may be taken against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

State Board of Pharmacy  
1/1/18



## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Astell Rite Value Pharmacy

⑧ Explain, in the space provided below, how the Unsatisfactory/Warning/Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

**Explanation of Correction:**

- 1. Pharmacist shifts 8AM 1st  
10AM 2nd, 11AM 3rd  
Will maintain ratio
- 2. End plan is to close Dispensary in 30 days until tech will no fill until 2nd shift pharmacist is present
- 3. Log Sign sheet for full time
- OK

**Additional comments:**

1/1/18

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

3616T  
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Life Value Pharmacy  
Address 2411 E. 12th St. City Wichita, KS Zip 67203  
Pharmacist License # 24140  
NAME OF PERSON RESPONSIBLE James H. Axtell

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.122 (1)(6)  
Explanation of violation Pharmacy is not compliant with ISPP rules: install temp. & humidity monitors in both ante rooms. Install humidity monitor in both ante rooms.
2. Law/Rule 291.122 (1)(6)  
Explanation of violation Pharmacy is not compliant with ISPP rules: install temp. & humidity monitors in both ante rooms.
3. Law/Rule 291.122 (1)(6)  
Explanation of violation Pharmacy is not compliant with ISPP rules: install temp. & humidity monitors in both ante rooms.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 4/10/18 disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By James H. Axtell  
Agent, Texas State Board of Pharmacy  
Date 4/10/18

Signed

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Life Value Pharmacy

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

1. Clean room Designs has installed thermometer & humidity meter in NON-haz ante room & installed humidity meters in both ante rooms. We are able to monitor both rooms to maintain  $\pm 68^{\circ}\text{F}$  &  $\pm 60\%$  humidity.
2. We have made adjustments to maintain NON-haz clean room at a minimum pressure of 0.02.
3. We have repainted w/ epoxy paint & tested w/ alcohol wipe. The cracks & crevices & seams have all been silicone caulked. Blemishes have been fixed on walls. All panels & light fixtures have been sealed. We installed stainless shelves for storage off floor.

Additional comments:

2-13-18

Date

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

License #

19414 36160

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Phcy Lic # <u>19414</u>
Expiration Date <u>2/29/19</u>

**NOTICE OF INSPECTION**  
Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500  
Austin, Texas 78701-3942  
(512) 305-8000

<input type="checkbox"/> Compliance
<input checked="" type="checkbox"/> Investigation

Name of Individual <u>Patrick Hagen</u>	Title <u>RPh</u>	R.Ph. Lic. # <u>54889</u>	Expires <u>12/18</u>
Name of Facility <u>Axkh Rite-Value Pharmacy, LLC</u>	Class of Pharmacy License <u>AS</u>		
Address <u>304 1/2 Charles Drive</u>			
City/State <u>Whiteword TX</u>	Zip <u>76273</u>	Phone # <u>(817) 544 3214</u>	
DEA Registration # <u>BA6242762</u>	Expiration Date <u>6/20</u>		
Date <u>Jan 9, 2018</u>	Time of Entry <u>945am</u>		

**PURPOSE OF INSPECTION**

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> Routine                         | <input type="checkbox"/> Pre-Inspection                    | <input type="checkbox"/> Rank Change                                |
| <input type="checkbox"/> New Pharmacy                    | <input type="checkbox"/> Change of Ownership               | <input type="checkbox"/> Reverse Rank Change                        |
| <input type="checkbox"/> Complaint                       | <input checked="" type="checkbox"/> Follow-up to Complaint | <input checked="" type="checkbox"/> Licensee Request                |
| <input type="checkbox"/> Follow-up to Warning Notice     | <input type="checkbox"/> Follow-up to Theft/Loss Report    | <input checked="" type="checkbox"/> Sterile Compounding (High Risk) |
| <input type="checkbox"/> Follow-up to Disciplinary Order | <input type="checkbox"/> Other _____                       |   |

**ACKNOWLEDGEMENT**

This is to acknowledge that Texas State Board of Pharmacy Agent Adrianne M. Bauer has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

- I am the RPh for the above-described facility.
- I have read this Notice of Inspection and understand its contents and purpose.
- I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.
- I have had the purpose of the entry into the above-described facility by the Board's agent stated to me, and
- I have consented to an inspection of the above-described facility voluntarily and without any manner of threats

Witnesses:

Adrianne M. Bauer  
Signature

\_\_\_\_\_  
Signature

[Signature]  
Signature



# TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: A (A-S B C C-S (BEDS) D Other

Name of Pharmacy  
Pharmacist in Charge  
Personnel

Arkell Life Value Pharmacy Inc  
James Thomas Carter  
Scattered

TSBP License #

19414

Lic 34110 Exp 2/19

Lic \_\_\_\_\_ Exp \_\_\_\_\_

Lic \_\_\_\_\_ Exp \_\_\_\_\_

Lic \_\_\_\_\_ Exp \_\_\_\_\_

Lic \_\_\_\_\_ Exp \_\_\_\_\_

KEY: Circled items need improvement, ✓ items in Column One Refer to Legal Division (R/L) for review and possible discipline.  
✓ items in Column Two receive a Warning Notice (W/N)  
For an explanation of specific violations noted, refer to remarks section of inspection report

R/L	W/N	
1		Licenses not posted
2		Insufficient Equipment
3		Orderly/Clean
4		Balance Failed
5		Equipment Inspection
6		Inadequate Library
7		Improper security
8		Environment
9		Delinquent licenses/certifications
36		No notification of substitution
90		No complaint notification
38		Area for non sterile compounding
43		Records for non sterile compounding
47		Out of date/mislabeled drug stock
48		Improper drug storage
53		Illegal possession of C/S
57		Corresponding Responsibility
59		Improper drug destruction
61	✓	Improper supervision of supportive personnel
62		Aiding and abetting
65		Improper registration procedures
66		Grey Market diversion/Samples
76	✓	No PIC (fulltime)
34		Notification Violation
79		Names tags
60		Improper documentation of training
92		Improper automated dispensing procedures

R/L	W/N	
		Date of last inventory
15		No PIC inventory
69		No annual inventory
68		No change of ownership inventory
31		Closed Phcy/Change of owner improper
17		Incomplete inventory
18	✓	Records not available
46		Improper distribution
54		Improper prepackaging procedures
24		Theft/Loss not reported
30		Invoices not dated/initialed
86		Absence of RPh pick up records
19		Rx lacks proper information
25		No documentation of refill authorization
32		Rx label is incorrect
40		Non emergency C-II Rx
26		C II Rx noncompliance
37		Illegal dispensing
45		Improper dispensing/labeling
44		Refill CIII-V over 5x/6mo
55		Refill prn past one year
78		Counseling area
80		No counseling by RPh
56		Improper transfer of Rx
50		Out of state verbal Rx for C/S
49		Substitution noncompliance
33		Rx records not in numerical order

R/L	W/N	
10		Rxs not separated
35		Invoices not separated
67		No written information
21		Computer records incomplete
22		Computer system noncompliance
82		PMR Incomplete
83		PMR Absent
84		No drug regimen review
16		No perpetual inventory
27		Improper inpatient records
51		Improper ER dispensing
75	✓	Improper absence of RPh procedures
70		No P&P manual
71		Incomplete P&P manual
72		Improper procedures for IV preparation
81		Area for preparation of sterile products
85		Patient Care Guidelines incomplete
87		Quality Control/Assurance
88		Cytotoxic/Biohazardous Procedures
89		Refrigerator Temperature Log
28		No provision log
29		Incomplete provision log
52		Improper provision/dispensing in Class D
63		Prohibited drugs in Class D pharmacy
64		Violation of limited formulary
91		RPh visits/contact documentation
73		Formulary not complete



# Texas State Board of Pharmacy

Inspection Report for Pharmacies Compounding Sterile Preparations

Circle One: Class A-5 Class B Class C-5

Name of Pharmacy

TSPB License #

Deficiency key: Circled items need improvement (N/I). Refer to Legal Division (R/L) for review and possible discipline, and Warning Factors (W/N) which require a written response with an explanation of correction(s). For an explanation of specific violations noted, refer to remarks section of inspection report. Note: "M" = Multiple Codes

R/L Code W/N

Environment	
M	Is cleanroom clean/free of objects that shed particles? (109) Contains only appropriate supplies? (110) Used only for sterile prep? (120)
M	Does ante-area provide at least ISO Class 8 under dynamic conditions? (101) Contain a hands-free sink with hot/cold running water? (115)
M	Does buffer area provide at least ISO Class 7 under dynamic conditions? (102) Area free from sources of water (e.g., sink/floor drains)? (106)
108	Is there hands-free access to the buffer area?
113	Are floors, walls, ceilings & fixtures smooth/impermeable and free from cracks & crevices? Does floor covering enable regular disinfection? (117)
118	Are supplies stored above the floor to permit adequate floor cleaning?
127	Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area/room and ante-area/room and between the ante-area/room and the general environment? Pressure between ISO 7 & general environment shall not be less than 0.02" water column
M	Are temperature and humidity monitored (documented) and within required range? (116) Thermometer available for cleanroom and refrigerator? (167)
Primary Engineering Control (PEC) Device - i.e., Laminar Air Flow Hood, BSC, CAI, or CACI	
126	Is the Laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02-0.05" water?
121	Is the PEC able to maintain at least ISO Class 5 conditions, while compounding sterile preparations?
M	Are hazardous drugs prepared in a Class II or III vertical flow BSC or CACI located in an ISO 7 area physically separated from other areas? (246)
M	Does the BSC or CACI have not less than 0.01" negative pressure adjacent to the positive pressure ISO 7 environment? (247)
M	Does the CAI provide unidirectional flow? (105) If the CAI or CACI is used for high risk compounded sterile preparations, then is the CAI/CACI placed in an ISO 8 environment? (104)
122	If the CAI is not required to be placed in an ISO 7 environment, does the pharmacy maintain documentation from the manufacturer?
M	PEC certified by independent contractor every 6 months & when relocated? (124) Are prefilters inspected periodically & replaced as needed? (125)
128	Are differential pressures monitored and documented at least every work shift (minimum daily) or by a continuous recording device?
Equipment and Supplies	
M	Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? (174) Does the pharmacy have lint-free towels or wipes? (177) Does the pharmacy have masks, caps, gowns with tight cuffs, shoe covers, and beard covers? (180)
M	Does pharmacy have handwashing agents w/ bactericidal action? (176) Disinfectant cleaning solutions and dedicated cleaning supplies? (175)
M	Does the pharmacy have hazardous spill kits, if applicable (179)? Appropriate disposal containers for needles and syringes? (171)
170	Does the pharmacy have sterile IPA, sterile gloves, and waterless alcohol-based surgical hand scrub?
178	Does the pharmacy have appropriate filters and filtration equipment?
181	If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy on a daily basis-Is it documented?
172	Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?
High-Risk Sterile Preparations (CSPs)	
103	If high-risk CSPs are compounded, does buffer area provide physical separation from other compounding areas?
M	Is sterility testing performed under the following conditions: CSPs prepared in groups > 25? (231) MDV prepared for multiple pts or when exposed > 12 hrs at 2-8°C before sterilized? (232) Exposed > 6 hrs at warmer than 8°C before sterilized? (233)
237	Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen free water, and then thoroughly drained or dried immediately before use for high-risk compounding?
238	Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2 micron filter to remove particulate matter? Sterilization by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer pore size filter within an ISO Class 5 environment or better
165	Are filter integrity tests being performed and documented (e.g., bubble point)?
239	Are pre-sterilization procedures (weighing & mixing) completed in an ISO Class 8 environment or better?
Library	
M	Does the pharmacy have: Reference on injectable drugs (154), Specialty Reference (155), Applicable USP Chapters (156)?

R/L Code W/N



Hazardous Sterile Preparations			
M		Do personnel wear protective apparel (242); use safety/containment techniques (243); dispose of waste appropriately (244); affix proper label (245)?	
248		If using a BSC or CACI, does pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	
249		Does pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment?	
250		Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	
Personnel Cleansing, Garbing and Hand Hygiene			
202		Does hand sanitizing and gowning occur in the ante area (outside the buffer area)? Do compounding personnel don clean non shedding gowns with sleeves that fit snugly around wrist and enclosed at the neck. Is the order of garbing appropriate? (180)	
M		Do personnel remove cosmetics (194); hand, wrist, and body jewelry or piercings (195); artificial nails? Are natural nails kept neat and trim? (196) Do personnel remove debris underneath fingernails using nail cleaner under warm water? (200)	
192		Are personnel with apparent illness or open lesions compounding sterile preparations?	
241		When personnel temporarily exit the ISO 7 environment, are re-donning procedures properly followed?	
M		Do personnel engage in proper hand hygiene? (201) Do personnel dry hands and forearms using lint free disposable towels or hand dryer? (201)	
204		Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside buffer area & prior to donning sterile gloves?	
206		Is sterile IPA applied to gloves throughout the day & when non-sterile surfaces are touched?	
Cleaning and Disinfection Procedures			
182		Does pharmacy have written procedures regarding cleaning & disinfecting (e.g., beginning of shift, every 30 minutes, before each batch, & spills)?	
230		Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	
228		Are supplies and equipment that are removed from shipping cartons wiped with a disinfecting agent - such as sterile 70% IPA?	
M		Are all areas properly cleaned? Daily (floors, DCA)? (226) Weekly, Monthly (walls, ceilings, shelving)? (227) Does pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, and name(s) of person(s) carrying out the cleaning)? (229)	
Environmental Sampling			
271		Is surface sampling conducted in all ISO classified areas on a periodic basis? Are these results evaluated and addressed? (270) i.e. Action Levels followed?	
M		Is viable air sampling performed? (272) And documented by properly trained individuals for all risk levels every 6 months? (273)	
Records of Compounded Sterile Preparations			
252		Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?	
M		Do records include: date (253); formula (254); who prepared (255); who checked (256); quantity (257); container used and number of units prepared (258); criteria for BUD (259); and documentation of performance of quality control procedures? (260) Other?	
M		Are batch compounding records complete? (261) Are master worksheets developed and approved by RPh (262)?	
General Operational Requirements			
166		Is RPh available at all times (24/7)?	
M		Are written SOPs followed to ensure accountability, accuracy, quality, safety, and uniformity? (187) Does pharmacy have all required written procedures (e.g., pharmaceutical care services, viable air sampling plan, and recalls)? Does pharmacy follow recall procedures? (188)	
158		If pharmacy compounds commercially available products, does pharmacy meet requirements for such compounding?	
275		Does pharmacy dispense prescriptions to patients in other states without proper licensure in those states?	
Office Use Compounding/Distribution			
163		Does pharmacy have written agreement with prescriber? Does written agreement meet all requirements?	
162		If pharmacy is distributing compounded sterile preparations to another pharmacy, does pharmacy meet requirements for such distribution?	
Quality Control and Verification of Compounding Accuracy			
207		Does a RPh review all compounding records for accuracy and perform final check? Are periodic in-process checks defined in written procedures? (185)	
191		Are all drug components manufactured in an FDA-registered facility? Are Certificates of Analysis available, if applicable?	
Label			
M		Is CSP properly labeled to include: generic name (209); compounded by pharmacy (210); BUD (211)? If prepared in batch, do labels contain: unique lot# (213); quantity (214); cautionary statements (215); and device-specific instructions, if applicable (216)?	
220		Are CSPs assigned a beyond use date that is based upon the specified labeling for the drug, appropriate literature sources, and/or direct testing?	
Training and Competency Testing			
129		Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	
130		Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	
142	✓	Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation and testing (e.g., media fill testing, gloved fingertip/thumb testing)? Does pharmacy have an on-the-job training program?	
144	✓	Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel?	



Ordered to

Remarks

Cell 4434-NI. Ensure delivered prescriptions include the following statements: "Complaints Concerning: 1891.3 Pa (D)(A)(ii) and "Written Information..." 291.33(c)(1)(F)(iii)  
 Cell 1942. Ensure prescription drug label includes brand name, generic name, strength, and name of prescriber.  
 Cell 45-NI. Ensure prescription label bears a statement indicating it is a compounded product. Ensure label bears "For Office Use Only - Not for Resale."  
 Cell 195-NI. Ensure SOPs address RPh in process checks of office use products

Action Taken

See warning notices

- (1) ☒ Inspection  
 (2) ☐ Pre-Inspection  
 (3) ☐ Partial Inspection  
 (4) ☐ Visit  
 (5) ☐ Other \_\_\_\_\_

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Adrian Medina  
 Agent of the Texas State Board of Pharmacy

1/9/2020  
 Date

4:30pm  
 Time of Exit

Authorized Individual for the Pharmacy

James Thomas Astell, Jr. RPh  
 Printed Name and Title of Authorized Individual



Phcy. Lic. # 19414  
 Expiration Date: 2/20/19

**NOTICE OF INSPECTION**  
 Texas State Board of Pharmacy  
 333 Guadalupe Street, Suite 3-500  
 Austin, Texas 78701-3942  
 (512) 305-8000

☐ Compliance  
☒ Investigation

Name of Individual <u>Patrick Hagan</u>	Title <u>RPh</u>	R.Ph. Lic. # <u>54889</u>	Expires <u>12/18</u>
Name of Facility <u>Axlell Rite-Value Pharmacy, Inc</u>		Class of Pharmacy License <u>A S</u>	
Address <u>304 1/2 Charlie Dr.</u>			
City/State <u>Wintersboro, TX</u>	Zip <u>76773</u>	Phone # <u>(817) 564-3216</u>	
DEA Registration # <u>BA 6242767</u>		Expiration Date <u>6/20</u>	
Date <u>Jan 10, 2018</u>		Time of Entry <u>9:15am</u>	

**PURPOSE OF INSPECTION**

- ☐ Routine  
☐ New Pharmacy  
☐ Complaint  
☐ Follow-up to Warning Notice  
☐ Follow-up to Disciplinary Order  
☐ Pre-Inspection  
☐ Change of Ownership  
☐ Follow-up to Complaint  
☐ Follow-up to Theft/Loss Report  
☒ Other Continue Inspection from 1/9/18  
☐ Rank Change  
☐ Reverse Rank Change  
☐ Licensee Request  
☐ Sterile Compounding (High Risk)

**ACKNOWLEDGEMENT**

This is to acknowledge that Texas State Board of Pharmacy Agent Adrian N. Bauer has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

- I am the RPh for the above-described facility;
- I have read this Notice of Inspection and understand its contents and purpose;
- I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
- I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
- I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Signature [Signature]

Witnesses:

Signature [Signature]

Signature \_\_\_\_\_



TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT  
CLASS: A A-S B C C-S (BEDS ) D Other

CLASS: A A-S B C C-S (BEDS) D Other

Name of Pharmacy

**Pharmacist in Charge**

**Persepolis**

**TEEP License #**

14

11

11

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11

**KEY:** Circled items need improvement. - Items in Column One Refer to Legal Division (R/L) for review and possible discipline

• **Items in Column Two receive a Warning Notice (W/N).**

For an explanation of specific violations noted, refer to remarks section of inspection report

REL	W/N	REL	W/N	REL	W/N
1				10	
2		15		35	✓
3		60		67	
4		68		21	
5	✓	31		22	
6		17		82	
7		18		83	
8		46		84	
9		54		16	
36		24		27	
39		30	✓	51	
38		86		75	
43	✓	19		70	
47		25		71	
48		32		72	
53		40		81	
57		26		85	
59		37	✓	87	
61		45		88	
62		44		89	
65		55		28	
68		78		29	
76		80		52	
34	✓	56		63	
79		50		64	
90	✓	49		91	
92		33		73	



Transcript:

Remarks

Code 0102: Ensure reference library is available to all RPhs  
 Code 14N2: Ensure proper written controlled substance prescriptions  
 bear the prescriber's manual signature. Ensure prescriptions  
 obtained out by NP/PA, bear name of NP/PA & their  
 supervising physician, and if a c/s both DEA #s.  
 Code 21N2: Ensure all dispensing RPhs dispensing log.  
 Code 60N2: Ensure documentation of initial tech training  
 is available for each technician.  
 Code 200N2: Ensure staff use a nail cleaner.  
 Code 204N2: Ensure staff apply alcohol scrub to hands  
 prior to donning sterile gloves over inside buffer room.  
 Code 209N2: Cleaning log shall bear time and each  
 cleaning.  
 Code 163N2: Ensure written agreements are available  
 for both Pharmacist/Vet.

Action Taken

See Warning Notices

- (1) ☒ Inspection  
 (2) ☐ Pre-Inspection  
 (3) ☐ Partial Inspection  
 (4) ☐ Visit  
 (5) ☐ Other \_\_\_\_\_

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

1/10/2018

Date

Time of Exit

Printed Name and Title of Authorized Individual

Dr. David P. Miller, President

09/12

Texas State Board of Pharmacy

last page





**ARL BIO PHARMA**  
 840 RESEARCH PARKWAY, SUITE 546  
 OKLAHOMA CITY, OK 73104  
 PHONE (405) 271-1144  
 FAX (405) 271-1174

## Certificate Of Analysis

**CLIENT:** Astell Rite-Value Pharmacy, Inc.  
 304 1/2 Charlie Drive  
 Whitesboro, TX 76273

*made on 12-8-16*  
*Exp date 1-7-17*  
*before test results*

**ARL #:** 392811-01

**LOT #:** 677285323

**DESCRIPTION:** Tropicamide/Phenylephrine 1%/2.5% Opth Solution

**DATE RECEIVED:** 02/01/2017

**STORAGE:** 20°C to 25°C (68°F to 77°F)

**CONTAINER:** Two 3 mL dropper bottles w/3 mL each in a brown bag

*(With Exp)*  
*before test results*

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Phenylephrine HCl Specifications = 90% - 115%	2.5	%	2.464	98.6%	HPLC	2/2/2017
Tropicamide Specifications = 90% - 110%	1.0	%	0.9726	97.3%	HPLC	2/6/2017

The analyses referenced in this report are for non-cGMP purpose only. The method(s) used for testing are not validated. Specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

*WTY*

Wen Yang - Chemist

02/06/2017

Date Reported

ARL Form QLF-078-V4 03/05/2010



## Logged Formula Worksheet

01/09/2018 2:53:22 PM

Page 1


 AXTELL-RITE VALUE PHARMACY  
 304 1st Chance Dr. PO BOX 9  
 WHITEBORO, TX 76273 PH: (800) 554-3216

## TROPICAMIDE/PHENYLEPHRINE HCL 1%/2.5% OPTH SOLUTIO

Tall Man:

 Flavor:  
 Quantity made: 15 ML

 Batch yield: 15 000  
 Qty remaining: 15 000

 Schedule:  
 PCCA ID  
 Route of admin:
NIOSH Hazard ☐
 Active ☒  
 Formula ID: 0172  
 Log ID: 00007

 Date made: 12/08/2016  
 Lot number: 12082016@21  
 Beyond use date: 01/07/2017 5:44 PM  
 60 days after compounding date

 Pharmacist: TOM AXTELL  
 Technician: SEE INITIALS  
 Misc. Note:  
 NDC1:

Time to make: 0

Picture

 Description:  
 Packaging:  
 Equipment:

 Labeling:  
 Stability information:

Chemicals	NIOSH Hazard	Schedule	Quantity used	QS (balance)
1 TROPICAMIDE USP POWDER	<input type="checkbox"/>	L	0.15 GM	<input type="checkbox"/>
Lot #: 114419/F Hazard code: H 1	Mfg: MEDISCA, INC. Volume: Potency:	CAS: 1508-75-4 Stock: 1.101	Whlar: MEDISCA, INC. ChemInvID: 0	NDC
Balance info: Purity:			Each ML contains 0.01 GM or 1%	NDC
2 PHENYLEPHRINE HCL USP POWDER	<input type="checkbox"/>		0.375 GM	<input type="checkbox"/>
PHENYLEPHRINE HCL Lot #: 1506150019 Hazard code: -	Mfg: LETCO Volume: Potency:	CAS: 1508-75-4 Stock: 15.25	Whlar: LETCO COMPANIES ChemInvID: 0	NDC
Balance info: Purity:			Each ML contains 0.025 GM or 2.5%	NDC
3 SODIUM METABISULFITE 1% (W/V) WATER FOR INJ	<input type="checkbox"/>		1.5 ML	<input type="checkbox"/>
Lot #: 012345 Hazard code: H F PH PR	Mfg: MEDISCA, INC. Volume: Potency:	CAS: 515 Stock: 315	Whlar: MEDISCA, INC. ChemInvID: 0	NDC
Balance info: Purity:			Each ML contains 0.1 ML or 10%	NDC
4 EDETATE DISODIUM 1% (W/V) WATER FOR INJEC	<input type="checkbox"/>		0.75 ML	<input type="checkbox"/>
Lot #: 85747 Hazard code: H F PH PR	Mfg: MEDISCA, INC. Volume: Potency:	CAS: 49.25 Stock: 49.25	Whlar: MEDISCA, INC. ChemInvID: 0	NDC
Balance info: Purity:			Each ML contains 0.05 ML or 5%	NDC
5 BENZALKONIUM CHLORIDE 1% (W/V) WATER FOR	<input type="checkbox"/>		0.3 ML	<input type="checkbox"/>
Lot #: C148206 Hazard code: H F PH PR	Mfg: PROFESSION Volume: Potency:	CAS: 85.075 Stock: 85.075	Whlar: PROFESSIONAL COMPOUN ChemInvID: 0	NDC
Balance info: Purity:			Each ML contains 0.02 ML or 2%	NDC

 Date entered: 12/08/2016 5:44:19 PM Last modified: 01/09/2018 2:55:33 PM by: AXTELL TOM/SEE INITIALS.  
 Checked by: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Logged Formula Worksheet

01/09/2018 2:53:22 PM

Page 2



AXTELL/RITE VALUE PHARMACY

304 1/2 Charlie Dr. PO BOX 9

WHITESBORO, TX 76273 Ph: (803) 564-3216

TROPICAMIDE/PHENYLEPHRINE HCL 1%/2.5% OPTH SOLUTIO

Tab Man:

Flavor:  
Quantity made: 15 MLBatch yield: 15 000  
Qty remaining: 15 000Schedule  
PCCA IDNIOSH Hazard ☐Active ☒  
Formula ID: 6772  
Log ID: 66323

Route of admin:

## Chemicals NIOSH Hazard Schedule Quantity used QS (balance)

1 HYDROCHLORIC ACID 10% INJECTABLE ☐ 0.15 GTTS ☐  
 Lot # N/A CAS [REDACTED] Stock 102 971 8113 NDC  
 Hazard code: H F PH PR Volume: Potency: QS amount: Whislr STORE  
 ChemInviD0  
 Purity: Each ML contains 0.01 GTTS or 0.05%  
 Balance info: NDC

2 SODIUM HYDROXIDE 10% SOLUTION SOLUTION ☐ 0.15 GTTS ☐  
 Lot # N/A CAS [REDACTED] Stock 1 018 667 561 82 NDC  
 Hazard code: H F PH PR Volume: Potency: QS amount: Whislr Store  
 ChemInviD0  
 Purity: Each ML contains 0.01 GTTS or 0.05%  
 Balance info: NDC

3 WATER (STERILE FOR INJECTION) INJECTABLE ☐ 15 ML ☒  
 Lot # 26-070-JT CAS [REDACTED] Stock 28 498 6398 NDC  
 Hazard code: H F PH PR Volume: Potency: QS amount: 0.10 Whislr PROFESSIONAL COMPOUN  
 ChemInviD0  
 Purity: Each ML contains 1 ML or 100%  
 Balance info: NDC

## Log Instructions &amp; Notes

Originally made as: 15 TROPICAMIDE/PHENYLEPHRINE HCL 1%/2.5% OPTH SOLUTIO

Calculated lot number: 12082018@21 Beyond use date: 01/07/2017

## FORMULA INSTRUCTIONS

- 1 Dissolve Phenylephrine in Water for injection, (Use approximately 70% of water for injection)
- 2 Adjust the pH to 4-4.5 with hydrochloric acid or sodium hydroxide
- 3 Dissolve Tropicamide in Step 2
- 4 Add Sodium Metabisulfite 1%, Edetate Disodium 1% and Benzalkonium Chloride 1% to Step 3 & mix well
- 5 Adjust the pH to 4-4.5
- 6 Bring to final volume with water for injection and mix thoroughly
- 7 Filter with a 0.22 micron filter and place in sterile droptainer

\*\*\* PROTECT FROM LIGHT &amp; STORE ROOM TEMP\*\*\*

Date entered: 12/08/2016 5:44:19 PM Last modified: 01/09/2018 2:55:33 PM by: AXTELL, TOM/SEE INITIALS.

Checked by: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**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 03548**)  
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: Braun Pharma, LLC

Physical Address: 2060 N. Clark St., Chicago IL 60614

Mailing Address: 2060 N. Clark St.

City: Chicago State: Illinois Zip Code: 60614

Telephone: 773-549-0634 Fax: 773-549-2753

Toll Free Number: 877-549-6907 (Required per NAC 639.708)

E-mail: braundrug@aol.com Website: www.braunrx.com

Managing Pharmacist: Sharron Seymour License Number: 051.289557

**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.

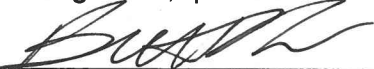
Within the last five (5) years:

- 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

Brett Pine

Print Name of Authorized Person

5-30-2018

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: Illinois  
 Parent Company if any: Optio Rx, LLC - 100% Member  
 Mailing Address: 2060 N. Clark St.  
 City: Chicago State: Illinois Zip: 60614  
 Telephone: 773-549-0634 Fax: 773-549-2753  
 Contact Person: Sharron Seymour

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation? N/A - LLC
  - a) N/A - LLC  

Name
Address
  - b) \_\_\_\_\_  

Name
Address
  - c) \_\_\_\_\_  

Name
Address
  - d) \_\_\_\_\_  

Name
Address
- 2) Provide the number of shares issued by the corporation. N/A - LLC
- 3) What was the price paid per share? N/A - LLC
- 4) What date did the corporation actually receive the cash assets? N/A - LLC
- 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 - LLC %: \_\_\_\_\_  
 Name: N/A - LLC %: \_\_\_\_\_

**Hours of Operation for the pharmacy:**

Monday thru Friday <u>9</u> am <u>7</u> pm	Saturday <u>9</u> am <u>4</u> pm
Sunday <u>Closed</u> am <u>Closed</u> 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, Brett Pine

Responsible Person of Braun Pharma, 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

Brett Pine

Print Name of Authorized Person

5-30-2018

Date

# AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Illinois )  
Cook ) ss.  
COUNTY )

I, Brett Pine, 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 for Braun Pharma, 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, Brett Pine, 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  
30 day of May, 2018.

Christine M. Solorio  
NOTARY PUBLIC

Brett Pine  
Name

*Brett Pine*





## Braun Pharma, LLC

### Officers:

Brett Pine – President  
2060 N. Clark Street, Chicago, IL 60614

### Owners:

OptioRX, LLC – 100% Member  
1247 Waukegan Rd, Glenview, IL 60015

**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 02236  
 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: Wedgewood Village Pharmacy, LLC d/b/a Diamondback Drugs

Physical Address: 7631 E. Indian School Road Ste. 105, Scottsdale, AZ 85251

Mailing Address: Same as above

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Telephone: 480-946-2223 Fax: 866-646-2235

Toll Free Number: 866-646-2223 (Required per NAC 639.708)

E-mail: kory.muto@diamondbackdrugs.com Website: www.diamondbackdrugs.com

Managing Pharmacist: Kory Muto License Number: AZ--S020692

**TYPE OF PHARMACY AND**

**SERVICES PROVIDED**

Yes/No

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

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.

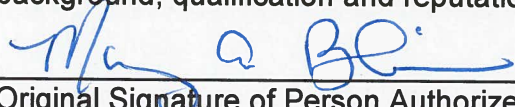
Within the last five (5) years:

- 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

\_\_\_\_\_  
 Marcy Bliss  
 Print Name of Authorized Person

6/7/18  
 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: Delaware

Parent Company if any: See attached. (Owner/Officer information)

Mailing Address: 405 Heron Drive, Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Fax: 856-832-1431

Contact Person: Marcy Bliss - CEO/President/Secretary/Treasurer

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
  - d) N/A  

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

\*\*Not applicable

List any physician shareholders and percentage of ownership.

Name: None. %:

Name:  %:

**Hours of Operation for the pharmacy:**

Monday thru Friday 6 am 7 pm                      Saturday 7 am 2 pm

Sunday N/A 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

**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.

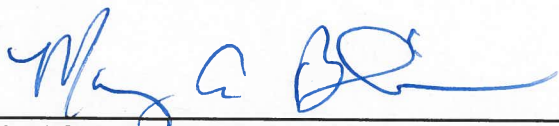
List of officers and directors

STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I,     Marcy Ann Bliss      
Responsible Person of     Wedgewood Village Pharmacy, LLC d/b/a Diamondback Drugs      
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

    Marcy Ann Bliss - CEO/President/Treasurer/Secretary    

Print Name of Authorized Person

    6/7/18    

Date



# AFFIDAVIT for Out-of-State Pharmacy License

STATE OF \_\_\_\_\_ )  
 ) ss.  
 \_\_\_\_\_ COUNTY )

I, Marcy Ann Bliss, 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 CEO/President/Treasurer/ for Wedgewood Village Pharmacy, (the Secretary LLC d/b/a Diamondback Drugs 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.

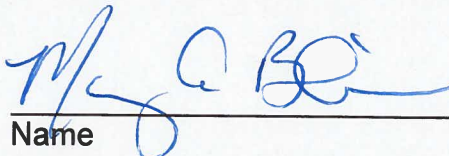
3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

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, Marcy Ann Bliss, 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  
7 day of June, 2018.

  
 NOTARY PUBLIC

BRIDGETTE A CONNOR  
 Commission # 50048680  
 Notary Public, State of New Jersey  
 My Commission Expires  
 October 31, 2021



# CORPORATE OWNER/OFFICER INFORMATION

## WEDGEWOOD VILLAGE PHARMACY, LLC CORPORATE INFORMATION

On or about July 31, 2018, Wedgewood Village Pharmacy Intermediate Holdings, LLC (“*Wedgewood Holdings*”) will purchase all of the issued and outstanding stock of TW Diamondback Holdings Corp. (the “*Company*”). The Company owns 100% of the limited liability company interests of Diamondback Drugs of Delaware, L.L.C. (“*Diamondback Drugs*”), which operates a traditional compounding pharmacy in Scottsdale, Arizona. In connection with the stock purchase, Diamondback Drugs will merge into Wedgewood Village Pharmacy, LLC (“*Wedgewood*”), a subsidiary of Wedgewood Holdings, and all of Diamondback Drugs’ assets, liabilities and operations will become vested in Wedgewood, and the separate existence of Diamondback Drugs shall cease. Wedgewood will continue to operate Diamondback Drugs as Wedgewood Village Pharmacy, LLC d/b/a Diamondback Drugs. Wedgewood will also continue to operate its pharmacy, Wedgewood Pharmacy, in Swedesboro, NJ. The ownership structure of Wedgewood Village Pharmacy, LLC after this transaction will be as follows:

Wedgewood Village Pharmacy, LLC will have two members:

1. Wedgewood Village Pharmacy Intermediate Holdings, LLC (56.5%)

c/o New Harbor Capital  
500 West Madison, Suite 2830  
Chicago, IL 60661  
(312) 876-8605

2. TW Diamondback Holdings Corp. (43.5%)

c/o Tailwind Management LP  
485 Lexington Avenue, 23rd Floor  
New York, NY 10017  
(212) 271-3800

*\*all stock of TW Diamondback Holdings Corp. is held by Wedgewood Village Pharmacy Intermediate Holdings, LLC.*

Wedgewood Village Pharmacy, LLC will have the following four officers:

1. Marcy Ann Bliss

CEO, President, Treasurer and Secretary

2. Thomas Joseph Formolo

Assistant Secretary

3. Jocelyn Rose Stanley

Assistant Secretary

4. Edward Michael Lhee

Assistant Secretary

RESPONSE TO DISCIPLINARY  
QUESTION #3

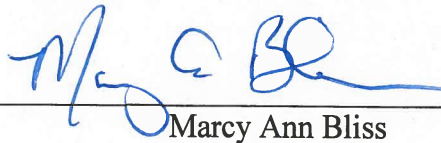
*Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?*

First, Wedgewood Village Pharmacy, LLC ("*Wedgewood*") wishes to clarify that the answer to this question is "No" with respect to Diamondback Drugs of Delaware, LLC, which currently holds the license that is the subject of this change-of-ownership application, and its compounding pharmacy in Scottsdale, Arizona. However, because Wedgewood currently operates another compounding pharmacy in Swedesboro, New Jersey called Wedgewood Pharmacy, out of an abundance of caution and in the interest of full disclosure, Wedgewood wishes to divulge the following related to its other facility in New Jersey:

On March 19, 2015, Wedgewood finalized a consent order with the Minnesota Board of Pharmacy ("*Minnesota Consent Order*"), a copy of which is attached hereto. Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs ("*Michigan LARA*") and the Alabama Board of Pharmacy ("*Alabama BOP*") to resolve "sister state" actions that arose out of the Minnesota Consent Order. The Michigan and Alabama consent orders are attached hereto.

The facts underlying the Minnesota Consent Order are as follows. Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a \$10,000 civil penalty but admitted no wrongdoing. Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama consent order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibition on "sister state" actions.

Finally, on February 27, 2018, Wedgewood was issued an administrative citation and a \$1,000 fine as a result of an investigation by the California Board of Pharmacy (the "*California Board*"). The citation is not a discipline by the California Board and payment of the fine does not constitute any admission of any wrongdoing by Wedgewood. A copy of the citation is attached hereto.

  
\_\_\_\_\_  
Marcy Ann Bliss

Date: 6/2/18



# 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](mailto:Pharmacy.Board@state.mn.us)

Web Site: [www.pharmacy.state.mn.us](http://www.pharmacy.state.mn.us)

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

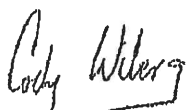
Gregory P. Bulinski  
Attorney  
Bassford Remele  
33 South Sixth Street, Suite 3800  
Minneapolis, MN 55402-3707

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 Wiberger, 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. Pontilces, 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

M. Bliss  
MARCY BLISS, 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 21<sup>st</sup> day of January, 2015.

MINNESOTA BOARD  
OF PHARMACY

Cody Wiberg

CODY WIBERG  
Executive Director

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: Mr. A. B.

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

James S. Ward  
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

Non-Resident Pharmacy  
Permit Number: 112625

BEFORE THE ALABAMA STATE  
BOARD OF PHARMACY

CASE NO: 18-L-0086

## STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: 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 Berglund and Bob Goeitz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Hartford Remick and Rachel O. Fontikes, 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 impose 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.

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 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 BLISS, 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 21<sup>st</sup> 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 Gostz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullinski, Esq., of Bassford Remole 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, 2012, 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. BO  
MARCY BLESS, PRESIDENT  
Wedgewood

Karen Bergerud  
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 21<sup>st</sup> 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. Elzondo  
Kelly K. Elzondo (B45584)  
Assistant Attorney General  
Attorney for Complainant  
Dated: 5-1-2016

AGREED TO BY:

Alison Lylich  
Alison Lylich, Pharmacist-in-Charge  
Wedgewood Village Pharmacy  
Respondent  
Dated: 5/31/16

Alan T. Rogalski  
Alan T. Rogalski (B44580)  
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

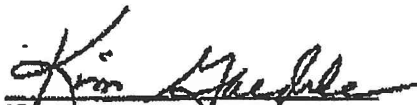
The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 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 306, 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 30870, 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 53-16-137238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

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: 3-1-2016

Alison Lynch  
Alison Lynch, Pharmacist-in-Charge  
Wedgewood Village Pharmacy  
Respondent  
Dated: 3/31/16

Alan T. Rogalski  
Alan T. Rogalski (P4550)  
Attorney for Respondent  
Dated: 3/31/2016



**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.

**February 27, 2018**

**CERTIFIED MAIL**

WEDGEWOOD VILLAGE PHARMACY LLC  
ATTN: MARCY ANN BLISS, CEO  
405 HERON DR SUITE 200  
SWEDESBORO, NJ 08085

Tony J. Park  
Attorney at Law  
49 Discovery, Suite 240  
Irvine, CA 92618

**RE: CI 2017 77042**  
**WEDGEWOOD VILLAGE PHARMACY LLC**  
**NRP 1826**

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation and Fine, CI 2017 77042 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

Failure to pay any imposed fine(s) within 30 days of the date of this letter may result in disciplinary action being taken. The timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

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).

Please contact Associate Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely

A handwritten signature in black ink that reads "Virginia Herold". The signature is fluid and cursive, with the first name "Virginia" being more prominent than the last name "Herold".

Virginia Herold  
Executive Officer  
Board of Pharmacy

**DECLARATION OF SERVICE BY CERTIFIED MAIL****RE: WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826****Citation 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 February 27, 2018, I served the attached:

Decision letter from office conference.

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, addresses as follows:

**NAME****CERTIFIED MAIL NO**

WEDGEWOOD VILLAGE PHARMACY LLC  
ATTN: MARCY ANN BLISS, CEO  
405 HERON DR SUITE 200  
SWEDESBORO, NJ 08085

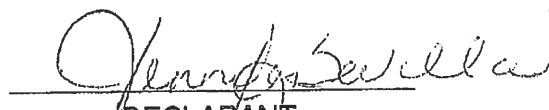
7017 0530 0001 1516 3558

Tony J. Park  
Attorney at Law  
49 Discovery, Suite 240  
Irvine, CA 92618

7017 0530 0001 1516 3565

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 27, 2018, at Sacramento, California.

  
\_\_\_\_\_  
DECLARANT  
Jennifer Sevilla  
Associate Enforcement Analyst



**BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**

**CITATION AND FINE**

<b>Citation Number</b>	<b>Name, License No</b>
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

**JURISDICTION:** Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

<b>VIOLATION CODE SECTION</b>	<b>OFFENSE</b>	<b>AMT OF FINE</b>
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

# 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 \_\_\_\_\_)  
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: Pharmaco Inc., dba Premier Infusion Care

Physical Address: 19500 Normandie Ave, Torrance, CA 90502

Mailing Address: 19500 Normandie Ave

City: Torrance State: CA Zip Code: 90502

Telephone: (866) 365-2525 Fax: (866) 383-2525

Toll Free Number: (866) 365-2525 (Required per NAC 639.708)

E-mail: contracting@premierinfusion.com Website: www.premierinfusion.com

Managing Pharmacist: John K. Rice, Rph, MBA License Number: 33317

### TYPE OF PHARMACY AND

### SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail  
☐ ☒ Hospital (# beds \_\_\_\_\_)  
☐ ☒ Internet  
☐ ☒ Nuclear  
☐ ☒ Ambulatory Surgery Center  
☐ ☒ Community

☒ ☐ Other: Home infusion, specialty Pharmacy,

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,**

101341

# 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

John K. Rice, PPh, MBA

Print Name of Authorized Person

Date

6/12/18

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: California  
 Parent Company if any: Pharmaco, Inc  
 Mailing Address: 19500 Normandie Ave  
 City: Torrance State: CA Zip: 90502  
 Telephone: (806) 305-2525 Fax: (806) 383-2525  
 Contact Person: Sina Refua, Pharm D.

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>Saman Refua</u>	<u>Alonzo Ave, Encino, CA 91316</u>
	Name	Address
b)	<u>John K. Rice, Rph, MBA</u>	<u>Granado Drive, Rancho Palos Verde, CA 90275</u>
	Name	Address
c)	<u>Sina Refua, Pharm D.</u>	<u>Century Park East #1912N, Los Angeles, CA 90067</u>
	Name	Address
d)	<u>_____</u>	<u>_____</u>
	Name	Address

2) Provide the number of shares issued by the corporation. 1209.5

3) What was the price paid per share? \$300,000 \$248.04 PER SHARE

4) What date did the corporation actually receive the cash assets? 2-2-2004

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

List any physician shareholders and percentage of ownership.

Name: \_\_\_\_\_ %: \_\_\_\_\_  
 Name: \_\_\_\_\_ %: \_\_\_\_\_

**Hours of Operation for the pharmacy:**

Monday thru Friday 8:30 am 7 pm      Saturday 9 am 5 pm  
 Sunday 10 am 6 pm      24 Hours on call

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

**PHARMACO, INC.**  
**A CALIFORNIA CORPORATION DBA PREMIER INFUSION CARE**  
**AS OF JUNE 8, 2018**

**STOCK LEDGER**

Name of Shareholder	Place of Residence	From Whom	Certificates Issued		Certificates Surrendered		Consideration	Date of Transfer
			No.	No. of Shares	No.	No. of Shares		
<i>All previous stock certificates Nos. 1-25 for Pharmaco, Inc. have been cancelled as of October 22, 2012 and share certificates re-issued to current shareholders as set forth below, representing 100% of the issued and outstanding shares of Pharmaco, Inc.</i>								
Saman Refua	CA	Original Issuance (Replacement Certificate)	26	737.08	—	—	\$248.04/share	Original issuance on 2/2/2004; replacement certificate No. 26 issued on 10/22/2012
John K. and Deborah Lee Rice Family Trust Dated June 17, 2008	CA	Original Issuance (Replacement Certificate)	27	333.9	—	—	\$248.04/share	Original issuance on 2/2/2004; replacement certificate No. 26 issued on 10/22/2012
Sina Refua	CA	Original Issuance (Replacement Certificate)	28	138.52	—	—	\$248.04/share	Original issuance on 2/2/2004; replacement certificate No. 26 issued on 10/22/2012
Maria Lozzano	CA	Original Issuance (Replacement Certificate)	29	13	29	13	\$39,572 (\$3,044/share)	CANCELLED Original issuance on 10/22/2012; Certificate No. 29 cancelled on 2/1/2018 in connection with equity buy-out for all 13 shares

STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, John K. Rice, RPh, MBA

Responsible Person of Pharmaco, Inc. dba Premier Infusion care

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.

John K. Rice, RPh

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

John K. Rice, RPh, MBA

Print Name of Authorized Person

6/18/18

Date

# AFFIDAVIT for Out-of-State Pharmacy License

STATE OF \_\_\_\_\_ )  
 \_\_\_\_\_ ) ss.  
 \_\_\_\_\_ COUNTY )

I, John K. Rice, RPh, MBA, 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 Pharmaco, Inc., dba Premier Infusion 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, John K. Rice, RPh, MBA, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

John K. Rice  
 Name

SUBSCRIBED AND SWORN TO  
 before me, a notary public this  
 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_  
 NOTARY PUBLIC

See attached



**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)

*(The following section is crossed out with a large X)*

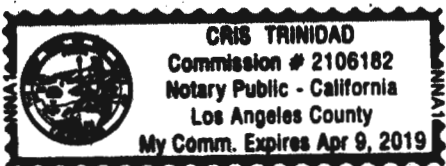
\_\_\_\_\_  
 Signature of Document Signer No. 1

\_\_\_\_\_  
 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 Los Angeles

Subscribed and ~~sworn~~ to (or affirmed) before me  
 on this 12<sup>th</sup> day of June, 2018,  
 by John K. Rice  
 (1) \_\_\_\_\_



(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)*  
 Signature of Notary Public

Seal  
 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: Affidavit for out-of-state Pharmacy License Document Date: June 12, 2018  
 Number of Pages: 1 Signer(s) Other Than Named Above: No other Signers



# 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: JCB Laboratories, LLC

Physical Address: 7335 W. 33rd St. N.

City: Wichita State: KS Zip Code: 67205

Telephone: (316) 773-0405 Fax: (316) 773-0406

Toll Free Number: (877) 405-8066 (Required per NAC 639.708)

E-mail: licensing@jcblabs.com, tflinkman@jcblabs.com Website: www.jcblabs.com

Supervising Pharmacist: Tanis Flinkman Nevada License #: ~~64028~~ 19859 ✓

### 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): 01-0744677Please provide the name of the facility as registered with the FDA and the registration number:  
JCB Laboratories; 177167470Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.  

---

Please provide the name and Nevada license number of the supervising pharmacist:

Name: Tanis Flinkman Nevada License Number: 64028A 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

Alexander Govze

Print Name of Authorized Person

6/13/2018

Date

## APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

**OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**State of Incorporation: DelawareParent Company if any: Fagron Holding USA, LLCAddress: 2400 Pilot Knob RoadCity: St. Paul State: MN Zip: 55120Telephone: (651) 681-9517 Fax: (651) 681-9001Contact Person: Dolly Bergan

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. JCB Laboratories is an LLC. Please see attached.

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

**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

GMP

**Fagron  
Sterile  
Services****NON-PUBLICLY TRADED LIMITED LIABILITY COMPANY INFORMATION****OWNER:** FAGRON HOLDING USA, LLC**BUSINESS ADDRESS:** 2400 PILOT KNOB RD., #200, ST. PAUL, MN 55120**TELEPHONE NUMBER:** 651-681-9517**FORMED IN THE STATE OF:** DELAWARE**INCORPORATION DATE:** MAY 10, 2010**FEIN:** 42-1771479

Please note that Fagron Holding USA, LLC is a holding company and that JCB Laboratories LLC has its own officers as indicated to run the business with a FEIN of 01-0744677 and was formed in Kansas on 09/24/2002.

**FULL NAME/TITLE:** Alexander Govze, Officer**BUSINESS ADDRESS:** 2400 Pilot Knob Road, St. Paul, MN 55120**TELEPHONE NUMBER:** (612) 810-8388**FULL NAME/TITLE:** Jason McGuire, Officer**BUSINESS ADDRESS:** 8710 E 34th St N, Wichita, KS 67226**TELEPHONE NUMBER:** (316) 773-0405

JCB Laboratories



**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: Wells Pharmacy Network, LLC.

Physical Address: 450 US HWY 51 BYP N

City: Dyersburg State: TN Zip Code: 38024

Telephone: (731) 882-7000 Fax: (731) 882-7100

Toll Free Number: (800) 852-5689 (Required per NAC 639.708)

E-mail: RegulatoryAffairsTenneWellsRx.com Website: www.WellsRx.com

Supervising Pharmacist: John Guthrie Nevada License #: 19762 ✓

**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): 3012526962

Please provide the name of the facility as registered with the FDA and the registration number:

Wells Pharmacy Network, LLC.

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.

NIA

Please provide the name and Nevada license number of the supervising pharmacist:

Name: John Guthrie Nevada License Number: 19762A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: NIAThis 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

WILLIAM E. MCKILLED

Print Name of Authorized Person

3/22/2018

Date



## APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: FL  
 Parent Company if any: NIA  
 Address: 3420 Fairlane Farms Rd Suite 300  
 City: Wellington State: FL Zip: 33414  
 Telephone: (561) 793-1568 Fax: (561) 223-3885  
 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)	<u>Shirley Ann Eis</u>	<u>364 Woodbine Rd Stamford, CT 06903</u>
	Name	Address
b)	<u>Rachel Shapiro McKim</u>	<u>145 Corte Madera Center Suite 169 Corte Madera, CA 94925</u>
	Name	Address
c)	<u>Douglas Keith Garvey</u>	<u>3420 Fairlane Farms Rd Ste 300 Wellington FL 33414</u>
	Name	Address
d)	<u>William Edward McMillen</u>	<u>22107 Martella Ave Boca Raton, FL 33433</u>
	Name	Address

- 2) Provide the number of shares issued by the corporation. 3,212,630
- 3) What was the price paid per share? .01 per share par value
- 4) What date did the corporation actually receive the cash assets? Began September 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



STATE OF TENNESSEE  
DEPARTMENT OF HEALTH  
DIVISION OF HEALTH LICENSURE AND REGULATION  
OFFICE OF HEALTH RELATED BOARDS  
665 Mainstream Drive, Second Floor  
Nashville, TN 37243  
<http://tn.gov/health>

Tennessee Board of Pharmacy  
Manufacturer/Wholesaler/Distributor  
1-800-778-4123 or 6152531299

June 7, 2017

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION: Manufacturer/Wholesaler/Distributor  
NAME: WELLS PHARMACY NETWORK, LLC.  
ADDRESS: 450 US Hwy 51 BYP N, Dyersburg TN 38024  
LICENSE NUMBER: 4828  
ISSUE DATE: May 05, 2017  
EXPIRATION DATE: May 31, 2019  
CURRENT STATUS: Licensed  
STATUS DATE: May 05, 2017  
SPECIAL ENDORSEMENT: Controlled Substance Registration  
Sterile Compounding



COMMENTS: There is no derogatory information in our files concerning this facility.

Sincerely,

*Keshia Evans*

Tennessee Board of Pharmacy

VERFFACLTU



450 US Highway 51 Bypass North | Dyersburg, TN 38024 | 800.852.5689

#### Disciplinary Explanation

On October 24<sup>th</sup>, 2014 Wells Pharmacy Network LLC., Ocala, FL accepted a consent agreement with a warning and fine from the Maine Board of Pharmacy for failure to notify of PIC change within 7 days.

On March 31<sup>st</sup>, 2015 Wells Pharmacy Network LLC., Ocala, FL accepted a consent agreement from the Arizona Board of Pharmacy based on the subsequent inspection by the Arizona Board of Pharmacy after receipt of a 483 from FDA.

On November 1<sup>st</sup>, 2016 Wells Pharmacy Network LLC., Ocala, FL accepted a consent agreement from the Texas Board of Pharmacy reprimanding its license based upon review of the Arizona Consent Agreement.

On September 28<sup>th</sup>, 2016 Wells Pharmacy Network, LLC., Ocala, FL executed a Voluntary Agreement to Restrict Sterile Compounding with the Florida Department of Health and that restriction was noted on the FDOH website. This Agreement was faxed to all Board's of Pharmacy on September 28<sup>th</sup>, 2016. The FDOH and Wells agreed that once Wells gave the FDOH a detailed explanation of the corrective actions and remedial measures taken (and documentation confirmation of same) that the voluntary inspection would be lifted within 72 hours of notice to resume sterile compounding. On November 4<sup>th</sup>, 2016, Wells submitted its corrected actions and 72 hour notice to the FDOH. On November 5<sup>th</sup>, 2016, the sterile compounding restriction was lifted by the FDOH and Wells sterile compounding license was returned to "active" on the FDOH website. Wells Pharmacy Network notified all non-resident pharmacy boards on September 28, 2016 via facsimile.

In April 2017, Wells Pharmacy Network LLC, Ocala, FL accepted a settlement agreement from the Hawaii Board of Pharmacy agreeing to pay administrative costs after Wells Pharmacy Network reported disciplinary action taken by Maine, Arizona and Florida. The Hawaii Board of Pharmacy approved the settlement as its June 15, 2017 meeting and mailed such referenced agreement on June 20, 2017.

The California Board of Pharmacy filed an accusation against Wells Pharmacy Network, LLC., Dyersburg, TN facility dated October 21<sup>st</sup>, 2016. This matter has been resolved. Please see attached letter from Wells Pharmacy Network's outside counsel for an explanation.

On November 4<sup>th</sup>, 2016, the Alabama Board of Pharmacy issued Wells Pharmacy Network, LLC., Ocala, FL a notice of emergency suspension of license as to sterile compounding to stay in effect for 120 days and set the matter for hearing on January 24<sup>th</sup>, 2017. This hearing was postponed with the emergency suspension left in place. On January 20<sup>th</sup>, 2017 Wells Pharmacy Network LLC., Dyersburg, TN received Notice of Emergency Suspension of License as to Sterile Compounding from the Alabama Board of Pharmacy dated January 10<sup>th</sup>, 2017. Wells Pharmacy Network met informally with the General Counsel and Executive Secretary of the Board to resolve the concerns from both ESO's. The informal meeting had productive results which were presented to the Board in Executive Session. From Executive Session, the Alabama Board of Pharmacy conveyed to Wells Pharmacy Network that patient access to customized medications was unimportant to the Board. General Counsel for the Board offered Wells Pharmacy Network request a voluntary surrender of its Alabama permits with payment of \$10,000 in costs with all charges dismissed with prejudice from the Board. This request was granted by the Board and a Consent Order reflecting this Agreement has been executed by Wells Pharmacy Network. The Board countersigned on June 13, 2017 and was received by Wells Pharmacy Networks outside counsel on June 21, 2017.



450 US Highway 51 Bypass North | Dyersburg, TN 38024 | 800.852.5689

The New Hampshire Board of Pharmacy denied Wells Pharmacy Network, LLC., Ocala, FL license renewal on February 15, 2017. Wells Pharmacy Network, LLC appeared before the Board of Pharmacy on April 4, 2017 to appeal the New Hampshire Board of Pharmacy decision and provided additional information requested at the appearance to the Board including its NABP inspection report. The New Hampshire Board of Pharmacy issued its decision to Wells Pharmacy Network on July 20, 2017 reaffirming its denial.

On May 17, 2017, Wells Pharmacy Network, LLC., Ocala, FL received the adoption of the Imposition of Civil Fine Order by the Alaska Board of Pharmacy in the amount of \$1,000 for a technical violation of its professional licensing statutes and regulations. Wells Pharmacy Network disputed the allegation of neglecting to reveal derogatory information concerning criminal convictions of employees as the information was greater than 15 years old (a violation of the FCRA), a misdemeanor not covered by standard background checks, the NABP or FBI background checks. Wells Pharmacy Network voluntarily accepted the fine as an employee did not follow policy on reporting employee disciplinary matters and waived its rights to a hearing.

On May 18, 2017 Wells Pharmacy Network, LLC., Ocala, FL received the attached copy of the fully executed Letter of Admonition from the Colorado Board of Pharmacy. This Letter was based on findings that the June 9, 2015 Arizona Consent Order, previously disclosed to all pharmacy boards, provided grounds for disciplinary action.

On June 6, 2017 Wells Pharmacy Network, LLC., Ocala, FL signed a Consent Order from the Kentucky Board of Pharmacy agreeing to pay a fine for failing to timely report the June 9, 2015 Arizona Board of Pharmacy Consent Order.

On August 14, 2017 Wells Pharmacy Network, LLC., Ocala, FL accepted a reprimand and payment of costs of \$468.00 from the Wisconsin Pharmacy Examining Board. The Wisconsin Pharmacy Examining Board concluded Wells Pharmacy Network, LLC. engaged in unprofessional conduct as defined by the Wisconsin Administration Code by having been subject to other disciplinary action by the State of Florida Board of Pharmacy. Wells Pharmacy Network, LLC. has paid the costs to the Wisconsin Pharmacy Examining Board.

On October 5<sup>th</sup>, 2017 Wells Pharmacy Network, LLC., Ocala, FL agreed to the attached Stipulation and Consent Order with the Board of Pharmacy State of Idaho. Wells Pharmacy Network was willing to settle and comply going forward with all the requirements of the Idaho Telehealth Access Act including paying a fine, reviewing the licenses for any provider sending a prescription for an Idaho resident, and refusing to fill any prescription for an Idaho resident from a provider who is not fully licensed in Idaho. However, the Board and Wells Pharmacy Network agreed Wells Pharmacy Network would not expressly admit to violations for these interpretations that are not clear under the Act and for which Wells Pharmacy Network did not know in advance following the recent enactment of the Act.

Wells Pharmacy Network, LLC ("WPN") submitted to the Utah Board of Pharmacy an application for a Pharmacy Class C Pharmaceutical Wholesaler, Manufacturer, Distributor for its Dyersburg, Tennessee 503b facility. As part of the application package, WPN included its disciplinary explanation for both the Dyersburg, Tennessee and Ocala, Florida facilities which had been previously submitted to the Utah Board of Pharmacy in prior years renewals. The Utah Board of Pharmacy pended review of the Pharmacy Class C application and issued the attached Stipulation and Consent Orders against the Dyersburg, Tennessee Class D license and the Ocala, Florida Class D license for 2 disciplinary actions that had been timely submitted to the Utah Board of Pharmacy – one in 2015 and one in mid-2017 each of which have been fully corrected. On January 16<sup>th</sup>, 2018 Wells Pharmacy Network, LLC agreed to accept the fine of \$500.00 which has been paid for each of the Orders as the Utah Board of Pharmacy was within its rights to discipline WPN.



STATE OF MAINE  
BOARD OF PHARMACY

IN RE:

WELLS PHARMACY NETWORK LLC

Complaint No. 2013 PHA 9589

)  
)  
)  
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CONSENT AGREEMENT

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Wells Pharmacy Network LLC in the State of Maine. The parties to this Consent Agreement are: Wells Pharmacy Network LLC ("Wells Pharmacy"), 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, Wells Pharmacy was licensed by the Board as a mail order pharmacy, license no. MO40001342, located at 1210 SW 33<sup>rd</sup> Avenue, Ocala, Florida.
2. The Board received a change in Pharmacist in Charge application from Wells Pharmacy on October 23, 2013, which disclosed that on October 3, 2013, Robert J. Pruneau took over as the Pharmacist in Charge of Wells Pharmacy.
3. Board Investigator Thomas Avery filed a complaint with the Board alleging that Wells Pharmacy had failed to timely notify the Board of the change in the Pharmacist in Charge as required, which the Board docketed as Complaint No. 2013 PHA 9589.

In re: Wells Pharmacy  
2013 PHA 9589

1 of 4

Consent Agreement

4. Title 32 M.R.S. § 13753(1)(C) requires that change of a Pharmacist in Charge requires notice to the Board no later than seven (7) days after the change. In addition, upon a change in Pharmacist in Charge, a mail order pharmacy shall file a new application with the Board no later than seven (7) days after the change. Board Rule Chapter 11, § 3.
5. Wells Pharmacy was required to file an application and notify the Board of the change in the Pharmacist in Charge no later than October 10, 2013, but failed to do so until October 23, 2013.
6. On June 5, 2014, following a presentation of the complaint, the Board voted to offer Wells Pharmacy this Consent Agreement in order to finally resolve Complaint No. 2013 PHA 9589.
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 October 3, 2014, the Board will resolve this matter by holding an adjudicatory hearing.

#### COVENANTS

8. Wells Pharmacy admits the facts stated above and that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. §§ 8003(5-A)(A)(4),(5), 32 M.R.S. § 13753(1)(C), 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. Wells Pharmacy agrees to accept the following discipline:
  - a. A WARNING; and



- b. A CIVIL PENALTY in the amount of seven hundred fifty dollars (\$750.00), 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 Wells Pharmacy 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. Wells Pharmacy 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.



WELLS PHARMACY

DATED:

10/24/14BY: 

Authorized Representative

Ben Davis - CEO

Printed Name

DATED:

11/6/2014  
JOSEPH BRUNO, R.Ph., President  
MAINE BOARD OF PHARMACY

DATED:

November, 2014  
MICHAEL MILLER  
Assistant Attorney General

JANET T. MILLS  
ATTORNEY GENERAL



TEL: (207) 626-8800  
TTY USE/FIS CALL MAINE RELAY 711

STATE OF MAINE  
OFFICE OF THE ATTORNEY GENERAL  
6 STATE HOUSE STATION  
AUGUSTA, MAINE 04333-0006

RECORDING OFFICES  
84 HANCOCK ST. 2ND FLOOR  
BANGOR, MAINE 04401  
TEL: (207) 941-3070  
FAX: (207) 941-3075

415 CONGRESS ST., STE. 301  
PORTLAND, MAINE 04101  
TEL: (207) 822-0260  
FAX: (207) 822-0259

14 ACORN HIGHWAY, STE. 1  
CARIBOU, MAINE 04736  
TEL: (207) 496-3792  
FAX: (207) 496-3291

September 18, 2014

Susan B. Morrison, Esq.  
Law Offices of Susan B. Morrison, P.A.  
1200 W. Platt St., Suite 100  
Tampa, FL 33606

Re: Maine Board of Pharmacy Complaint No. 2013 PHA 9589  
Wells Pharmacy Network LLC

Dear Attorney Morrison:

As you know, at its June 5, 2014 meeting, the Maine Board of Pharmacy voted to offer Wells Pharmacy Network LLC ("Wells Pharmacy") a Consent Agreement in order to resolve the above referenced complaint filed against its license, and set the matter for an adjudicatory hearing in the event that Wells Pharmacy does not accept the Consent Agreement. Enclosed please find the Consent Agreement proposed by the Board to resolve this complaint. Pursuant to a request to change the deadline for acceptance, please note that the Consent Agreement must now be accepted by October 3, 2014.

If Wells Pharmacy decides to accept the Consent Agreement, please have an authorized representative sign and date it and return it to Kelly McLaughlin, Senior Consumer Assistance Specialist, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333. Ms. McLaughlin will see that an authorized Board representative and I sign the document. You will then receive a copy of the fully-executed Consent Agreement. If you have any questions about this matter, please call me at 626-8891.

Sincerely,

MICHAEL MILLER  
Assistant Attorney General

Enclosure

cc: Kelly McLaughlin, Senior Consumer Assistance Specialist (w/ enc.)

**TD Bank** **PERSONAL MONEY ORDER**

DATE: 10/24/2011

PAY TO THE ORDER OF: *TREASURER, STATE OF MAINE*

Seven Hundred Fifty AND 00/100

NOT TO EXCEED \$1,000.00

67004470-1

10/24/2011

2750.00

*J. Bauman*

1210 5th St. Apt. 111-34474

6700447011 0112013351 6265005099

Law Offices of  
**SUSAN B. MORRISON, P.A.**  
 Admitted to Practice in Florida, New York and Pennsylvania

1200 W. Platt Street, Suite 100  
 Tampa, Florida 33606 USA  
 Telephone 813 902 9293  
 Facsimile 813 902 9275  
 Email [smorrisonlaw@tampabay.rr.com](mailto:smorrisonlaw@tampabay.rr.com)

December 13, 2013

Via U.S. Mail / Email/ [kelly.l.mclaughlin@maine.gov](mailto:kelly.l.mclaughlin@maine.gov)

Kelly L. McLaughlin  
 Senior Consumer Assistant Specialist  
 State of Maine  
 Department of Professional  
 and Financial Regulations  
 Office of Professional and Occupational Regulation  
 Board of Pharmacy  
 Complaints and Investigation  
 35 State House Station  
 Augusta, Maine 04333-0035

Re: Complaint # 2013PHA9589  
 License # MO 40001342

Dear Ms. McLaughlin:

This letter is submitted on behalf of this firm's client, Wells Pharmacy Network, LLC. ("Wells") in response to your October 30, 2013, letter with enclosed Complaint addressed to Colleen Schapiro, Wells' Managing Member.

The letter was not received by Ms. Schapiro until November 11<sup>th</sup>. Thus, Wells' response contained herein is timely submitted within the 33 day response window referenced in your letter.

Wells' October 22, 2013 Change of Pharmacist in Charge Application identified Robert Pruneau as the new pharmacist in charge ("PIC") with an effective date of change of October 3, 2013, as so noted in the Complaint by Board of Pharmacy Investigator and Complainant, Thomas Avery. Mr. Pruneau was hired by Wells as Vice President of Pharmacy and intended to assume the role of PIC at the commencement of his employment. However, Mr. Pruneau had advised Wells' management prior to accepting his position that he had a pre-planned two week European vacation scheduled for the middle two weeks of October. Wells prepared the application, but was unable to submit it to the Board until October 22, 2013, because the Application required Mr. Pruneau's signature, and he was unavailable to sign it until he returned to the office on the 22<sup>nd</sup>.

Kelly L. McLaughlin  
 Page 2  
 December 13, 2013

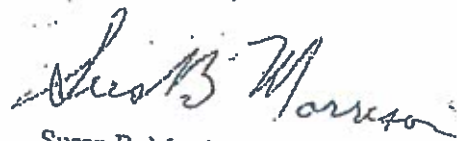
Wells regrets that it was unable to satisfy the seven (7) day Notice requirement set forth in Maine Board of Pharmacy Rules Chapter 11, Section 3. However, it was unable to do so because of Mr. Pruneau's two week absence. The violation was certainly not intentional. In hindsight, it might have been more prudent to merely change the effective date of the PIC change to October 22, 2013, since Wells' prior PIC continued to serve in that role until Mr. Pruneau's return.

Wells understands the importance of fully complying with all statutes and rules applicable to its pharmacy practice and licensure status. It also recognizes the importance of your Department's role in ensuring public health, safety and welfare. We assure you that despite the late timing of the Change Application, Wells' pharmacy professionals have at all times conducted their pharmacy practices professionally and with the utmost care and consideration for the safety of the patients it serves.

We therefore respectfully request that the Complaint be dismissed or closed, without any further action. Mr. Pruneau advised that he just received a call from you inquiring about Wells' response and advising him that this matter is on the Board of Pharmacy Agenda for Tuesday's Board Meeting. Because Wells' pharmacy and officers are located in Florida, Wells would like to request permission to call-in to the meeting at such time that this matter is called up for discussion in order to further respond to any questions or concerns that the Board might have.

We thank you in advance for your prompt reply to the call-in request, and further request that you provide an appropriate call-in number.

Very truly yours,



Susan B. Morrison

cc: Ben David, President and CEO  
 Robert Pruneau, Vice President of Pharmacy



Paul R. LePage  
GOVERNOR

STATE OF MAINE  
DEPARTMENT OF PROFESSIONAL  
AND FINANCIAL REGULATION  
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION  
BOARD OF PHARMACY  
COMPLAINTS AND INVESTIGATION  
35 STATE HOUSE STATION  
AUGUSTA, MAINE  
04333-0035

Ann L. Head, Esq.  
COMMISSIONER

Geraldine L. Betts  
ADMINISTRATOR

October 30, 2013

Colleen Shapiro, Managing Member/Secretary/Director  
11101 S. Crown Way, Suite 5  
Wellington, FL 33414

Re: Complaint #2013 PHA 9589 License #MO 40001342 (Expiration Date: 12/31/2013)

Against: Wells Pharmacy Network L.L.C.  
1210 SW 33<sup>rd</sup> Ave, Ocala, FL 34474-2853

Pharmacist-in-charge: No Pharmacist-in-charge on record at the time of the alleged incident.

NOTICE OF COMPLAINT

Dear Ms. Shapiro:

Thomas Avery, Chief Field Investigator, has filed a complaint against the license issued to the above named pharmacy by the Board of Pharmacy. A copy of the complaint is enclosed. Please mail to this office a detailed response to the complaint within 33 days of your receipt of this letter.

Be sure to include the complaint number shown above on your response. A copy of your response will be forwarded to the complainant, who will have 15 days to file an optional reply. If the complainant does file a reply, we will send you a copy. A complete description of the complaint process is included in the Administrative Complaint Procedures enclosed with this letter.

If you have any questions, feel free to call me. Do not contact any members of the board. This prohibition is necessary to prevent board members bias.

Sincerely,

Kelly L. McLaughlin, Senior Consumer Assistant Specialist  
(email: kelly.l.mclaughlin@maine.gov)

cc: Michael Miller, Assistant Attorney General  
Geraldine L. Betts, Board Administrator  
Thomas Avery, Chief Field Investigator  
Shane Savage, Complaint Officer

Enc.

Board Staff (207) 624-8621  
Main Receptionist (207) 624-8603  
TTY users call Maine relay 711

PRINTED ON RECYCLED PAPER  
[www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing)

OFFICE LOCATION: GARDINER ANNEX  
16 NORTHERN AVENUE, GARDINER, MAINE

Geraldine.L.Betts@maine.gov  
Direct Line: (207) 624-8625  
Fax: (207) 624-8637



Maine Department of Professional and Occupational Regulation  
Office of Licensing and Registration  
Board of Pharmacy  
Complaints & Investigations  
35 State House Station Augusta Me 04333  
(207)624-8621

PROFESSIONAL LICENSURE COMPLAINT

<u>PRINT YOUR NAME (COMPLAINANT):</u>  Thomas E. Avery Investigator Board of Pharmacy	<u>LICENSEE COMPLAINED ABOUT:</u>  Wells Pharmacy Network L.L.C..
<u>TODAY'S DATE:</u>  October 29, 2013	<u>LICENSEE'S ADDRESS:</u>  P1210 Southwest 33 <sup>rd</sup> Ave., Ocala FL. 34474
<u>YOUR SIGNATURE:</u>  <i>Thomas E. Avery</i>	<u>TYPE OF LICENSE HELD:</u> Mailorder.. Pharmacy MO40001342

PLEASE BE ADVISED THAT A COPY OF YOUR COMPLAINT WILL BE SENT TO THE LICENSEE FOR A RESPONSE.

Clearly explain your complaint. It is important to list the facts and details in the order they occurred, including names, dates, places and times. Include copies of any documents which support your complaint. If you require more space, include extra sheets. Return this form with any documentation to the address at the top of this form.

The Maine Board of Pharmacy received a Change of Pharmacist in Charge application on October 23, 2013 for the Wells Pharmacy Network located in Ocala Florida. According to the document Robert Pruneau took over as Pharmacist in Charge on October 3, 2013.

Allegation: Failure to notify Board of Pharmacy within 7 days of change of P.I.C..

Violation: Maine Board of Pharmacy Rules Chapter 11, Section 3





STATE OF MAINE  
DEPARTMENT OF PROFESSIONAL  
AND FINANCIAL REGULATION  
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION  
COMPANY APPLICATION

RECEIVED

OCT 23 2013

APPLICANT INFORMATION (please print)			
NAME OF MAIL ORDER PHARMACY Wells Pharmacy NETWORK, LLC			
FEIN OR SSN [REDACTED]			
PHYSICAL LOCATION OF THE MAIL ORDER PHARMACY 1210 SW 33rd Ave			
CITY Ocala	STATE FL	ZIP 34474	COUNTY MARION
MAILING ADDRESS 1210 SW 33rd Ave			
CITY Ocala	STATE FL	ZIP 34474	COUNTY MARION
PHONE # (352) 622-2913		FAX # (352) 401-5650	
PERSON RESPONSIBLE FOR COMPLETING AND SUBMITTING APPLICATION (must be an owner or officer of the entity) BEN DAVID CEO			
By my signature, I hereby certify that the information provided on this application is true and accurate to the best of my knowledge and belief. By submitting this application, I affirm that the Office of Professional and Occupational Regulation will rely upon this information for issuance of my license and that this information is truthful and factual. I also understand that sanctions may be imposed including denial, fines, suspension or revocation of my license if this information is found to be false.			
SIGNATURE [Signature]		DATE 10/22/13	

Board of Pharmacy  
Change of Pharmacist in Charge  
for a Mail Order Pharmacy  
Required Fee: \$100.00 (Non Refundable)

Maine Mail Order Pharmacy License # MO 40001342		Office Use Only: Check # 3975 Amount: 100-- Cash # 00143 Lic. # Issue Date Exp. Date	
Expiration Date 12/31/13		1457 - \$100.00	
PAYMENT OPTIONS: Make checks payable to "Maine State Treasurer" - If you wish to pay by Mastercard or Visa, fill out the following:			
NAME OF CARDHOLDER (please print name on card)			
I authorize the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation to charge my <input type="checkbox"/> VISA <input type="checkbox"/> MASTERCARD the following amount: \$			
Card number:		Expiration Date	
SIGNATURE		DATE	



## SECTION 1: COMPANY INFORMATION

Name of Mail Order Pharmacy	
Wells Pharmacy Network, LLC	
Mail Order Pharmacy Telephone Number	Mail Order Pharmacy Fax Number
(352) 622-2913	(352) 401-5750
Toll-Free Telephone Number	Email Address
(800) 622-4570	regulatoryaffairs@wellsrx.com
Web Address	DEAL (dealer discount) rules, terms, conditions (if applicable) must be provided with each order
www.wellsrx.com	FW 3512515
All Trade Names or Business Names of the Mail Order Pharmacy	
Wells Pharmacy Network, LLC	

## SECTION 2: PHARMACIST IN CHARGE INFORMATION (32 MRSA §13702-A (23) "Pharmacist in charge means the pharmacist who is responsible for the licensing of the pharmacy," and the contact person for this office for licensing the mail order pharmacy.)

Last Name	First Name	Middle
Pruneau	Robert	J
Contact Address		
1210 SW 33rd Ave		
City	State	Zip Code
Ocala	FL	34474
Telephone Number	Email Address	
352-622-2913	regulatoryaffairs@wellsrx.com	
License Number	State Issued	License Expiration Date
PS18878	Florida	2/30/15

## EFFECTIVE DATE OF CHANGE

Effective date you, the pharmacist in charge, will take over as PIC
10/3/13
INITIALS OF APPLICANT
37

RECEIVED

OCT 23 2013

# SECTION 2 Cont'd. - PHARMACIST IN CHARGE INFORMATION

THIS SECTION MUST BE COMPLETED BY THE PHARMACIST IN CHARGE ("PIC"). Check appropriate response to the questions below. Any YES response must be fully explained by written statement on a separate sheet of paper, signed and dated, and submitted with your application.

**CRIMINAL BACKGROUND DISCLOSURE NOTE:** Failure to disclose criminal convictions may result in denial, fines, suspension and/or revocation of a license.

<p>Have you ever been denied registration by the U.S. Drug Enforcement Administration (DEA) or have you ever had a DEA Registration modified, restricted, suspended or revoked? Has any state or province denied, restricted, modified, suspended or revoked your state permit to prescribe or dispense controlled substances? If yes:</p> <ol style="list-style-type: none"> <li><input type="checkbox"/> DEA action</li> <li><input type="checkbox"/> Other State or Province (Name) _____</li> <li>Submit a copy of the official action by the entity.</li> <li>Provide a detailed explanation in your own words on a separate sheet of paper.</li> </ol>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>Have you ever received a sanction from Medicare or from a state Medicaid program?</p> <ol style="list-style-type: none"> <li>Medicare OR Medicaid Program (State) _____</li> <li>Submit a copy of the official action by the entity.</li> <li>Provide a detailed explanation in your own words on a separate sheet of paper.</li> </ol> <p>Clarification on programs:</p> <ul style="list-style-type: none"> <li>Medicare – Health program administered by the United States government for people that are (1) ages 65 or older, (2) under the age of 65 with certain disabilities, and/or (3) all ages with end-stage renal disease.</li> <li>Medicaid – Health program administered by the United States government for people with limited incomes.</li> <li>MaineCare – Health program administered by the State of Maine with similar eligibility requirements as Medicaid.</li> </ul>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>Have you ever been convicted by any court of any crime? If yes, enclose a detailed description of what happened (including dates) and a copy of the court judgment.</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>Has any jurisdiction taken disciplinary action against any professional license you hold or have held, or denied your application for licensure? If yes, enclose a detailed explanation and copies of all documents.</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>

*BP*

INITIALS OF APPLICANT

Published under appropriation 01402A4380012  
35 State House Station, Augusta ME 04333

Revised 08/2012  
Website: [www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing)

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OCT 23 2013

## SECTION 3: NOTICES

### 10 Day Notification Requirement

This applicant/licensee must report in writing to the Board the following information no later than 10 days after the change or event, as the case may be:

- a. Change of name or address of the licensee;
- b. A criminal conviction of the licensee or anyone listed on this application as having an ownership interest in the licensee;
- c. A revocation, suspension, or other disciplinary action taken in this or any other jurisdiction against any occupational or professional license held by the applicant/licensee or anyone listed on this application as having an ownership interest in the licensee; or
- d. Any material change in the conditions or qualifications set forth in the original application for licensure submitted to the Board.

### Notice to Consumers (Board Rule Chapter 11, Section 5)

A mail order prescription pharmacy and mail order contact lens supplier shall include with each prescription filled prominent notice that complaints against the mail order prescription pharmacy may be filed with the Complaint Coordinator, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME 04333.



INITIALS OF APPLICANT

Published under appropriation 01402A4380012  
35 State House Station, Augusta ME 04333

Revised 08/2012  
Website: [www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing)

RECEIVED

OCT 23 2013

**MAIL ORDER PHARMACY - CHANGE OF PHARMACIST IN CHARGE - Checklist affirmation**  
 Please check mark each box to affirm that you have enclosed the information and documents required for this application. This affirmation checklist does not replace the requirements outlined in the Board of Pharmacy Laws and Rules. Please review them carefully for more detailed and clarifying information. This checklist is designed as a tool to confirm that your application is complete and ready to forward to our office.

**CHECKLIST**—please checkmark as an indicator that you have completed the following.

- ☒ Each section of the application has been completed.  
☒ Each page of the application, where noted, has been initialed.  
☒ Signature present where noted.  
☒ Check made payable to Treasurer State of Maine in the amount of \$100.00 is enclosed, or Credit card authorization completed.  
 N/A A copy of the consent agreement or order issued by the Board or jurisdiction is enclosed if licensure discipline has been indicated.  
 N/A A copy of the Court Judgment and Decision is enclosed if convicted of a crime, including a written statement, in your words, regarding the details of the crime.

#### SECTION 4: CERTIFICATION AND SIGNATURES

Read the statement below and sign where indicated as your certification of the information provided on this application.

By my signature, I hereby certify that the information provided on this application and in accompanying documents is true and accurate to the best of my knowledge and belief. By submitting this application I understand that the Maine Board of Pharmacy will rely upon this information as truthful and factual. I also acknowledge that an incomplete, altered (including the use of any white out substance), defaced, including use of white out, or compromised application will not be accepted and will be returned and fees forfeited. This includes, but not limited to, unanswered questions, lack of appropriate signature, illegible, missing supporting documents, and/or missing or wrong fee.

Printed Name of Mail Order Pharmacy Owner or Officer	Title
BEN DAVID	CEO
Signature of Mail Order Pharmacy Owner or Officer	Date
<i>[Signature]</i>	10/22/13

Also, as the Pharmacist in Charge certify by my signature that I have read and understand the Maine Board of Pharmacy laws and rules and related laws and rules as it applies to a Mail Order Pharmacy. I also certify that the management of the pharmacy will be vested with the pharmacist in charge in all matters directly or indirectly related to the practice of pharmacy or in any matters related to health, welfare, and safety of the public, as required by laws and rules.

Printed Name of PIC	Title
Robert Pruneau	PIC
Signature of PIC	Date
<i>[Signature]</i>	10/22/13



*Agreed Board Order #L-15-037*  
*Wells Pharmacy Network LLC*  
*Page 2*

Respondent, 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 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 Respondent's license is reprimanded.

RE: IN THE MATTER OF                      BEFORE THE TEXAS STATE  
WELLS PHARMACY NETWORK LLC        BOARD OF PHARMACY  
(PHARMACY LICENSE #28293)

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28293 issued to Wells Pharmacy Network LLC (Respondent), 1210 Southwest 33<sup>rd</sup> Avenue, Ocala, Florida 34474.

By letter dated May 5, 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) and (13); and 565.002(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2013), as alleged in the Count below.

The conduct described in the Arizona State Board of Pharmacy Consent Agreement is substantially similar to conduct described in:

Section 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and

Sections 291.133(d)(12)(C)(v); 291.133(d)(13); 291.133(d)(14); and 291.133(e) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

COUNT

On or about June 9, 2015, the Arizona State Board of Pharmacy entered a Consent Agreement against the Arizona pharmacy permit number Y005709 held by Wells Pharmacy Network. The Order was based on findings of fact regarding inspections by the United States Food and Drug Administration (FDA) conducted at the pharmacy's licensed location in Ocala, Florida, between February 21, 2014, and March 7, 2014. During the inspections, FDA identified violations of law concerning the pharmacy's sterile compounding operation. In addition, a compliance inspection by the Arizona State Board of Pharmacy on October 7 and 8, 2014, identified violations related to maintaining proper records of quality assurance of compounded preparations. The Agreement imposed a one year probation, \$9,000 civil penalty and an unannounced random inspection by the Board within one year of the entry of the agreement.

By letter dated May 5, 2016, 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, Colleen Stacy Shapiro, Board Member of Wells Pharmacy Network, LLC, on behalf of Respondent; and Michael R. Sharp, Legal Counsel for



Agreed Board Order #L-15-037  
 Wells Pharmacy Network LLC  
 Page 3

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of November, 2016.

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:

Colleen Stacy Shapiro, Board Member, Wells Pharmacy Network, LLC  
 For and on behalf of Wells Pharmacy Network LLC

Michael R. Sharp, Legal Counsel for Wells Pharmacy Network, LLC  
 Law Firm of Sharp & Cobos  
 4705 Spicewood Springs Road, Suite 100  
 Austin, Texas 78759

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel  
 Texas State Board of Pharmacy







## Department of Health

License Number: PH27462

*Data As Of 11/5/2016*

<b>Profession</b>	Pharmacy
<b>License</b>	PH27462
<b>License Status</b>	CLEAR/
<b>Qualifications</b>	Special Sterile Compounding
<b>License Expiration Date</b>	2/28/2017
<b>License Original Issue Date</b>	02/06/2014
<b>Address of Record</b>	1210 SW 33 AVE OCALA, FL 34474
<b>Controlled Substance Prescriber</b>	No
<b>Discipline on File</b>	No
<b>Public Complaint</b>	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.





1210 SW 33<sup>rd</sup> Avenue | Ocala, FL 34474 | 800.622.4510

November 4, 2016

Edwin A. Bayo, Esq.  
Grossman, Furlow & Bayo, LLC  
2022-2 Raymond Diehl Road  
Tallahassee, FL 32308

Dear Mr. Bayo,

Per Florida Department of Health's request, Wells Pharmacy Network is notifying you of our completed corrective actions as stated from our September 20, 2016 response letter and the Company's intent to resume sterile compounding at 9 am on November 09, 2016 for the purpose of dispensing and shipping.

**Observation 1:**

***The cleanrooms are negative pressure and are used for both hazardous and non-hazardous drugs. Compounding records document that hazardous drugs (HD) and chemotherapy and non HD drugs were compounded in the same room and PEC on the same day. Non-hazardous drugs must be compounded in a positive pressure room and not exposed to contamination with HD.***

**Response to Observation 1:**

The negative pressure cleanrooms were used to compound hazardous drugs and non-hazardous drugs between the dates of 19 July 2016 and 14 September 2016. Between each lot compounded during this timeframe, a chemical deactivating cleaning agent (CIP 100) was used to ensure cross contamination between batches did not occur. However, this chemical clean was not documented as an additional clean in our normal process. The current cleaning documentation practice was driven by tasks created in Simplifi<sup>797</sup> software system. The software was not updated to include chemical cleans during this time frame. Prior to 19 July 2016, all non-hazardous drugs were only compounded within the positive pressure cleanroom.

As a precautionary measure, a voluntary recall has been issued for all products compounded in the negative pressure cleanroom during the timeframe of 19 July 2016 and 14 September 2016 (Attachment 2 – Recall Spreadsheet). No adverse reactions have been reported by customers or physicians regarding the sterile lots listed in the recall.

In addition to the recall, Wells Pharmacy Network has tested several lots of non-hazardous products that were compounded during this timeframe in the negative pressure cleanroom for potency testing to confirm no trace hazardous drug exists within the non-hazardous products (Attachment 3 – Dyna Labs Reports).

The Cleaning of ISO 5 Enclosures procedure (Attachment 4 – Cleaning, Disinfection, Operation and Maintenance of ISO 5 Enclosures) was updated and effective on 16 September 2016 to include the use and documentation of use of the chemical deactivating cleaning agent to clean the compounding hood in-between lots of different products.

Furthermore, each class of product shall be compounded in their respective areas going forward. All non-hazardous medications shall be compounded in the positive pressure cleanroom, chemotherapy medications shall be compounded in the negative pressure chemotherapy cleanroom, and hazardous medications shall be compounded in the negative pressure hazardous compounding cleanroom. Under no circumstance will any of these products be produced in another cleanroom with a different class of products.



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### **Completion of Observation 1**

Corrective actions completed in full at time the September 20, 2016 response was submitted.

### **Observation 2:**

***A fungal contamination in the cleanroom starting in January was not identified until May.***

### **Response to Observation 2:**

Fungal recoveries were observed in the environmental monitoring results in the positive cleanroom beginning 22 February 2016 (no excursions were noted in January) and included corrective actions by the onsite Microbiologist to address accordingly as listed in each respective investigation. However, in June and July 2016 respectively it was noted that sterility results of four (4) products were suspect. Upon further investigation, it was determined that the annex room that is adjacent to the compounding room contained fungal growth that began to show a drift of environmental contamination into the adjacent compounding cleanroom. The root cause of the issue was determined to be caused by a leaking pipe above the cleanroom which has since been resolved.

The laminar flow hood used to test the products for sterility indicated similar fungal recovery as seen in the annex room. The suspect sterility products were sent to a third party testing laboratory and was determined that product was not compromised by the environmental conditions at the time (Attachment 5 – Mold Remediation Plan). No adverse reactions have been reported by customers or physicians regarding the sterile lots listed in the recall.

Although no sterility failures or adverse events have been noted to date at Wells Pharmacy Network, as a precautionary measure, Wells Pharmacy Network ceased all sterile compounding on September 14, 2016 and a patient level voluntary recall was issued for all sterile products compounded between 22 February 2016 and 14 September 2016.

On 02 September 2016, the remaining lots prepared between 20 June 2016 and 15 July 2016 in the positive cleanroom were pulled from the shelves internally and sent for testing with a third party laboratory (Attachment 6 – Sterile product removed from inventory). An aliquot sample from each vial is being tested for sterility and endotoxin. Interim results indicate no suspect sterility or endotoxin results. The results for all vials sent for testing will be available starting 27 September 2016 for some lots and with all lots off test by 07 October 2016.

Additionally, a robust cleaning program was implemented on 02 August 2016 to include new cleaning agents (Attachment 7 – Cleaning and Disinfection of Classified Areas (the cleaning program has since been revised and enhanced)).

A robust environmental monitoring procedure (Attachment 8 – Environmental Monitoring of the Cleanroom) was implemented on 16 September 2016 to include dynamic monitoring of contact sites and personnel contact plates for each lot compounded to provide visibility into the environmental conditions during each lot compounded. No compounded sterile batch will be released until environmental monitoring data for that lot is completed and reviewed by the Quality Assurance department.

Tracking and trending of the environmental monitoring data was implemented on 16 September 2016 with management review (Attachment 9 – EM Tracking and Trending Spreadsheet). A procedure was developed and implemented on 30 September 2016 (Attachment 10 – Tracking and Trending Program). In the event an actionable environmental monitoring excursion is noted, Wells Pharmacy Network will open an investigation and determine the root cause and discard the batch associated with the EM.



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The environmental monitoring program now has oversight by the Senior Director of Quality Assurance. The affected cleanroom has since undergone planned renovation activities as well as a complete post construction clean and decontamination with Vaporized Hydrogen Peroxide by a third party company.

#### **Completion of Observation 2**

The lots prepared between June 20, 2016 and July 15, 2016 in the positive cleanroom that were pulled from the shelves internally and sent for testing with a third party laboratory have been completed and indicate no suspect sterility or endotoxin results.

Bloquell, a third party decontamination company, was on site October 26, 27 and 28 to fog the cleanrooms with vaporized hydrogen peroxide. The validated method provided by Bloquell has been shown to provide a log<sup>6</sup> reduction in microorganisms within the cleanroom space. Biological indicators shall be used to confirm the efficacy of the fogging process and will be available for confirmation from the required incubation period along with a summary report expected on November 06, 2016.

Breach cleaning of the areas began October 24, 2016 consisting of full cleaning ceiling, walls, equipment, surfaces, and floors and was completed in all rooms on October 31, 2016.

Validation of the Lighthouse continuous monitoring system for pressure, temperature, humidity, viable and non-viable air samples has begun with an expected completion date of November 04. The continuous monitoring system shall begin routine monitoring on November 07. The continuous monitoring system will capture compounding conditions inside the cleanroom space as well as inside the biological safety cabinets and laminar flow hoods.

Environmental Monitoring Performance Qualification began October 28 and will continue through November 17 to validate the fitness of the cleanrooms. This monitoring shall include viable air samples, non-viable air samples, and contact plate samples during static and dynamic conditions.

Routine environmental monitoring shall commence following the environmental monitoring performance qualification on November 21. Routine environmental monitoring includes contact plates during dynamic conditions and cleanroom viable air samples and contact plates during static conditions.

#### **Observation 3:**

***Surface sampling is done after cleaning.***

#### **Response to Observation 3:**

Routine environmental monitoring was performed during the day after compounding activities prior to the evening clean; however, the surfaces of the tables, carts, and ISO 5 laminar flow hoods were wiped per procedure after the completion of compounding for the day. Environmental monitoring surface sampling was originally designed to evaluate the cleanliness of the room and not designed to determine the conditions during compounding.

On 16 September 2016, the new Environmental Monitoring procedure became effective (Attachment 8 – Environmental Monitoring of the Cleanroom) that evaluates the cleanliness of the room on a routine basis as well as capturing the dynamic conditions of the surfaces and personnel during each compounding lot. Training for all technicians performing the environmental monitoring was completed on 16 September 2016.



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### **Completion of Observation 3**

Corrective actions completed in full at time the September 20, 2016 response was submitted. Environmental Monitoring to qualify the fitness of the cleanrooms began on October 28, 2016. Routine Environmental Monitoring per batch is scheduled to begin on November 04, 2016, upon resuming sterile compounding.

### **Observation 4:**

*Certification does not document the use of the fume hood and that weighing and mixing in the ISO 7 was conducted during the certification.*

### **Response to Observation 4:**

The certification of the fume hoods were not performed during dynamic conditions that mimic normal operating conditions. Wells Pharmacy Network states the certification of the hood is within specification for static conditions. Wells Pharmacy Network understands dynamic conditions will portray realistic conditions as to the functionality of the equipment during compounding. The dynamic certification of the fume hoods was performed on 29 and 30 September 2016. In addition to the certification, a smoke study was performed and video recorded on 29 September 2016 to ensure the designed function of the fume hood was not compromised by the compounding activities taking place in the hood during dynamic conditions.

### **Completion of Observation 4**

Certification of the cleanrooms under static conditions was performed October 17 and continued through October 27 in the cleanroom spaces respectively. The certification included, but is not limited to, video recorded static smoke studies, performance testing of the HEPA filters, particle testing, etc. Dynamic smoke studies are scheduled to be performed on November 02, 2016 per Wells Pharmacy Network Smoke Study procedure (Attachment 1).

### **Observation 5:**

*Documentation of validation is not available. Depyrogenated glassware is held in an area that is not certified for up to 30 days.*

### **Response to Observation 5:**

The oven validation documentation was filed at Wells Pharmacy Network's offsite warehouse; however, the documentation was unable to be located at the time of the inspection. The 2014 validation documents were reviewed by the inspector during the inspection. The 2015 oven validations were completed in January and June of 2015 (Attachment 23 – Oven Validation 2015). Wells Pharmacy Network agrees that an oven validation is vital to ensuring the sterility of our products and is in the process of developing a robust oven validation program that includes equipment and cycle validation with an expected completion date of November 2016.

In addition, the depyrogenated glassware that was held in a controlled not classified area for up to 30 days was moved into classified glassware environment (ISO 8) on 30 September 2016 to assure sterility. A study is currently being developed to test the glassware to validate an appropriate hold time to ensure sterility assurance and shall be completed by November 2016. As indicated by the sterility testing reports of all sterile products to date, the sterility of Wells Pharmacy Network's product has not been impacted by the depyrogenated glassware.

### **Completion of Observation 5**

Glassware hold time study was completed with negative sterility results (Attachment 6). The glassware stored in the unclassified area was removed, recleaned, rewrapped, and depyrogenated. The glassware hold study shall



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be repeated as the glassware is now stored in a classified ISO 8 cleanroom space as indicated in the procedure (Attachment 2 – Sterilized Glassware Hold Study).

**Observation 6:**

*The gloves and masks are not labeled for use with hazardous drugs.*

**Response to Observation 6:**

Wells Pharmacy Network takes seriously the health and wellbeing of the compounding technicians. Upon discovery of the observation above, Wells Pharmacy Network immediately contacted multiple cleanroom suppliers to order the appropriate gloves and masks. After discussing with multiple vendors, there are no masks on the market that are labeled for chemotherapy use. Wells Pharmacy Network chose the most aggressive sterile mask on the market to provide the most protection against hazardous drugs. The glove and mask descriptions are as follows:

Gloves: Medline Nitrile Sterile Exam Gloves

Masks: Sterile pouch style facemask, head loop, gamma irradiated, low linting, latex free

The specification sheets for each are attached (Attachment 18).

**Completion of Observation 6**

Corrective actions completed in full at time the September 20, 2016 response was submitted.

**Observation 7:**

*Documentation of training in safe handling of hazardous drugs was not provided.*

**Response to Observation 7:**

Although hazardous drug handling training is provided to each pharmacy technician upon hire through on the job training as well as reading of the procedure, documentation of such training has not occurred. As a result, a more robust training program for handling of hazardous drugs was developed and implemented on 23 September 2016 (Attachment 11 – Handling of Cytotoxic or Hazardous Compounds). Formal refresher training was provided for all staff handling the hazardous drugs on 22 September 2016 and 23 September 2016 and documented (Attachment 12 – Training on Handling of Cytotoxic or Hazardous Compounds).

**Completion of Observation 7**

Corrective actions completed in full at time the September 20, 2016 response was submitted.

**Observation 8:**

*Hands are washed in the unclassified area, then sterile shoe covers are donned over the booties worn in the unclassified space, masks are donned (technician placed the straps over ears and under the bouffant and instructed the inspector in the same method which required touching hair and skin with the cleansed hands). Hands are not rewashed, hand sanitizer is applied prior to gloving.*

**Response to Observation 8:**

The normal process for gowning in the hazardous and positive cleanroom is to don the mask and first pair of sterile booties, wash hands in the sink located in the classified area and enter the ISO 7 ante room for donning





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sterile garments. However, due to the design of the chemotherapy cleanroom, the current practice is to wash hands in the controlled not classified area, don facemask, don sterile booties, and sanitize hands prior to adding sterile gloves.

Wells Pharmacy Network agrees with the observation of the Florida Department of Health and has updated their gowning practice in the chemotherapy area as follows (Attachment 13 - Gowning Procedure and Requirements for Entry into Classified Areas for Ocala, Florida – Effective 30 September 2016):

Upon entry into the controlled not classified area, thoroughly wash hands with Antimicrobial Soap for approximately 60 seconds up to the elbow if in short sleeve gown and hands only if in long sleeve gown, focusing under the nails with a sterile nail pick and in skin creases.  
 Rinse up towards elbow, not down towards fingertips.  
 Dry hands with a low linting disposable wipe, wiping towards elbow not fingertips if in short sleeve gowning.  
 Don sterile gloves.  
 Apply facemask.  
 Apply sterile booties.  
 Remove sterile gloves and sanitize hands with Sterillium.  
 Don sterile gloves.  
 Continue with donning sterile garments.

Training on the updated gowning procedure was provided to the sterile technicians on 28 September 2016.

**Completion of Observation 8**

Corrective actions completed in full at time the September 20, 2016 response was submitted.

**Observation 9:**

***Didactic training is delinquent.***

**Response to Observation 9:**

Didactic training for the sterile compounding technicians and pharmacists are performed on an annual basis via Critical Point (an extension of Simplifi797) software system. However, in 2015 didactic training was performed through the freeCE program with a hardcopy filed in each employee's training binder (Attachment 14 – Didactic Training). Formal didactic training has been performed throughout the year (2016) with the expected completion of December 2016. In addition, several training sessions have been performed with the sterile compounding team with the new procedures that have been implemented. The following training procedures were completed at the time of the Florida Department of Health inspection:

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Procedure	Date Technicians and Pharmacists Trained					
	Harmony SanFillipo	Donna Mast	Paul Mast	Daniel Lakatos	Anthony Campbell, RPh	Michael Farfaglia, RPh
Gowning Validation	8/5/16	8/5/16	8/5/16	8/5/16	8/9/16	8/5/16
Cleaning and Disinfection of Classified Areas	8/5/16	8/5/16	8/5/16	8/5/16	8/9/16	8/5/16
Filter Integrity Testing	7/18/16	7/18/16	7/18/16	7/18/16	7/6/16	*
Good Documentation Practices	7/18/16	7/18/16	7/18/16	7/18/16	7/18/16	*
Gowning Procedure and Requirements for entry into Classified Areas	7/18/16	7/18/16	7/18/16	7/18/16	7/5/16	*
Fingertip Monitoring	8/30/16	3/21/16	8/30/16	4/19/16	1/29/16	8/23/16

\* These trainings were performed on 8/5/16; however, the training form has inadvertently been misplaced. A retraining of the procedures was performed and documented on 9/26/16.

Didactic training for Michael Farfaglia was completed in June 2016. Didactic training for all sterile technicians was completed 27 September 2016. Didactic training for Anthony Campbell will be completed by 07 October 2016.

#### **Completion of Observation 9**

Didactic training is current with all sterile technicians and sterile pharmacists as of October 03, 2016. A procedure is currently in the revision process to include didactic training requirements and ensure all didactic training is performed annually (Attachment 3: Sterile Compounding Personnel Qualification – Draft with an expected implementation date of November 04, 2016).

#### **Observation 10:**

***Final visual inspection check of the product is conducted by technicians instead of the pharmacist 64B16-27.1001 FAC.***

#### **Response to Observation 10:**

Visual inspection is currently performed informally during the labeling of vials by the sterile compounding technicians. The formal visual inspection is performed by the Quality Control personnel in a lightbox with a black and white background. 100% of the vials are visually inspected. Once completed, the pharmacist signing off on the batch views vials at random to confirm the visual inspection. 100% visual inspection is performed by a pharmacist once the vials are dispensed from inventory and brought to the second pharmacist verification station prior to shipment. At this checkpoint, pharmacists verify the product, label, crimp/seal, as well as visually inspecting the vials against a fluorescent light background for particulates or visual defects.

Wells Pharmacy Network has updated the process to include a pharmacist 100% visual inspection of all sterile products immediately after compounding and prior to being labeled. This visual inspection is performed against a black and white background in the lightbox. The procedure was updated with the final version expected to be effective on 07 October 2016 (Attachment 21 – Visual Inspection Program).

#### **Completion of Observation 10**

Visual inspection procedure has been finalized and all pharmacists have been trained. The procedure shall be implemented as the sterile compounding resumes within the facility (Attachment 4).



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**Observation 11:**

***BUD for some products lack justification. Potency and stability has not been conducted for HCG, Sermorelin, Cyclosporin, Mitomycin and Testosterone.***

**Response to Observation 11:**

Potency has previously been conducted for various Testosterone injection products (Attachment 15 – Dyna Labs Potency Reports), and a stability study has been initiated. However potency and/or stability studies have not been performed for HCG, Sermorelin, Cyclosporin, and Mitomycin. The BUD for these products were previously determined based on the USP<797> and USP<795> recommendations of 180 days for non-aqueous formulations (Attachment 20 – USP <795> BUD).

No compendial method exists for testing of Sermorelin currently. Additionally, the USP assay for HCG is dated with the use of animals for testing. A confirmation of label claim for Sermorelin and HCG via ELISA is currently pending with a third party testing laboratory with an expected completion date of 18 November 2016 (Attachment 22 – Email from RayBiotech). In addition, Wells Pharmacy Network has developed a stability time study to include sterility and endotoxin testing of Sermorelin and HCG at multiple time points to confirm the assigned Beyond Use Date (BUD). Mitomycin and Cyclosporin have been sent to a third party testing laboratory for potency and stability testing to confirm the current assigned BUD and expect results by 14 October 2016.

**Completion of Observation 11**

Wells Pharmacy Network will compound HCG and Sermorelin with an assigned BUD of 180 days per the USP<797> and <795> guidelines for non-aqueous products since there is no readily available compendia method. Wells Pharmacy Network begin a stability program on HCG and Sermorelin consisting of endotoxin and sterility testing at multiple time points to confirm the container closure over time.

Wells Pharmacy Network will prepare a batch of Mitomycin to send to a third party laboratory for a time study to confirm assigned BUD.

Cyclosporin time study is currently underway to confirm the BUD. The first time point has past and testing confirmed the product was within specification at 30 days. The next time point to test is at day 60 on November 11, 2016.

**Observation 12:**

***Does not have a formal training program for patients and caregivers in the proper storage, handling, use and disposal of compounded sterile products. There is no procedure for patients to ask questions and report concerns or adverse events.***

**Response to Observation 12:**

As part of Wells Pharmacy Network's commitment to patient and caregiver safety, Wells has developed a formal program to distribute information pamphlet with each shipment on the proper storage, handling, use, and disposal of compounded sterile products (Attachment 16 – Patient and Caregiver Training Procedure). In addition, the information pamphlet includes the following:

Call your doctor for medical advice about side effects.

You may report effects to the FDA at 1-800-FDA-1088.

A Wells Pharmacy Network pharmacist would like to answer any questions. For consultation please call 1-800-622-4510.



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A generic pamphlet was developed to send to patients with each sterile hazardous product. Circulation of this pamphlet began on 30 September 2016.

**Completion of Observation 12**

Wells Pharmacy Network ceased sterile compounding activities on September 14, 2016. A Generic Pamphlet for Sterile Medication handling, storage, and disposal (Attachment 5) has been created however has not been circulated as sterile compounding has not occurred. When sterile compounding resumes, the pamphlet will be included with all sterile compounded drug shipments.

All renovation activities within the Wells Pharmacy Network facility are finalized as of October 24, 2016. All other corrective actions listed in our response letter dated September 20, 2016 have been completed in its entirety and successfully tested. Wells Pharmacy Network is providing the Florida Department of Health 72 hours notice of its plans to resume sterile compounding with the intent to dispense with this letter. Please do not hesitate to contact me should you have any questions.

Sincerely,

Melissa Stefko

Digitally signed by  
Melissa Stefko  
Date: 2016.11.03 20:30:12  
+0400

Melissa Stefko  
Senior Director of Quality Assurance



1210 SW 33<sup>rd</sup> Avenue | Ocala, FL 34474 | 800.622.4510

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**Attachments**

Attachment 1: Smoke Study Procedure

Attachment 2: Sterilized Glassware Hold Study

Attachment 3: Sterile Compounding Personnel Qualification - Draft

Attachment 4: Visual Inspection

Attachment 5: Generic Pamphlet for Sterile Medication handling, storage, and disposal

Attachment 6: Glassware study results



State Board of Pharmacy

Re: Wells Pharmacy Network, LLC (NABP # 1002752)

To Whom It May Concern:

This firm serves as Regulatory Counsel for Wells Pharmacy Network, LLC ("Wells"). We would like to notify you of our client's current regulatory situation with the Florida Department of Health ("DOH") and the Food and Drug Administration ("FDA").

Our client was recently inspected by the FDA and DOH. As a result of that inspection, and effective September 14, 2016, our client has voluntarily ceased its sterile compounding operations until such time as necessary corrective actions can be implemented to address the FDA and DOH's alleged concerns. Wells has agreed with the FDA and the DOH to submit evidence of each corrective action taken as well as any subsequent testing confirming/validating the corrective measures implemented to successfully resolve all stated concerns. Once all of these corrective measures have been successfully resolved and documented to the FDA and DOH, Wells is permitted to resume sterile compounding. Enclosed is a copy of the Voluntary Agreement to Restrict Practice of Sterile Compounding accepted by the DOH.

Wells takes its legal and ethical responsibilities very seriously. Our client understands that the FDA and various states have been responding to and increasing the legal oversight and safety of compounded medications. The oversight of compounding facilities—as well as the various compounding facilities' response to the updated laws and potential regulations—has presented challenges during what has been a multiyear transition period. Wells has responded to these challenges by investing in the upgrade of its facility to meet the upcoming USP 800 regulation and firmly believes it operates a high quality facility with the resolution of the aforementioned appropriate procedures.

When issues have arisen, such as from the FDA, Wells has worked with the FDA to clarify and respond to those concerns. In fact, the FDA acknowledged at this recent inspection the previous 483 observations had been corrected by Wells. Even when the FDA has taken positions that might push the limits of existing laws—such as in 2013 when the FDA's authority was questioned by the U.S. GAO—Wells' goal has been to focus on safe practices and future upgrades. (See "Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight," U.S. Government Accountability Office, 7/31/13,

State Board of Pharmacy  
September 28, 2016  
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available at <http://www.gao.gov/products/GAO-13-702> (noting the FDA's unclear authority at that time to oversee compounding pharmacies).)

Providing some context, the FDA's efforts in this area have resulted in a learning curve for a vast number of 503a compounding pharmacies. Since 2012, over 300 different 503a compounding pharmacies have been issued either a Warning Letter or an FDA Form 483. The total number of FDA Form 483s issued since 2012 is more than 350. According to the FDA website: "A Form FDA-483 is issued when investigators observe any significant objectionable conditions." (See "Compounding: Inspections, Recalls, and other Actions" (updated as of 9/27/2016), U.S. Food and Drug Administration website, available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm>).

Our reference to these enforcement statistics is not to take the position that objectionable conditions are acceptable. Instead, the reference concisely reveals the challenges almost all compounding pharmacies are experiencing in attaining full compliance with the new laws and standards. Moreover, the practices and safety standards of compounding pharmacies continue to develop.

It is important to note that there have been no adverse events reported to date from the FDA and DOH's alleged concerns.

Please let me know if you have any questions. Requests for additional information or copies of any relevant documents can be directed to me at (850) 385-1314 or at [e.bayo@gfblawfirm.com](mailto:e.bayo@gfblawfirm.com).

Sincerely,



Edwin A. Bayó

cc: Wells Pharmacy Network

**STATE OF FLORIDA  
DEPARTMENT OF HEALTH**

**DEPARTMENT OF HEALTH,  
Petitioner,**

**v.**

**CASE NO. 2016-23508**

**WELLS PHARMACY NETWORK, LLC,  
Respondent.**

**VOLUNTARY AGREEMENT TO RESTRICT PRACTICE  
OF STERILE COMPOUNDING**

Ben David, C.F.O., as owner and/or institutional representative of **Wells Pharmacy Network, LLC**, permit number **PH27462**, hereby agrees to restrict practice of **Wells Pharmacy Network, LLC**, as a Special Sterile Compounding Pharmacy in the State of Florida and states as follows:

1. Respondent understands that this Agreement constitutes a legal obligation within the meaning of Section 456.072(1)(k), Florida Statutes. Respondent further understands that any violation of the terms of this Agreement by Respondent shall constitute sufficient probable cause for the issuance by Petitioner of an Emergency Suspension of Respondent's license to practice pharmacy in the State of Florida.



2. Petitioner has received a complaint in this matter containing allegations that Respondent may have compounded sterile products without being in compliance with Rule 64B16-27.797, Florida Administrative Code.

3. So as to avoid the necessity of an order restricting or suspending its license to practice as a Special Sterile Compounding Pharmacy in the State of Florida, Respondent has agreed to voluntarily restrict its practice in the State of Florida. Respondent ceased sterile compounding on September 14, 2016.

**Immediately upon executing this Agreement, Respondent shall cease compounding sterile products and shall cease dispensing or shipping sterile products it has previously compounded.**

4. Respondent has agreed with the United States Food and Drug Administration ("FDA") to cease sterile compounding until the necessary corrective actions can be implemented to address the FDA's alleged concerns. Respondent shall, under separate cover, submit to the Department of Health each of the corrective actions taken as well as any subsequent testing confirming the corrective actions to successfully resolve

and address the FDA's alleged concerns and demonstrate compliance with Rule 64B16-27.797, Florida Administrative Code. Upon successful completion of the stated corrective actions, Respondent shall give the Department of Health 72-hour advance notice of its intent to resume sterile compounding.

5. Respondent understands that this Agreement in no way precludes additional proceedings by Petitioner for any acts or omissions by Respondent not referenced in this matter.

6. Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action.

7. Respondent, being fully advised of the consequences of so doing and having the opportunity to consult with counsel of his/her choosing, hereby agrees that upon his/her execution of this Agreement, it shall immediately be made accessible to the public. In addition, Respondent's licensure status and profile with the Board of Pharmacy will reflect the restriction stated herein.

EXECUTED this 27<sup>th</sup> day of September, 2016.

[Signature] CEO

Institutional Representative for  
Wells Pharmacy Network, LLC  
License No. PH27462

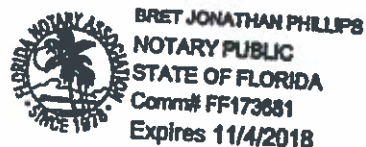
STATE OF Florida  
COUNTY OF Palm Beach

Before me, personally appeared Ben David,  
whose identity is known to me by Professional relationship (type  
of identification) and who, under oath, acknowledges that his/her signature  
appears above.

Sworn to and subscribed before me this 27<sup>th</sup> day of September, 2016.

[Signature]  
NOTARY PUBLIC

My Commission Expires: 11/4/2018



**FILED**DEPARTMENT OF HEALTH  
DEPUTY CLERKSTATE OF FLORIDA  
DEPARTMENT OF HEALTH

CLERK:

DATE

*Sandra Beenard*  
10.5.16DEPARTMENT OF HEALTH,  
Petitioner,

v.

WELLS PHARMACY NETWORK, LLC,  
Respondent.**VOLUNTARY AGREEMENT TO RESTRICT PRACTICE  
OF STERILE COMPOUNDING**

Ben David, CEO as owner and/or Institutional representative of **Wells Pharmacy Network, LLC**, permit number **PH27462**, hereby agrees to restrict practice of **Wells Pharmacy Network, LLC**, as a Special Sterile Compounding Pharmacy in the State of Florida and states as follows:

1. Respondent understands that this Agreement constitutes a legal obligation within the meaning of Section 456.072(1)(k), Florida Statutes. Respondent further understands that any violation of the terms of this Agreement by Respondent shall constitute sufficient probable cause for the issuance by Petitioner of an Emergency Suspension of Respondent's license to practice pharmacy in the State of Florida.

EXHIBIT "2"


DATED: 10/24/14

WELLS PHARMACY

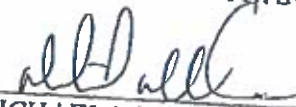
BY:   
Authorized Representative

Ben Davis - CEO  
Printed Name

DATED: 11/6/2014

  
JOSEPH BRUNO, R.Ph., President  
MAINE BOARD OF PHARMACY

DATED: November, 2014

  
MICHAEL MILLER  
Assistant Attorney General

In re: Wells Pharmacy  
2013 PHA 9589

4 of 4

Consent Agreement

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PROF & VOCATIONAL  
LICENSING DIVISION  
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2. Petitioner has received a complaint in this matter containing allegations that Respondent may have compounded sterile products without being in compliance with Rule 64B16-27.797, Florida Administrative Code.

3. So as to avoid the necessity of an order restricting or suspending its license to practice as a Special Sterile Compounding Pharmacy in the State of Florida, Respondent has agreed to voluntarily restrict its practice in the State of Florida. Respondent ceased sterile compounding on September 14, 2016.

**Immediately upon executing this Agreement, Respondent shall cease compounding sterile products and shall cease dispensing or shipping sterile products it has previously compounded.**

4. Respondent has agreed with the United States Food and Drug Administration ("FDA") to cease sterile compounding until the necessary corrective actions can be implemented to address the FDA's alleged concerns. Respondent shall, under separate cover, submit to the Department of Health each of the corrective actions taken as well as any subsequent testing confirming the corrective actions to successfully resolve

and address the FDA's alleged concerns and demonstrate compliance with Rule 64B16-27.797, Florida Administrative Code. Upon successful completion of the stated corrective actions, Respondent shall give the Department of Health 72-hour advance notice of its intent to resume sterile compounding.

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7. Respondent, being fully advised of the consequences of so doing and having the opportunity to consult with counsel of his/her choosing, hereby agrees that upon his/her execution of this Agreement, it shall immediately be made accessible to the public. In addition, Respondent's licensure status and profile with the Board of Pharmacy will reflect the restriction stated herein.

1 THOMAS C. HORNE  
 2 Attorney General  
 (Firm State Bar No. 14000)

3 MONTGOMERY LEE  
 4 Assistant Attorney General  
 State Bar No. 005658  
 1275 W. Washington, CIV/LES  
 5 Phoenix, Arizona 85007-2997  
 Tel: (602) 542-7980  
 6 Fax: (602) 364-3202

7  
 8 Attorneys for the Arizona State Board of Pharmacy

RECEIVED  
 PROF & VOCATIONAL  
 LICENSING DIVISION

10 BEFORE THE ARIZONA STATE BOARD OF PHARMACY

12 In the Matter of

Board Case No. 14-0019-PHR

13 Wells Pharmacy Network,

14 CONSENT AGREEMENT FOR  
 PROBATION, CIVIL PENALTY,  
 COSTS AND INSPECTION

15 Holder of Pharmacy Permit No. Y005709  
 16 in the State of Arizona.

17  
 18 In the interest of a prompt and judicious settlement of this case, consistent with the  
 19 public interest, statutory requirements and the responsibilities of the Arizona State Board  
 20 of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Wells Pharmacy Network,  
 21 holder of Pharmacy Permit Number Y005709 in the State of Arizona ("Respondent"),  
 22 and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law  
 23 and Order ("Consent Agreement") as a final disposition of this matter.  
 24  
 25  
 26

EXHIBIT "3"



EXECUTED this 27<sup>th</sup> day of September, 2016.

[Signature]

Institutional Representative for  
Wells Pharmacy Network, LLC  
License No. PH27462

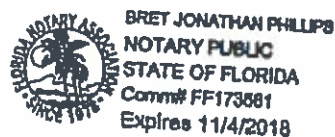
STATE OF Florida  
COUNTY OF Palm Beach

Before me, personally appeared Ben David,  
whose identity is known to me by Professional Relationship (type  
of identification) and who, under oath, acknowledges that his/her signature  
appears above.

Sworn to and subscribed before me this 27<sup>th</sup> day of September, 2016.

[Signature]  
NOTARY PUBLIC

My Commission Expires: 11/4/2018



b. A CIVIL PENALTY in the amount of seven hundred fifty dollars (\$750.00), 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 Wells Pharmacy 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. Wells Pharmacy 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.

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4. Title 32 M.R.S. § 13753(1)(C) requires that change of a Pharmacist in Charge requires notice to the Board no later than seven (7) days after the change. In addition, upon a change in Pharmacist in Charge, a mail order pharmacy shall file a new application with the Board no later than seven (7) days after the change. Board Rule Chapter 11, § 3.
5. Wells Pharmacy was required to file an application and notify the Board of the change in the Pharmacist in Charge no later than October 10, 2013, but failed to do so until October 23, 2013.
6. On June 5, 2014, following a presentation of the complaint, the Board voted to offer Wells Pharmacy this Consent Agreement in order to finally resolve Complaint No. 2013 PHA 9589.
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 October 3, 2014, the Board will resolve this matter by holding an adjudicatory hearing.

#### COVENANTS

8. Wells Pharmacy admits the facts stated above and that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. §§ 8003(5-A)(A)(4),(5), 32 M.R.S. § 13753(1)(C), 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. Wells Pharmacy agrees to accept the following discipline:
  - a. A WARNING; and

In re: Wells Pharmacy  
2013 PHA 9589

2 of 4

Consent Agreement

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LICENSING DIVISION  
OCT 10 2014  
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STATE OF MAINE  
BOARD OF PHARMACY

IN RE:

WELLS PHARMACY NETWORK LLC )

Complaint No. 2013 PHA 9589 )

CONSENT AGREEMENT

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LICENSING DIVISION

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Wells Pharmacy Network LLC in the State of Maine. The parties to this Consent Agreement are: Wells Pharmacy Network LLC ("Wells Pharmacy"), 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, Wells Pharmacy was licensed by the Board as a mail order pharmacy, license no. MO40001342, located at 1210 SW 33<sup>rd</sup> Avenue, Ocala, Florida.
2. The Board received a change in Pharmacist in Charge application from Wells Pharmacy on October 23, 2013, which disclosed that on October 3, 2013, Robert J. Pruneau took over as the Pharmacist in Charge of Wells Pharmacy.
3. Board Investigator Thomas Avery filed a complaint with the Board alleging that Wells Pharmacy had failed to timely notify the Board of the change in the Pharmacist in Charge as required, which the Board docketed as Complaint No. 2013 PHA 9589.

In re: Wells Pharmacy  
2013 PHA 9589

1 of 4

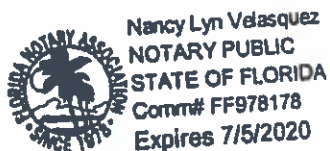
Consent Agreement

EXHIBIT "1"

STATE OF Florida )  
 ) SS.  
 COUNTY OF Seminole )

On this 26<sup>th</sup> day of April, 2017, before me personally appeared  
Colleen Stacy Shapiro, to me known to be the person described, and who executed the  
 foregoing instrument on behalf of WELLS PHARMACY NETWORK, LLC as its  
member/secretary, and acknowledged that he/she executed the same as his/her  
 free act and deed.

This 7-page SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION  
 FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER document dated  
April 26, 2017 was acknowledged before me by  
 [Date Document Signed by Respondent]  
Colleen Stacy Shapiro this 26 day of April, 2017,  
 [Name of Person Signing Document]  
 in the City of Winter Park, in the County of Seminole, in the State of  
Florida. Colleen S Shapiro



[Signature]  
 Name: Nancy Lyn Velasquez  
 Notary Public, State of Florida

My Commission expires: 7/5/20

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF WELLS PHARMACY  
 NETWORK, LLC; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR  
 DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" THROUGH "3";  
RICO CASE NO. PHA 2016-30-L

APPROVED AND SO ORDERED:  
 BOARD OF PHARMACY  
 STATE OF HAWAII

Keri Okamura  
 KERRI OKAMURA  
 Chairperson

6/15/17  
 DATE

Garrett A. Lau  
 GARRETT A. LAU  
 Vice Chairperson

Marcella Chock  
 MARCELLA CHOCK

Mary Jo Keeffe  
 MARY JO KEEFFE

Carolyn S. J. Ma  
 CAROLYN S. J. MA

Ronald Weinberg  
 RONALD WEINBERG

Julie Yurie Takishima-Lacasa  
 JULIE YURIE TAKISHIMA-LACASA

PVL 05/26/16



2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous pharmacy permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., C.7., and C.8. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.



4. Respondent being at all times relevant herein the holder of a miscellaneous permit acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the Maine Agreement.

6. Respondent represents Exhibit "2" is a true and correct copy of the Florida Agreement.

7. Respondent represents Exhibit "3" is a true and correct copy of the Arizona Agreement.

8. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

9. Respondent further understands that RICO enters into this settlement agreement, and agrees to the specific terms contained in this settlement agreement, based upon Respondent's representations made herein.

10. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's miscellaneous permit. Respondent states it does not compound drugs in the State of Hawaii.

11. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

12. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2016-30-L.

13. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

14. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

#### C. TERMS OF SETTLEMENT:

1. Administrative costs. Respondent agrees to pay costs in the amount of TEN THOUSAND AND NO/100 DOLLARS (\$10,000.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn.: John T. Hassler, Esq., 235 S. Beretania Street, 9<sup>th</sup> Floor, Honolulu, Hawaii 96813. Payment shall be due at the time this Settlement Agreement is returned to RICO.

4. Respondent provided a copy of a Consent Agreement issued to Respondent by the Maine Board of Pharmacy in Complaint No. 2013 PHA 9589 (hereinafter "the Maine Agreement") (Exhibit "1"). The Maine Agreement was based on allegations Respondent failed to timely notify of changes to the required pharmacist in charge, issued a warning, and imposed a civil penalty of \$750.00.

5. Respondent also provided a copy of a Voluntary Agreement to Restrict Practice of Sterile Compounding issued to Respondent by the Florida Department of Health filed on October 5, 2016 (hereinafter "the Florida Agreement") (Exhibit "2"). The Florida Agreement alleged from February 21, 2014 through March 7, 2014, representatives of the United States Food and Drug Administration ("FDA") conducted an inspection of Respondent's facility located in Ocala, Florida. Thereafter, the FDA issued a report detailing potential violations. A subsequent investigation was conducted by the Florida Department of Health. Following that investigation, Respondent voluntarily agreed to restrict sterile compounding while it addressed Florida's concerns. The restriction was lifted by the Florida Department of Health on November 5, 2016.

6. Respondent also provided a copy of a Consent Agreement for Probation, Civil Penalty, Costs and Inspection issued to Respondent by the Arizona Board of Pharmacy in Board Case No. 14-0019-PHR (hereinafter "the Arizona Agreement") (Exhibit "3"). The Arizona Agreement was based on discrepancies observed during inspections by representatives of the United States Food and Drug Administration during inspections in Florida and imposed civil penalties and costs totaling \$11,345.37.

7. RICO alleges that disciplinary action was taken against Respondent by the states of Maine, Florida, and Arizona.

8. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

9. The Board has jurisdiction over the subject matter herein and over the parties hereto.

**B. REPRESENTATIONS BY RESPONDENT:**

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

DARIA A. LOY-GOTO

6175

JOHN T. HASSLER

5311

Regulated Industries Complaints Office

Department of Commerce and Consumer Affairs

State of Hawaii

Leiopapa A Kamehameha Building

235 South Beretania Street, Suite 900

Honolulu, Hawaii 96813

Telephone: 586-2660

DEPT. OF COMMERCE  
AND CONSUMER AFFAIRS

2017 JUN 16 P 12:41

HEARINGS OFFICE

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LICENSING DIVISION

2017 MAY 16 A 9:49

DEPT OF COMMERCE  
AND CONSUMER AFFAIRS  
STATE OF HAWAIIAttorneys for Department of Commerce  
and Consumer AffairsBOARD OF PHARMACY  
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS  
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of ) PHA 2016-30-L

WELLS PHARMACY NETWORK, LLC, )

Respondent. )

SETTLEMENT AGREEMENT PRIOR TO  
FILING OF PETITION FOR DISCIPLINARY  
ACTION AND BOARD'S FINAL ORDER;  
EXHIBITS "1" THROUGH "3"

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION  
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS, REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent WELLS PHARMACY NETWORK, LLC (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

**A. UNCONTESTED FACTS:**

1. At all relevant times herein, Respondent was the holder of miscellaneous permit number PMP 797, issued by the Board of Pharmacy (hereinafter the "Board"). The miscellaneous permit was issued on or about August 2, 2012. The miscellaneous permit will expire or forfeit on or about December 31, 2017.

2. Respondent's mailing address for purposes of this action is 1210 S.W. 33<sup>rd</sup> Avenue, Ocala, Florida 34474.

3. RICO received a request for investigation from the Board after Respondent reported disciplinary actions taken by the states of Maine and Arizona on a December 14, 2015 renewal application. Respondent later reported disciplinary action by the State of Florida.

I HEREBY CERTIFY THAT THE ATTACHED  
IS A TRUE AND CORRECT COPY OF THE  
ORIGINAL ON FILE IN THE DEPARTMENT  
OF COMMERCE & CONSUMER AFFAIRS.

*Jai H*

1 pyrogens of batch-produced sterile injectable drug products compounded from one or more non-  
 2 sterile ingredients. The circumstances are as follows:

3 14. Between May 2015 and March 2016, Respondent shipped about 2,890 batch-  
 4 produced non-sterile to sterile compounded injectable drug products into California without  
 5 documentation of end product sterility or pyrogen testing.<sup>2</sup>

6 **PRAYER**

7 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
 8 and that following the hearing, the Board of Pharmacy issue a decision:

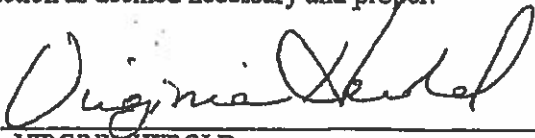
9 1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1325, issued to  
 10 Wells Pharmacy Network LLC;

11 2. Revoking or suspending Non-Resident Pharmacy Permit Number NSC 99824, issued  
 12 to Wells Pharmacy Network LLC;

13 3. Ordering Wells Pharmacy Network LLC to pay the Board of Pharmacy the reasonable  
 14 costs of the investigation and enforcement of this case, pursuant to Business and Professions Code  
 15 section 125.3; and,

16 4. Taking such other and further action as deemed necessary and proper.

17  
 18 DATED: 10/14/16

  
 VIRGINIA HEROLD  
 Executive Officer  
 Board of Pharmacy  
 Department of Consumer Affairs  
 State of California  
 Complainant

19  
 20  
 21  
 22  
 23 SA2016102809  
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24  
 25  
 26  
 27  
 28 <sup>2</sup> A pyrogen is any substance or agent that causes fever.

## REGULATIONS

8. Section 1751 of title 16 of the California Code of Regulations (16 CCR 1751) states, in pertinent part: "(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7."

9. 16 CCR 1751.7 states, in pertinent part:

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

## COST RECOVERY

10. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licensee 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.

## FIRST CAUSE FOR DISCIPLINE

(Compounding Sterile from Non-Sterile Drugs in Improper Environment)

11. Respondent is subject to disciplinary action under Code section 4127.7 and 16 CCR 1751(c), by and through Code section 4301(o), in that Respondent compounded sterile injectable drugs from non-sterile ingredients in an improper environment. The circumstances are as follows:

12. On or about March 4, 2016, during an inspection of Respondent's premises, a Board inspector found that Respondent compounded non-sterile to sterile drugs in a clean room that was certified only as an ISO 7 environment, instead of the required ISO 5 environment.<sup>1</sup>

## SECOND CAUSE FOR DISCIPLINE

(Failure to Document Quality Assurance)

13. Respondent is subject to disciplinary action under 16 CCR 1751.7(c), by and through Code section 4301(o), in that Respondent failed to document end product testing for sterility and

///

<sup>1</sup> Clean rooms are classified by the International Organization for Standardization (ISO) according to the size of particles permitted in the air, from ISO 1 (smallest) to ISO 9 (largest).

1 products. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to  
2 the charges brought herein and will expire on May 1, 2017, unless renewed.

### 3 JURISDICTION

4 4. This Accusation is brought before the Board of Pharmacy (Board), Department of  
5 Consumer Affairs, under the authority of the following laws. All section references are to the  
6 Business and Professions Code unless otherwise indicated.

### 7 STATUTORY REFERENCES

8 5. Section 4301 of the Code states, in pertinent part:

9 The board shall take action against any holder of a license who is guilty of  
10 unprofessional conduct or whose license has been procured by fraud or misrepresentation or  
11 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the  
12 following:

13 ...

14 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting  
15 the violation of or conspiring to violate any provision or term of this chapter or of the  
16 applicable federal and state laws and regulations governing pharmacy, including regulations  
17 established by the board or by any other state or federal regulatory agency.

18 6. Section 4300.1 of the Code states:

19 The expiration, cancellation, forfeiture, or suspension of a board-issued license by  
20 operation of law or by order or decision of the board or a court of law, the placement of a  
21 license on a retired status, or the voluntary surrender of a license by a licensee shall not  
22 deprive the board of jurisdiction to commence or proceed with any investigation of, or  
23 action or disciplinary proceeding against, the licensee or to render a decision suspending or  
24 revoking the license.

25 7. Section 4127.7 of the Code states:

26 On and after July 1, 2005, a pharmacy shall compound sterile injectable products from  
27 one or more nonsterile ingredients in one of the following environments:

28 (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The  
cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

1 KAMALA D. HARRIS  
 Attorney General of California  
 2 KENT D. HARRIS  
 Supervising Deputy Attorney General  
 3 DAVID E. BRICE  
 Deputy Attorney General  
 4 State Bar No. 269443  
 1300 I Street, Suite 125  
 5 P.O. Box 944255  
 Sacramento, CA 94244-2550  
 6 Telephone: (916) 324-8010  
 Facsimile: (916) 327-8643  
 7 E-mail: David.Brice@doj.ca.gov  
*Attorneys for Complainant*

8  
 9 **BEFORE THE**  
**BOARD OF PHARMACY**  
**DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5887

12 **WELLS PHARMACY NETWORK LLC**  
 13 450 US Hwy 51 Bypass N  
 14 Dyersburg, TN 38024

**A C C U S A T I O N**

15 Non-Resident Pharmacy Permit No. NRP  
 1325  
 16 Non-Resident Pharmacy Permit No. NSC  
 99824

17 Respondent.

18  
 19 Complainant alleges:

20 **PARTIES**

21 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as  
 22 the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

23 2. On or about May 28, 2013, the Board of Pharmacy issued Original Non-Resident  
 24 Pharmacy Permit Number NRP 1325 to Wells Pharmacy Network LLC (Respondent). The Non-  
 25 Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought  
 26 herein and will expire on May 1, 2017, unless renewed.

27 3. On or about July 1, 2013, the Board of Pharmacy issued Original Non-Resident  
 28 Pharmacy Permit Number NSC 99824 to Respondent to compound injectable sterile drug

## **Exhibit A**

**Accusation No. 5887**




ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/23/2017

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
KENT D. HARRIS  
Supervising Deputy Attorney General

  
DAVID E. BRICE  
Deputy Attorney General  
*Attorneys for Complainant*

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8           15. In consideration of the foregoing admissions and stipulations, the parties agree that  
9   the Board may, without further notice or formal proceeding, issue and enter the following  
10 Disciplinary Order:

11 | **DISCIPLINARY ORDER**

12 IT IS HEREBY ORDERED that both Non-Resident Pharmacy Permit No. NRP 1325 and  
13 Non-Resident Sterile Compounding Permit No. NSC 99824 issued to Respondent Wells  
14 Pharmacy Network LLC shall be publicly reprovved by the Board of Pharmacy under Business  
15 and Professions Code section 495 in resolution of Accusation No. 5887, attached as exhibit A.

16 **Cost Recovery.** Respondent shall pay \$6,155.25 to the Board for its costs associated with  
17 the investigation and enforcement of this matter. Respondent shall be permitted to pay these  
18 costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as  
19 ordered, Respondent shall not be allowed to renew its Non-Resident Pharmacy Permit or its Non-  
20 Resident Sterile Compounding Permit until Respondent pays costs in full.

21 |||

22 || *///*

23 |||

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 5887, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

11. Respondent agrees that its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit are subject to discipline and agrees to be bound by the Disciplinary Order below.

## CONTINGENCY

12. 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 its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its 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 for Public Reprimand 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.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reapproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

JURISDICTION

3. On or about May 28, 2013, the Board issued Original Non-Resident Pharmacy Permit No. NRP 1325 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

4. On or about July 1, 2013, the Board issued Original Non-Resident Sterile Compounding Permit Number NSC 99824 to Respondent to compound injectable sterile drug products. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

5. Accusation No. 5887 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 21, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5887 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5887. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reapproval.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

///

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*Attorneys for Complainant*

8  
 9 **BEFORE THE**  
**BOARD OF PHARMACY**  
**DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5887

12 **WELLS PHARMACY NETWORK LLC**  
 13 **450 US Hwy 51 Bypass N**  
**Dyersburg, TN 38024**

OAH No. 2017011087

14 **Non-Resident Pharmacy Permit No. NRP**  
 15 **1325**  
**Non-Resident Sterile Compounding Permit**  
 16 **No. NSC 99824**

**STIPULATED SETTLEMENT AND**  
**DISCIPLINARY ORDER FOR PUBLIC**  
**REPROVAL**

[Bus. & Prof. Code § 495]

17 Respondent.

18  
 19 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
 20 entitled proceedings that the following matters are true:

21 **PARTIES**

22 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy  
 23 (Board). She brought this action solely in her official capacity and is represented in this matter by  
 24 Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney  
 25 General.

26 2. Wells Pharmacy Network LLC (Respondent) is represented in this proceeding by  
 27 attorneys Steven L. Simas and Daniel Tatick, whose address is: Simas and Associates, 3835  
 28 North Freeway Blvd., Suite 228, Sacramento, CA 95834.

**BEFORE THE  
BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

**WELLS PHARMACY NETWORK LLC  
450 US Hwy 51, Bypass N  
Dyersburg, TN 38024**

**Non-Resident Pharmacy Permit No. NRP 1325  
Non-Resident Sterile Compounding Permit No.  
NSC 99824**

Case No. 5887  
OAH No. 2017011087

**STIPULATED SETTLEMENT  
AND DISCIPLINARY ORDER  
FOR PUBLIC REPROVAL**

Respondent.

**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 at 5:00 p.m. on July 26, 2017.

It is so ORDERED on June 26, 2017.

**BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**



By

\_\_\_\_\_  
Amy Gutierrez, Pharm.D.  
Board President

May 26, 2017  
Page 4

When this legislation passes as expected, the very basis of the Board's Accusation will no longer exist. We believe this, along with WPN's responsiveness and corrections, was a major factor in the Board relenting on more serious discipline.

Clearly, WPN's use of an ISO 7 cleanroom had no adverse impact on the end product, nor did it negatively affect the patients consuming its drugs. The Board sought to punish WPN for actions that will, in all likelihood, no longer be violations of the Board's regulations. Thus, the Board relented with merely a public reproval.

### Conclusion

To conclude, WPN has been operating its Tennessee facility without incident. The Board was overzealous in its prosecution and failed to realize the acts with which it sought to punish WPN would no longer be punishable offenses. WPN continues to deliver high quality pharmaceutical products but understands its obligation to report any disciplinary action taken against it, no matter how minimal, to other Boards of Pharmacy across the country. WPN respectfully requests this letter serve as satisfaction of its reporting requirements.

If you have additional questions and/or concerns, please direct them to WPN directly. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel J. Tatick", followed by a stylized flourish or checkmark.

Daniel J. Tatick  
Simas & Associates, Ltd.

DJT:ms



May 26, 2017

Page 3

Nutek Corporation ("Nutek") and Steri-Tek, both California companies. Nutek/Steri-Tek use E-Beam sterilization which is approved by the Food and Drug Administration ("FDA"). Prior to the inspection, WPN utilized Eagle Laboratories and Dynalabs, both of which tested potency/purity and Endotoxins.

These facilities and their equipment met the stringent American National Standard ISO 11137 requirements for sterilization of health care products. Sterilization utilizing E-Beam technology at an FDA approved facility eliminated the need for the usual sterility, Endotoxin, and pyrogen testing. This form of terminal sterilization eliminates the requirement for employee media fill validation. Moreover, WPN demonstrated its dedication to the highest standards of continued education and training for its manufacturing employees by ensuring its employees completed requisite on-line courses in its on-line database. The database ensured prompt and timely completion of each required course and immediately records the date of each completed training and the recurring deadline for taking each course. Lastly, WPN revamped its Simplifi 797: Task Scheduler to ensure all cleaning steps and activities were listed and logged. As you can see, WPN took the necessary steps to address the Board's concerns.

### Changes in Regulations

We also believe that significant changes in California law have contributed to the Board's willingness to settle our client's case. California regulations are some of the strictest in the country. WPN had been operating its Tennessee facility in compliance with FDA regulations which mirrored the requirements of other jurisdictions. Unfortunately, California had changed the requirements in 2005 and no longer allowed for an ISO 7 cleanroom when compounding non-sterile to sterile drugs. This change required an ISO 5 cleanroom which created confusion and issues across the state.

Because of this confusion, the California Legislature has introduced a bill in January 2017, to change this law back to the prior version eliminating the need for an ISO 5 cleanroom. Senate Bill 510 addresses this change which was passed unanimously by the Senate on March 27, 2017, with the Board's support.<sup>1</sup> SB 510 is currently awaiting a vote in the California State Assembly which is expected to occur sometime in June, and is, likewise, expected to pass. The Board continues to support SB 510.

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<sup>1</sup> [https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill\\_id=201720180SB510](https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB510)

May 26, 2017

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hearing. The parties exchanged discovery and the matter was set to be heard at the Office of Administrative Hearing by an Administrative Law Judge over four (4) days, June 13-16, 2017.

### **Settlement and Public Reapproval**

On or about May 23, 2017, WPN entered into a stipulated settlement with the Board agreeing to the issuance of a Letter of Public Reapproval. As the result of a number of factors impacting its case, the Board settled for the lowest possible form of discipline, a public reapproval.

Although technically discipline, a reapproval does not, in any way, restrict or impact WPN's ability to continue to manufacture its product and ship those products to California. WPN's license is not on probation; nor does it have to provide the board with quarterly reports, have a monitor, or otherwise limit its operations. Because the Board's ultimate obligation is to ensure public safety and a reapproval has minimal impact on a licensee, the Board does not issue reapprovals freely. By doing so, the Board has agreed WPN poses no risk to the public's safety and should be permitted to continue its operation without the checks and balances seen in a probationary license.

In the face of legislative changes impacting the very code section the Board was seeking to enforce and the swift remediation and response of WPN, the Board was willing to relent on its pursuit of serious license discipline.

Due to the significant costs and uncertainty involved with taking the case to hearing, WPN agreed to the reapproval due to its minimal impact and because it provided a smooth transition into obtaining a 503b Outsourcing Facility license.

### **WPN's Immediate Response and Remediation**

Immediately after receiving the inspector's report and seven (7) months before the Accusation was even issued, WPN shut down all its manufacturing operations to California patients. WPN instituted and changed every itemized finding of the inspector including, but not limited to, constructing an ISO 5 cleanroom, updating and/or creating its standard operating procedures and revamping its on-line training database. WPN further submitted reports from its third-party vendor(s) responsible for conducting the sterility testing,

Steven L. Simas  
Justin D. Hein  
Lindsay H. Yoshitomi  
Daniel J. Tatick



TELEPHONE  
916.789.9800

FACSIMILE  
916.789.9801

May 26, 2017

SACRAMENTO  
SAN DIEGO  
SAN LUIS OBISPO  
SANTA ROSA

**Re:       *In the Matter of the Accusation Against Wells Pharmacy  
              Network, LLC***  
**Case No.: 5887; OAH Case No.: 2017011087**

**To Whom It May Concern:**

Our office represented Wells Pharmacy Network ("WPN") in the above-referenced matter against the California Board of Pharmacy ("Board"), which has since been resolved. Because WPN has active licenses in several other states, we wanted to explain the Accusation, the resolution reached, WPN's reasoning for agreeing to settle, the steps taken by WPN to remedy the situation, and the changing regulations. Each is discussed in further detail below.

### **Accusation**

On March 4, 2016, WPN's Tennessee facility was inspected by a Board inspector. The inspector determined WPN was using the improper cleanroom environment when compounding non-sterile to sterile drugs. WPN utilized an ISO 7 cleanroom when California Business and Professions Code § 4127.7 (at the time) required an ISO 5 cleanroom. Additionally, the Board inspector determined the sterile injectable drug products WPN was manufacturing were not adequately subjected to documented end product testing for sterility and pyrogens pursuant to Title 16 of California Code of Regulations § 1751.7.

After this inspection visit, on March 11, 2016, WPN immediately resolved all issues addressed in the report and reported same to the Board.

In spite of WPN's immediate efforts to comply with this unique California provision and the report of the Board inspector, on October 14, 2016, the Board still issued an Accusation regarding these former violations. The Accusation alleged two (2) causes for discipline. WPN timely filed its Notice of Defense denying the charges in the Accusation and requesting a

North Pointe Business Centre  
3835 North Freeway Blvd., Ste. 228, Sacramento, CA 95834

[www.simasgovlaw.com](http://www.simasgovlaw.com)

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."

Documents received/reviewed:

SOP Index

Pharmacist/Technician roster

Florida Community Pharmacy Inspection report

Florida Standards of Practice for Compounding Sterile Preparations (CSPs) report

Arizona prescriptions/orders report (sorted by date)

Arizona prescriptions/orders report (sorted by name)

Filling/compounding records for:

Rx [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED]

Compounding records for:

Lot 09022014@1, 09022014@2, 08142014@17, 08142014@20, 08142014@19

Article: Long-Term Stability of Trimix: A Three-Drug Injection Used to Treat Erectile Dysfunction

Compounding record for:

Lot 09022014@35

Article: Six-month Stability of Bevacizumab (Avastin) Binding to Vascular Endothelial Growth Factor after Withdrawal into a Syringe and Refrigeration or Freezing

Lab report for Lot 08252014@48

Reprint of office-use label

Use log for Flumethasone Pivalate Powder

Compounding record for:

Lot 09022014@53, 09022014@54

ScanRDI documentation:

Scan Bio II protocol using FIFU, Daily Control (FIFU/CB04)

Article: The ScanRDI Sterility Test Protocol as an Effective and Reliable Test for Sterile Compounded Preparations

Certificates of Compliance from Medrep Technologies for clean room and chemo room

Practitioner license verification screenprint

SOPs:

1.010, 1.030, 2.020, 2.030, 2.040, 3.010, 3.020, 3.030, 3.040, 3.050, 4.030, 4.070, 4.090, 4.110, 4.130, 4.200, 4.210, 5.010, 5.011, 5.040, 5.050, 5.070, 6.010, 6.020, 8.010, 9.010, 9.020, 9.040, 9.050, 9.060, 9.080, 9.090, 9.100, 9.110, 9.120, 9.140, 9.150, 9.161

Filling/compounding records for:

Rx [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED]

Copy of letter from WPN dated October 14, 2014

- Rx [REDACTED]-invoice indicates that the product was shipped to an address other than the patient's residence or prescriber office/home.
- Rx [REDACTED]-invoice indicates that the product was shipped to an address other than the patient's residence or prescriber office/home. Sterility testing was conducted using 4 X 3mL vials from a batch of 250 X 10mL vials. Verifying pharmacist is not documented in the compounding record.

Rx [REDACTED] (office use)-compounding record indicates a kit lot number of 02282014@9 with BUD 8-31-2014. The kit includes Chorionic Gonadotropin, Lyophilized 2,000 Unit vial Lot 02192014@11 with BUD 8-31-2014. The compounding record for lot 02192014@11 includes the following components:

Sodium Phosphate, Monobasic, USP Anhydrous Lot C152858, expiration date 5-1-2014  
Sodium Phosphate Dried Dibasic Powder Lot WWC150510, expiration date 5-30-2014

- As indicated, these two components have expiration dates that occur prior to the BUD stated for the compounded item as well as the kit. Sterility testing results do not include the number of containers/ total volume tested.
- Rx [REDACTED]-Sterility testing results do not include the number of containers/ total volume tested.

Rx [REDACTED] (office use)- compounding record indicates a kit lot number of 12092013@68 with BUD 6-30-2014. The kit includes Chorionic Gonadotropin, Lyophilized 11,000 Unit vial Lot 12042013@63 with BUD 6-30-2014. The compounding record for lot 12042013@63 includes the following components:

Sodium Phosphate, Monobasic, USP Anhydrous Lot C152858, expiration date 5-1-2014  
Sodium Phosphate Dried Dibasic Powder Lot C152701, expiration date 5-1-2014

- As indicated, these two components have expiration dates that occur prior to the BUD stated for the compounded item as well as the kit. Sterility testing results do not include the number of containers/ total volume tested.

A copy of a letter dated October 14, 2014 was received announcing that WPN will no longer be providing sterile compounded products for office use.

#### Potential concerns/violations:

Breach of sterile garbing SOP by technician in ante room.  
SOPs may not be indicative of current practices  
Lack of pharmacist verification during each step of compound preparation.  
Provision of patient written information not consistent.

Multiple inconsistencies in documentation practices of LFW and FW including:

- BUD
- Sterile filtration
- Sterility sampling
- Quality Assurance verification

Sterility sampling not compliant with USP<71> requirements for number of containers/total volume tested.  
Position of Quality Manager currently filled by a technician when pharmacist required by SOP.  
Beyond Use Date of compounds in excess of component Beyond Use Date/Expiration Date.

- Rx [REDACTED] (office use)-compounding record indicates that 2 vials were tested for sterility and endotoxins from a batch size of 50 vials.

For office use orders, current license numbers/expiration dates of practitioners are maintained electronically.

**Review of FDA Form 483 observations dated 3-7-2014:**

Observation 1-media fill testing results/SOPs were reviewed.

Observation 2-most recent clean room/hood certifications were conducted under operational conditions by new vendor.

Observation 3-SOPs/results were reviewed for routine air/surface and fingertip testing.

Observation 4-agents for disinfection/cleaning in SOP were present on USP<797> list.

Observation 5-Avastin syringes are tested for endotoxins and sterility (via Scan RD1); however, sampling plan is not compliant with USP<71> requirements.

Observation 6-current BUD meets requirements of R4-23-410(B)(3)(d).

Observation 7-sterile gowns not required for USP<797> compliance; however, observed breach of ante room protocol was described above.

Observation 8-ScanRD1 qualification was presented to FDA by WPN during exit interview.

Observation 9- not required in Arizona for pharmacy permittees.

Observation 10- not required in Arizona for pharmacy permittees.

Observation 11-calibration/maintenance of gauges performed by new environmental certification vendor.

**Additional observations:**

Distribution of Avastin was discussed in relation to compounding versus repackaging.

A copy of a prescription label was provided and found to be in substantial compliance with Arizona requirements.

Additional records were requested on October 10, 2014 and received on October 15, 2014:

**Of note:**

Rx [REDACTED] compounding record indicates a kit lot number of 01062014@15 with BUD 6-30-2014. The kit includes Chorionic Gonadotropin + B12, Lyophilized 10,000 Unit vial lot 12202013@2 with BUD 6-30-2014. The compounding record for lot 12202013@2 includes the following components:

Cyanocobalamin (Vit B12)-Dextrose Lot 10142013@66, BUD 4-12-2014.

Sodium Phosphate, Monobasic, USP Anhydrous Lot C152858, expiration date 5-1-2014

Sodium Phosphate Dried Dibasic Powder Lot WWC150510, expiration date 5-30-2014

- As indicated, these three components have BUD/expiration dates that occur prior to the BUD stated for the compounded item as well as the kit. Also, the amount of B12 is not stated in the drug name of the compound record. It is unknown if the amount is included on the final container label. Sterility testing results do not include the number of samples tested.

Following a review of the SOP index, several SOPs were requested.

- The majority of SOPs have not been reviewed within the past two years. Of note:
- SOP 5.040 Patient Counseling of Compounded Preparations-section 9.4 states that patient instructions and information shall be distributed with the preparation if available. This is not in compliance with Arizona requirements.
- SOP 8.010 Sterilization and Depyrogenation-section 9.2.8 requires bubble integrity testing when filtration is performed on high risk compounds. This was not documented for the above mentioned Hyaluronidase compound.
- SOP 9.040 Formula Worksheet-section 5.1 identifies the Quality Assurance Manager as a qualified pharmacist. The current Quality Manager is Travis Wood, CPhT. Section 9.7.6 requires a pharmacist to prepare the first formulation of a complex preparation which is then verified and approved by the Quality Manager which is not currently a pharmacist.

Ten random prescriptions/orders from the Arizona report were selected. Filling and compounding documentation was requested. Of note:

- Rx [REDACTED]-the compounding records contains no documentation of quality assurance verification of the capsule preparation.
- Rx [REDACTED] (office use)-preparation is autoclaved in bulk and then placed in final container. Item was tested for sterility and endotoxins, but procedure for how and when to obtain samples for testing is not documented. It appears that 4 x 10mL syringes were obtained from a 3000mL bulk.
- Rx [REDACTED] (office use)-compounding record indicates that 5 syringes were tested for sterility and endotoxins from a batch size of 790 syringes.
- Rx [REDACTED] (office use)-compounding record indicates that 5 syringes were tested for sterility and endotoxins from a batch size of 780 syringes.
- Rx [REDACTED] (office use)-compounding record indicates that 2 vials were tested for sterility and endotoxins from a batch size of 710 vials.
- Rx [REDACTED]-compounding record indicates that 2 vials were tested for sterility and endotoxins from a batch size of 480 vials.
- Rx [REDACTED]-compounding record indicates that 4 vials were tested for sterility and endotoxins from a batch size of 600 vials.
- Rx [REDACTED]-documentation of filter lot number/expiration date and bubble point testing not indicated in the compounding record. Sampling plan for sterility/endotoxin testing not indicated.
- Rx [REDACTED]-the compounding records contains no documentation of quality assurance verification of the tablet preparation.



- WPN explained that when the above orders were dispensed, the BUD was revised to 14 days. This is not documented in the compounding record.

Each of the above items were compounded from the following compounded bulk ingredients:

Lot 08142014@17 Papaverine HCl 40mg/mL (BUD 2/10/15)

Lot 08142014@19 Phentolamine 20mg/mL (BUD 2/10/15)

Lot 08142014@20 Alprostadil (M) 500mcg/mL (BUD 2/10/15)

- Inconsistencies were observed regarding BUD dating by edits in the Log Instructions and notes area.

Sterility and endotoxin testing results were provided. Most sterility testing is performed inhouse utilizing ScanRDI technology. Testing and control protocols were provided as well as an article comparing ScanRDI reliability to USP<71>.

- A review of the article describes a favorable comparison of results; however, the article states that the sampling plan of USP<71> regarding number of containers and total volume tested should be followed. WPN pulled 2 X 5mL samples from each of the above bulks, regardless of the number of containers/volume compounded. While this is current practice at WPN, this is not in compliance with USP<71> requirements.
- Additionally, WPN explained that sampling/testing is not formalized in WPN SOPs but was in development. However, a review of SOP 9.120-STERILE COMPOUNDING FINISHED PREPARATION TESTING found reference to USP<71> requirements to be followed in section 9.1.4.
- An article was provided to justify the 180 day BUD for the bulk compounds. A review of the article stated that a 6 month BUD was appropriate for a Trimix compound when frozen, but 1 month when refrigerated. There was no indication of a BUD recommendation for the individual components prior to compounding as Trimix. Also, the compounding records are unclear as to storage of the bulk prior to use in a final compound.

Lot 09022014@53 Hyaluronidase – Preservative Free 150 U/mL Injectable

Logged Formula Worksheet (LFW) not documented by a pharmacist, but a Formula Worksheet (FW) stapled to LFW was initialed by a pharmacist; however, WPN explained that the LFW is the compounding record.

- Sterile filtration indicated in the procedure, but no documentation of filter testing results.

Lot 09022014@35 Bevacizumab Test – (0.05mL Syringe, 31G, 5/16") 25mg/mL Injectable

The LFW has "20 labels" written over the record. WPN explained that 20 previously prepared syringes were placed in individual sleeves per prescriber request.

- A new lot number was assigned to this order. The record is confusing in that it reads as if the syringes were prepared and packaged, not just packaged. The BUD is manually struck through and edited with the BUD of the previously prepared syringes. An article was provided to justify the 90 day BUD.

introduced. He is a pharmacist in the compounding area and is responsible for sterility testing utilizing the ScanROI instrumentation.

- While observing activity in the ante room, a technician was viewed exiting the ante room, in full garb, to obtain items from a cart. The technician then crossed back over the line of demarcation within the ante room without re-garbing. When this observation was shared with Mr. Wood and Dr. Campbell, they indicated that this not in compliance with WPN SOPs. A few moments later, the same technician was observed working in the ante room without gloves or a mask in an area where those items were required.

Components are purchased primarily from PCCA, Medisca, Letco and Attix. One outdated item was found. The item, Flumethasone Pivolate, was labeled as manufactured by Farmabios from Italy. A Certificate of Analysis was requested but not available. It was stated that this item was obtained during the purchase of the pharmacy from Franck's Pharmacy. A computer search found that the item had not been used in any compounded items since March 2012. The item was removed from active stock and placed in quarantine. One individual is responsible for performing outdate checks and items are pulled from inventory with less than 30 days dating. Compounded items in anticipation of prescriptions/orders were properly labeled. At the rear of the building is a warehouse area that is not climate-controlled. This area houses non-drug items as well as a labeled quarantine area for expired/damaged items.

During the tour, the workflow of the compounding area was described. The Logged Formula Worksheet is the compounding record. The technicians weigh components on scales (+/- 3%) and the results are recorded in the compounding software. The technician proceeds to complete the compounded product and a pharmacist performs a final check.

- Although a pharmacist is present within the general compounding area, they do not perform/document a verification of components/weights prior to completion of the finished product.

Following final pharmacist check, the orders/prescriptions are packaged for shipment via UPS and Fed Ex. When asked about patient-written information, WPN does not provide written information with every order. This was explained as a software issue that is being addressed.

Training records of technicians were reviewed and were found to be in order. Technicians may perform low and medium risk compounding as determined by their level of training. WPN explained that technicians are registered in Florida and are not required to have additional certification. Florida does have a 3:1 technician:pharmacist ratio. Technicians are required to obtain continuing education. WPN sends technicians to a 40 hour compounding course provided by the Florida Pharmacist Association as well as on-the-job training.

Media fill testing results were in order. Fingertip/surface testing results were in order. Clean room and hood certifications were current and were conducted under operational (dynamic) conditions. All cleaning and equipment calibration is documented electronically.

A random sampling of compounding records were reviewed. The following were noted:

Lot 09022014@1 Trimix 17.65mg/0.59mg/5.9mcg Injectable 10mL

Beyond Use Date (BUD) indicated as 50 days after compounding date

Final container indicated as sterile vial but size/lot of the vial was not recorded

Storage indicated as Refrigerate

Lot 09022014@2 Trimix 30mg/2mg/20mcg Injectable 5mL

BUD Indicated as 180 days after compounding date

Storage indicated as Refrigerate



# Arizona State Board of Pharmacy

To : Hal Wand, Executive Director, ASBP  
Cheryl Frush, Deputy Director, ASBP

Date: 10/15/2014

From: Sandra Sutcliffe, CO ASBP  
Dennis Waggoner, CO ASBP

Subject: Wells Pharmacy Network

As directed by the Board, CO Sandra Sutcliffe and CO Dennis Waggoner visited Wells Pharmacy Network (Y005709) located at 1210 SW 33<sup>rd</sup> Avenue, Ocala, FL 34474 on October 7-8, 2014 to conduct an inspection and provide feedback related to the observations noted on FDA Form 483 issued 3-7-2014. The Notice of Inspection Rights was reviewed with Kris Fishman, Vice President of Pharmacy Operations, and Rita Weiss, RPh, Esq, Pharmacy Manager (as of 8-1-2014).

The purpose of the visit was discussed with Mr. Fishman and Ms. Weiss as well as Travis Wood, CPhT, Quality Manager. Ms. Sutcliffe stated that the inspection was to determine compliance with Arizona regulations as well as to discuss the observations of the FDA Form 483. Wells Pharmacy Network (WPN) is primarily a compounding pharmacy (>95%) providing both patient-specific prescriptions and office-use compounded products to practitioners. Sterile and non-sterile low, medium and high risk compounds are produced. Weekly Volume was provided as 3200 orders with 240 pharmacist hours utilized. Both Arizona and DEA licenses were produced and are current. A roster of pharmacists and technicians was provided including Florida license number and expiration date. WPN is licensed in all states where non-resident licensure is required. A copy of the most recent Florida inspection report was provided with no observations noted.

- WPN stated that they would be requesting an NABP inspection within the next few weeks as Texas is requiring a report prior to renewing that license. WPN will provide a copy of the NABP report to Arizona when completed.

The following records were requested initially:

- A report of all prescriptions/orders sent to Arizona for the past 12 months
- Training records for technicians
- Media fill and environmental testing results for the past 12 months
- Clean room and hood certifications
- SOP index
- Equipment calibration/maintenance records
- Cleaning documentation

A tour of the facility was requested. Receipt of prescriptions/orders are processed in a cubicle environment with both technicians and pharmacists present. The pharmacy area consists of several small suites for non-sterile compounding segregated primarily by dosage form, a storage room where components are stored, an ante room leading to a positive pressure clean room for sterile compounding, a pharmacist final-check room, a second ante room leading to a negative pressure clean room and a large central area where staging and quality assurance testing is conducted. Refrigerators are electronically monitored with alarms and emails for excursions. During the tour, Anthony Campbell, PharmD, was

Hal Wand, RPh MBA  
Executive Director  
Arizona State Board of Pharmacy  
January 26, 2015  
Page 7


paragraph), complete compliance on any given day may be unrealistic. Accordingly, we would appreciate some clarification regarding these issues.

Finally, Paragraph 6 on page 8 of the Consent Agreement states that if Wells "violates this Order in any way or fails to fulfill the requirements of this Order, Board, after giving the Respondent notice and the opportunity to be heard, make [sic] take disciplinary action against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated." Again, we are unclear whether not passing an inspection would constitute a violation of the Consent Agreement or a failure to fulfill its requirements, thereby resulting in further disciplinary action, which may include a suspension or revocation of Wells' permit. For these reasons, we would appreciate clarification regarding these issues.

Again, thank you for making time to speak with me last month and for the opportunity to submit Wells' responses. We appreciate the Board's consideration and we look forward to resolving this matter.

Very truly yours,

MILLIGAN LAWLESS, P.C.

By   
Bryan S. Bailey

BSB/me

Enclosures

cc: William Mc Millen, Managing Member  
Kris Fishman, Sr. VP, Operations  
Travis Weaver, Director of QA/QI

Hal Wand, RPh MBA  
 Executive Director  
 Arizona State Board of Pharmacy  
 January 26, 2015  
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Wells' pharmacists have decades of experience and they determined that, with respect to the Trimix injectables reviewed by the Compliance Officers, it was appropriate to have a BUD that was later than certain components of the injectables. However, since the Compliance Officers' inspection, Wells has updated and reduced the BUD for Trimix injectables.

Presently, Wells mixes its stock solutions, tests their sterility and assigns the following BUD:

<u>Chemical</u>	<u>BUD</u>	<u>Condition</u>	<u>Documentation</u>
Papaverine	90	Refrigerated	PCCA/Eagle BUD study <sup>1</sup>
Phentolamine	90	Refrigerated	PCCA/Eagle BUD study
Alprostadil	60	Refrigerated	PCCA/Eagle BUD study

After the solutions are mixed together, Wells' assigns a BUD based on the earlier of the product's storage method (i.e., 14-day BUD if refrigerated and 45-day BUD if frozen) or the earliest expiration date of any component. We believe this updated process for determining BUDs is consistent with both A.A.C. R-4-23-410(B)(3)(d) and USP <797> and the Compliance Officers' interpretation. However, if the Board believes additional revision is necessary, we respectfully request that the Board clarify how Wells should determine the BUD, so as to ensure future compliance.

## VII. Clarification of Consent Agreement Terms.

With respect to the Board's proposed Consent Agreement requiring probation, Paragraph 6 on page 2 states that the Consent Agreement "does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any." Wells is not aware of any other pending matters before the Board. However, since the Consent Agreement "may be considered in any future disciplinary action by the Board", we would appreciate it if the Board would clarify whether any other matters are currently pending.

In addition, Paragraph 4 on page 7 of the Consent Agreement states that Wells must "pass one (1) unannounced random inspection by Board compliance officers...." However, the Consent Agreement does not clarify what constitutes a "pass[ing]" inspection. For example, are no deficiencies required to pass? What if there are minor deficiencies? If so, what would constitute a "minor" deficiency and how many would be permitted? Obviously Wells intends to be in complete compliance; however, considering the size and complexity of Wells' pharmacy and human error, and the potential consequences of not passing an inspection (see next

<sup>1</sup> Enclosed as Exhibit 11 are the results of the PCCA/Eagle study

Hal Wand, RPh MHA  
 Executive Director  
 Arizona State Board of Pharmacy  
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Wells recently retained a consultant (Lou Diorio, RPh, LDT Health Solutions Inc.), with experience in both compounding and manufacturing to achieve a higher standard of quality. Based on the consultant's recommendations, Wells has changed sterile gloves to another model with better resistance to alcohol permeation, and Wells is experimenting with different labeling and documentation processes to minimize mislabeling.

Wells regrets its prior documentation discrepancies. However, we hope the Board will recognize the strides Wells has made to correct the issues causing the deficiencies and to minimize the risk of future discrepancies.

V. "Sterility sampling not compliant with USP <71> requirements for number of containers/total volume tested."

The Compliance Officers noted in their report that most "sterility testing is performed inhouse utilizing ScanRDI technology" and that "[t]esting and control protocols were provided as well as an article comparing ScanRDI reliability to USP <71>."

Wells mistakenly believed that its inhouse sterility testing with ScanRDI technology complied with USP <71>. Based on the Compliance Officers' comments, Wells recognized its error and, as a result of the inspection, it updated its sample sizes in compliance with USP <71>. Enclosed as Exhibit G are tables identifying the sample sizes Wells has been following since the inspection. Again, Wells regrets and apologizes for this error.

VI. "Beyond Use Date of compounds in excess of component Beyond Use Date/Expiration Date."

The Compliance Officers conducted a random sampling of Wells' compounding records regarding the Beyond Use Date (BUD) for several lots of Trimix injectable and found the BUD was later than certain components' BUD/expiration date.

The Board's cGCP acknowledge that, depending on the pharmacist's professional judgment, a compounded product's BUD may be later than its components' BUD/expiration dates. Specifically, A.A.C. R-4-23-410(B)(3)(d) states:

"A beyond-use-date [is] based on the pharmacist's professional judgment, but not more than the maximum guidelines recommended in the Pharmacy Compounding Practices chapter of the official compendium unless there is published or unpublished stability test data that shows a longer period is appropriate."

The Board's cGCP are consistent with USP <797> which states that "BUDs for compounded preparations are usually assigned on the basis of professional experience."



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 Executive Director  
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document verification of the components or weights before the finished product is completed – the pharmacist may assume responsibility for these items, which is what is assumed by Wells' pharmacists performing the final check.

However, in an effort to ensure compliance with the Board's interpretation, Wells has increased pharmacist activity in the non-sterile compounding area. For example, Wells has reduced some of the lab pharmacists' duties and increased their time monitoring and mentoring technicians. The pharmacists also have taken a more active role in compounding, to get hands on experience with manipulating the powders. We would appreciate the Board's clarification of its interpretation and confirmation that Wells' current practices are compliant.

IV. "Multiple inconsistencies in documentation practices of [Logged Formula Worksheets] and [Formula Worksheets] including:" Beyond Use Date, sterile filtration, sterility sampling, and quality assurance verification.

The Compliance Officers reviewed ten (10) random prescriptions/orders from the Arizona report which revealed that Wells failed to maintain proper compounding records of quality assurance verification, documentation of procedures for obtaining samples for testing, documentation of filter lot number/expiration date and bubble point testing in the compounding record, documentation of the sampling plan for sterility/endotoxin testing and failure to follow proper procedures/protocols for sterility and endotoxin testing sampling. On or about October 15, 2014, the Compliance Officers reviewed additional documents and identified additional discrepancies regarding the records, documentation, compliance with SOPs, testing procedures, sampling procedures and shipping procedures involving additional prescriptions/orders from the Arizona report.

While it is certainly no excuse, Wells recognized inconsistencies in and the need to improve its documentation practices and, in fact, it had reorganized its quality unit prior to the inspection. Unfortunately, the majority of issues noted by the Compliance Officers were in documents that were created prior to the reorganization.

Wells has consistently practiced Continuous Quality Improvement (CQI) and it continues to make strides to be USP <797> compliant.<sup>2</sup> At the heart of CQI is serial experimentation applied to everyday practices. For example, Wells retrains the applicable staff in the event of a breach of aseptic technique and it continually reviews and refines its processes, including documentation, gowns, storage, mixture and so forth. In addition, Wells is in the process of implementing many cGMP best practices on top of USP standards. For example, Wells' compounding staff wears sterile gowns, booties and face masks. Wells analyzes the efficacy of its cleaning agents and make changes to exceed required standards and Wells utilizes equipment

<sup>2</sup> Enclosed as Exhibit B is Wells' recently updated SOP 9.161 regarding its CQI program.

Hal Wand, RPh MBA  
 Executive Director  
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was preparing for and following the NABP's recommendations, in preparation for the NABP inspection. Unfortunately, in an effort to comply with the regulations and the NABP recommendations, Wells' current procedures got ahead of its SOPs, such that certain of Wells' current procedures differed from its written SOPs. As Wells explained to the Compliance Officers, at the time of the inspection, Wells was reviewing and, as appropriate, updating its SOPs to both ensure compliance and to ensure its SOPs were consistent with its current procedures.

Since the Board's inspection, Wells has updated a substantial number of SOPs, including each SOP noted by the Compliance Officers. Enclosed as Exhibit D is a copy of a portion of Wells' "SOP Change Request Number Log", which identifies a number of SOPs that have been updated following the inspection. Enclosed as Exhibit E are SOPs 5.040 and 9.040. You will note that SOP 5.040 now complies with A.A.C. R-4-23-402(I) and R-4-23-410(I)(5) regarding patient information, and SOP 9.040 no longer requires the Quality Manager to be a pharmacist.

III. "Lack of pharmacist verification during each step of compound preparation."

The Compliance Officers observed that the pharmacist in the general compounding area was not performing or documenting verification of the components or weights prior to the completion of the finished product. Rather, as the Compliance Officers also observed, the "technicians weigh components on scales (+/- 3%) and the results are recorded in the compounding software. The technician proceeds to complete the compounded product and a pharmacist performs a final check." We are confused by the Compliance Officers' finding and we respectfully request clarification.

Specifically, A.A.C. R-4-23-410(I)(2) states:

- "2. Components for pharmaceutical product compounding are accurately weighed, measured, or subdivided. To ensure that each weight, measure, or subdivision is correct as stated in the compounding procedures, a pharmacist:
  - a. Checks and rechecks, or assumes responsibility for checking and re-checking, the operations at each stage of the compounding process; and
  - b. Documents by hand-written initials or signature the completion and accuracy of the compounding process."

This is consistent with A.A.C. R-4-23-410(C)(1), which also states, among other things, that a pharmacist may assume responsibility for these items and document his initial or signature in the compounding record. In other words, neither regulation requires a pharmacist to perform or



Hal Wand, RPh MBA  
 Executive Director  
 Arizona State Board of Pharmacy  
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were no findings of "Substantially Non-Compliant"). A copy of the NABP inspection report and cover letter are enclosed as Exhibit A. Wells has made a few adjustments in response to the NABP findings, which are explained in Wells' January 14, 2015 response to the NABP. Wells' response is enclosed as Exhibit B.

Wells understands that it is easy to say it is committed to compliance, but hard to prove it. For that reason, we hope the Board will note that the few items of concern identified by the NABP inspection were unrelated to the items identified by the Board's Compliance Officers. Wells believes this is due to the compliance efforts Wells was implementing prior to and at the time of the Board's inspection and that Wells has implemented as a result of the Board's inspection. Wells understands that compliance is a journey, not a destination, and it will continue to review and improve its operations to ensure and maintain compliance.

The following responds to the "potential concerns/violations" in the Compliance Officers' October 15, 2014 report and the Board's proposed Consent Agreements.

**I. "Breach of sterile garbing SOP by technician in ante room."**

The Compliance Officers observed a technician exiting and re-entering the ante room without re-garbing and later observed the same technician working in the ante room without gloves or a mask.

As the Compliance Officers' noted, the technician's conduct violated Wells' standard operating procedure (SOP). Wells counseled the technician regarding the violations and the SOP on the same day the violations occurred and cautioned her that future violations could result in termination. Wells also retrained all sterile personnel regarding the SOP, which requires a sterile gown change before going into the clean room and working on preparations. No further violations have been noted. Enclosed as Exhibit C are Wells' training records for the technician at issue and other sterile personnel.

**II. "SOPs – may not be indicative of current practices", "Provision of patient written information not consistent" and "Position of Quality Manager currently filled by a technician when pharmacist required by SOP."**

The Compliance Officers observed that Wells' employees were not following Wells' SOPs regarding patient counseling of compounded preparations, sterilization and depyrogenation and pharmacist preparation of the first formulation of complex preparations, which is then verified and approved by the Quality Manager who was supposed to be a pharmacist.

Wells has permits in multiple states and, therefore, its operations must comply with multiple states' regulations. Compliance with these regulations requires continuous review and updating of Wells' current procedures and SOPs. In addition, at the time of the inspection, Wells

# MILLIGAN LAWLESS, P.C.

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January 26, 2015

VIA U.S. MAIL AND  
EMAIL: lwand@azpharmacy.gov

Hal Wand, RPh MBA  
Executive Director  
Arizona State Board of Pharmacy  
1616 West Adams, Suite 120  
Phoenix, Arizona 85005

Re: Wells Pharmacy Network – Pharmacy Permit No. Y005709  
Board Case No. 14-0019-PHR

Dear Director Wand:

Thank you again for the opportunity to submit this response to the "potential concerns/violations" identified by the Board's Compliance Officers as a result of the October 7 and 8, 2014 inspection and the additional time to respond to the Board's proposed Consent Agreements. Before responding to these items, I would like to clear up a potential misunderstanding and update the Board regarding Wells Pharmacy Network's ("Wells") recent inspection by the National Association of Boards of Pharmacy (NABP).

Wells has the utmost respect for the Board and its Compliance Officers and we are concerned the Board may have misunderstood Wells' August 1, 2014 response to the Board's July 11, 2014 letter and proposed Consent Agreement. In Wells' letter it declined the Board's offer to enter into the Consent Agreement and Wells requested a formal hearing, although Wells preferred not to submit to a formal hearing. Wells' request was based on its concerns with certain language in the Consent Agreement and its understanding that a formal hearing was the only means available to resolve its concerns.

Wells meant no disrespect to the Board and, again, it had no desire to escalate the matter. In fact, as mentioned in the Compliance Officers' report, at the time of the inspection, Wells was in the process of obtaining an inspection by the NABP, as required by the proposed Consent Agreement.<sup>1</sup>

The NABP inspection took place on December 9, 2014. The NABP's findings were overwhelmingly positive, with the NABP finding Wells' pharmacy "Substantially Compliant" with all but a few items, in which case the NABP found Wells' "Somewhat Compliant" (there

<sup>1</sup> Prior to renewing Wells' Texas pharmacy license, the Texas State Board of Pharmacy required Wells to be inspected by the NABP. Based on the NABP's findings, the Texas Board has since renewed Wells' license.

1 COPY OF THE FOREGOING MAILED  
2 this *02* day of *June*, ~~2014~~ to:  
*2015*

3 Montgomery Lee  
4 Assistant Attorney General  
5 1275 W. Washington Street, CIV/LES  
6 Phoenix, Arizona 85007  
7 Attorney for the State of Arizona

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Doc #4200554

1 required unannounced random inspection in paragraph 4 of this Order prior to the  
 2 expiration of the one (1) year probationary period, Respondent may petition the Board for  
 3 early termination of the probation by submitting such a request in writing and appearing  
 4 before the Board at a regularly scheduled meeting.

5 6. If Respondent violates this Order in any way or fails to fulfill the  
 6 requirements of this Order, the Board, after giving the Respondent notice and the  
 7 opportunity to be heard, make take disciplinary action against Respondent's permit. The  
 8 issue at such a hearing will be limited solely to whether this Order has been violated.

9  
 10 DATED this 09 day of June, 2014. 2015

11 ARIZONA STATE BOARD OF PHARMACY

12 (Seal)

13  
 14  
 15  
 16 By: 

KAMLESH GANDHI  
 EXECUTIVE DIRECTOR

17  
 18 ORIGINAL OF THE FOREGOING FILED  
 19 this 09 day of June, 2014 with:  
 20 2015

21 Arizona State Board of Pharmacy  
 1616 W. Adams St.  
 Phoenix, Arizona 85007

22 COPY OF THE FOREGOING MAILED  
 23 BY CERTIFIED MAIL  
 24 this 09 day of June, 2014  
 2015

25 Wells Pharmacy Network  
 1210 SW 33<sup>rd</sup> Ave.  
 Ocala, Florida 34474  
 26 Respondent

3. The conduct and circumstances described above constitute unethical conduct pursuant in violation of A.R.S. § 32-1901.01(A) (5) (Violating a federal or state law or administrative rule relating to the manufacture, sale or distribution of drugs, devices, poisons, hazardous substances or precursor chemicals).

4. The conduct and circumstances described above constitute unethical conduct pursuant to A.R.S. § 32-1901.01 (A) (5) by violating A.A.C. R4-23-402 (I), R4-23-410 (I) (2) (a) and (b), A.A.C. R4-23-410 (I) (5), A.A.C. R4-23-410 (J) (I) (d) and A.A.C. R4-23-670 (C) (1).

## ORDER

Based upon the above Findings of Fact and Conclusions of Law, the Board issues the following Order:

1. Respondent's permit no. Y005709 is placed on probation for a period of one (1) year.

2. Respondent shall pay a civil penalty of \$9,000.00 within 90 days of the effective date of this Order.

3. Respondent shall pay for the costs of the inspection conducted by Board compliance officers in October 2014 in the amount of \$2,345.37 within 90 day of the effective date of this Order.

4. Respondent shall submit to and pass one (1) unannounced random inspection by Board compliance officers within one (1) year of the effective date of this Order and shall pay for the costs of this inspection in an amount not to exceed \$3,000.00. Respondent shall pay for the costs of this inspection within 90 days of receiving written notification from Board staff of the incurred costs.

5. If Respondent pays the civil penalty in paragraph 2 of this Order, pays the costs of the October 2014 inspection in paragraph 3 of this Order, submits to and passes the unannounced random inspection in paragraph 4 of this Order and pays the costs of the

1 complex preparation which is then verified and approved by a pharmacist (quality  
2 manager).

3 10. At the October 7 and 8, 2014 inspection Board compliance officers  
4 reviewed ten (10) random prescription/orders from the Arizona report which revealed  
5 Respondent failed to maintain proper compounding records of quality assurance  
6 verification, documentation of procedures for obtaining samples for testing,  
7 documentation of filter lot number/expiration date and bubble point testing in the  
8 compounding record, documentation of the sampling plan for sterility/endotoxin testing  
9 and failure to follow proper procedures/protocols for sterility and endotoxin testing  
10 sampling.  
11

12 11. Board compliance officers reviewed additional documents requested from  
13 Respondent and received on or about October 15, 2014 which revealed additional  
14 discrepancies regarding the records, documentation, compliance with standard operating  
15 procedures, testing procedures, sampling procedures and shipping procedures involving  
16 Rx [REDACTED], Rx [REDACTED], Rx [REDACTED], Rx [REDACTED], Rx [REDACTED] and Rx [REDACTED] as  
17 more fully set forth in the compliance officers' report dated October 15, 2014, a copy of  
18 which is attached and is incorporated by this reference.  
19  
20

### 21 CONCLUSIONS OF LAW

22 1. The Board possesses jurisdiction over the subject matter and over  
23 Respondent pursuant to A.R.S. § 32-1901 *et seq.*

24 2. The Board may discipline permit holder if the Board determines that the  
25 permittee or the permittee's employee has engaged in unethical conduct. A.R.S. § 32-  
26 1927.02(A)(1).

1 October 10, 2014 requested additional documents which were provided by Respondent  
2 on October 15, 2014.

3 5. At the October 7 and 8, 2014 inspection Board compliance officers  
4 observed a technician working at Respondent's facility exiting and re-entering the ante  
5 room without re-garbing and later observed the same technician working in the ante room  
6 without gloves or a mask both activities were not in compliance with Respondent's  
7 standard operating procedures.  
8

9 6. At the October 7 and 8, 2014 inspection Board compliance officers noted  
10 that the pharmacist in the general compounding area was not performing or documenting  
11 a verification of the components or weights prior to the completion of the finished  
12 product.  
13

14 7. At the October 7 and 8, 2014 inspection Board compliance officers  
15 conducted a random sampling of the compounding records regarding the "Beyond Use  
16 Date" (BUD) for several lots of Trimix injectable.  
17

18 8. At the October 7 and 8, 2014 inspection Board compliance officers  
19 observed discrepancies in Respondent's compliance with sterility, endotoxin and sterile  
20 filtration testing results records.

21 9. At the October 7 and 8, 2014 inspection Board compliance officers  
22 observed that Respondent's employees were not following Respondent's standard  
23 operating procedures regarding patient counseling of compounded preparations,  
24 sterilization and depyrogenation and pharmacist preparation of the first formulation of a  
25  
26

1 ACCEPTED AND AGREED BY RESPONDENT

2 Wells Pharmacy Network

Dated: 2-2-15

3 Ben Daniel, CEO  
4 by Ben Daniel, CEO on behalf of Wells Pharmacy Network

5  
6 Subscribed and sworn to before me in the County of Palm Beach, State of  
7 Florida, this 31<sup>st</sup> day of March, 2014, by  
8 Ben Daniel, on behalf of Wells Pharmacy Network. 2015



BRET JONATHAN PHILLIPS  
NOTARY PUBLIC  
STATE OF FLORIDA  
Comm# FF173881  
Expires 11/4/2018

Bret J Phillips  
NOTARY PUBLIC

9  
10 My Commission expires: 11/4/2018

### 11 FINDINGS OF FACT

- 12 1. The Board is the duly constituted authority for licensing and regulating the  
13 practice of pharmacy in the State of Arizona.
- 14 2. Respondent is the holder of Pharmacy Permit Number Y005709.
- 15 3. From February 21, 2014 through March 7, 2014 representatives of the  
16 United States Food and Drug Administration ("FDA") conducted an inspection of  
17 Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala, Florida. As a result of that  
18 inspection, the FDA issued a report on March 7, 2014 which contained eleven (11)  
19 observations detailing potential violations. Based upon its concerns regarding the  
20 observations identified in the FDA report the Board directed its staff to conduct an  
21 inspection of Respondent's facility in Ocala, Florida.
- 22 4. On or about October 7 and 8, 2014 Board compliance officers conducted an  
23 inspection of Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala Florida and on  
24  
25  
26



1           8.     Respondent acknowledges and agrees that, upon signing this Consent  
2 Agreement and returning this document to the Board's Executive Director, it may not  
3 revoke its acceptance of the Consent Agreement or make any modifications to the  
4 document regardless of whether the Consent Agreement has been signed by the  
5 Executive Director. Any modification to this original document is ineffective and void  
6 unless mutually agreed by the parties in writing.

7           9.     This Consent Agreement is subject to the approval of the Board and is  
8 effective only when accepted by the Board and signed by the Board's Executive Director.  
9 In the event that the Board does not approve this Consent Agreement, it is withdrawn and  
10 shall be of no evidentiary value and shall not be relied upon nor introduced in any action  
11 by any party, except that the parties agree that should the Board reject this Consent  
12 Agreement and this case proceeds to hearing, Respondent shall assert no claim that the  
13 Board was prejudiced by its review and discussion of this document or any records  
14 relating thereto.

15          10.    If a court of competent jurisdiction rules that any part of this Consent  
16 Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement  
17 shall remain in full force and effect.

18          11.    Respondent understands that this Consent Agreement is a public record that  
19 may be publicly disseminated as a formal action of the Board and may be reported as  
20 required by law to the National Practitioner Data Bank and the Healthcare Integrity and  
21 Protection Data Bank.

22          12.    Respondent understands that any violation of this Consent Agreement  
23 constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-  
24 1901.01(A) and A.R.S. § 32-1927.02(A).

25          13.    Respondent agrees that the Board will adopt the following Findings of Fact.  
26 Conclusions of Law and Order.

RECITALS

1  
2           1.     Respondent has read and understands this Consent Agreement and has had  
3 the opportunity to discuss this Consent Agreement with an attorney, or has waived the  
4 opportunity to discuss this Consent Agreement with an attorney.

5           2.     Respondent understands that it has a right to a public administrative hearing  
6 concerning the above-captioned matter, at which hearing it could present evidence and  
7 cross examine witnesses. By entering into this Consent Agreement, Respondent  
8 knowingly and voluntarily relinquishes all right to such an administrative hearing, as well  
9 as rights of rehearing, review, reconsideration, appeal, judicial review or any other  
10 administrative and/or judicial action, concerning the matters set forth herein.

11          3.     Respondent affirmatively agrees that this Consent Agreement shall be  
12 irrevocable.

13          4.     Respondent understands that this Consent Agreement or any part of the  
14 agreement may be considered in any future disciplinary action by the Board.

15          5.     Respondent understands this Consent Agreement deals with Board  
16 Complaint No. 4338 involving allegations of unethical conduct against Respondent. The  
17 investigation into these allegations against Respondent shall be concluded upon the  
18 Board's adoption of this Consent Agreement.

19          6.     Respondent understands that this Consent Agreement does not constitute a  
20 dismissal or resolution of any other matters currently pending before the Board, if any,  
21 and does not constitute any waiver, express or implied, of the Board's statutory authority  
22 or jurisdiction regarding any other pending or future investigation, action or proceeding.

23          7.     Respondent also understands that acceptance of this Consent Agreement  
24 does not preclude any other agency, subdivision, or officer of this State from instituting  
25 any other civil or criminal proceedings with respect to the conduct that is the subject of  
26 this Consent Agreement.

1 THOMAS C. HORNE  
 2 Attorney General  
 (Firm State Bar No. 14000)

3 MONTGOMERY LEE  
 4 Assistant Attorney General  
 State Bar No. 005658  
 5 1275 W. Washington, CIV/LES  
 Phoenix, Arizona 85007-2997  
 Tel: (602) 542-7980  
 6 Fax: (602) 364-3202

7  
 8 Attorneys for the Arizona State Board of Pharmacy

9  
 10 **BEFORE THE ARIZONA STATE BOARD OF PHARMACY**

11  
 12 In the Matter of

13 Wells Pharmacy Network,  
 14

15 Holder of Pharmacy Permit No. Y005709  
 16 in the State of Arizona.

Board Case No. 14-0019-PHR

**CONSENT AGREEMENT FOR  
 PROBATION, CIVIL PENALTY,  
 COSTS AND INSPECTION**

17  
 18 In the interest of a prompt and judicious settlement of this case, consistent with the  
 19 public interest, statutory requirements and the responsibilities of the Arizona State Board  
 20 of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Wells Pharmacy Network,  
 21 holder of Pharmacy Permit Number Y005709 in the State of Arizona ("Respondent"),  
 22 and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law  
 23 and Order ("Consent Agreement") as a final disposition of this matter.  
 24  
 25  
 26



BY ORDER OF THE BOARD \_\*/

Dated: July 18<sup>th</sup>, 2017



Michael D. Bullek, BSP, R.Ph.  
Authorized Representative of the  
New Hampshire Board of Pharmacy

---

\_\*/ Board Member recused

that Wells has documented training deficiencies and cleaning deficiencies, and it further allowed technicians to verify products for the final visual check. The Board does note that Wells produced satisfactory standard operating procedures that Mr. Fishman stated employees will now be following. However, given Wells' failure to have sufficient procedures in place for so long and its failure to adopt the 797s, the Board is not confident yet that Wells will adequately comply with these standard operating procedures. The Board also has concerns that Wells just learned at the hearing of New Hampshire's restriction on distributing directly to veterinary practices.

For the reasons stated above, the Board finds that the five mitigating factors in Ph 905.01(c) have not all been met. Based on Wells' history of having insufficient procedures in place, the Board does not yet have confidence that the action is unlikely to occur again. The Board is also concerned that Wells was distributing directly to veterinary practices, in violation of RSA 318:14-a, III and Ph 404.02. Wells' application for renewal is therefore denied.

#### Lyophilization

The Board next considers whether, by engaging in lyophilization, Wells was engaged in the practice of manufacturing, thus necessitating a 503B permit. Mr. Fishman stated that Wells lyophilizes in order to keep the correct drug potency. He further stated Wells' average batch size when lyophilizing is 250–500 vials. Ph 404.04(b) specifically states that “[w]hen a compounder prepares more than 50 dosage units for non-patient specific preparations, the compounder shall be registered as a drug manufacturer or 503B with the FDA.” Therefore, if Wells wishes to continue lyophilizing, when it re-applies it must apply for and obtain as a 503B permit.

#### Conclusion

For the reasons stated above, the renewal application of Wells Pharmacy, Ocala Florida is DENIED.

Mr. Fishman's testimony, then, the Board determines that the mitigating factor in Ph 905.01(c)(1) has been met.

The Board questions whether, under Ph 905.01(c)(2), there was no intent to violate any provisions of RSA 318. The Board does find that Wells did not intend to violate RSA 318 with its past contamination problems, as the Board is satisfied that the airborne mold was caused by a leaky pipe that remained undiscovered. However, as the Board noted at the hearing, Wells' practice of distributing directly to veterinary practices is not in compliance with RSA 318:14-a, III and Ph 404.02. The Board understands from Mr. Fishman's testimony that Wells was unaware of this regulation in New Hampshire, but the Board notes that it is the responsibility all licensees and registrants to comply with the relevant laws.

The Board next finds that under Ph 905.01(c)(3), Wells has taken corrective action. Mr. Fishman testified that Wells has since demolished the contaminated compounding room, fixed the leak, and rebuilt the room to 800 standards. In addition, Wells recalled all the affected products and it now does daily testing for viables. The Board does note that Wells did not test frequently enough after first discovering the contamination. Mr. Fishman, however, admitted this and stated the individual responsible for overseeing quality during that time was no longer with the company due to the unacceptable response to this incident.

The Board finds that under Ph 905.01(c)(4), Wells made remunerations to the affected parties. As stated above, Wells recalled all affected products and no adverse effects were reported.

The Board finds, however, that under Ph 905.01(c)(5), it does not have confidence yet that the action is unlikely to occur again. The Board is concerned that Wells in the past failed to follow the guidance of the 2012 USP 797 Compounding Standards. The Board specifically notes

Ph 404.04(b) and (c) Regulatory Requirements for Sterile Compounding

(b) When a compounder prepares more than 50 dosage units for non-patient specific preparations the compounder shall be registered as a drug manufacturer or 503B with the FDA.

(c) Compounders supplying limited quantities, less than 50 dosage units, to providers for administration use shall have an MOU with the provider for each compounded product they supply to the provider. When a compounder provides a practitioner a non-patient specific preparation, the compounder shall provide the practitioner a copy of the test result for each lot provided to the practitioner.

Ph 404.02(u) Definitions

(u) "Limited quantities" means a batch with 50 or less dosage units provided to a hospital or practitioner to administer to their own patient.

**Findings of Facts and Rulings of Law**

In arriving at the decision below, the Board considered the original application packet from Wells, the documents Wells provided in anticipation of the hearing, and the testimony of Mr. Fishman.

Recent Disciplinary Action

The Board first considered, in light of the Board denying Wells' application due in part to the recent disciplinary actions of other states under Ph 905.01(a), whether all five mitigating factors if Ph 905.01(c) had been met.

The Board first finds that under Ph 905.01(c)(1), no harm resulted from the Wells' actions. Mr. Fishman testified that Wells took action to recall any affected drugs and notify the approximately 25,000 patients that were affected. Mr. Fishman testified that there were zero major adverse effects reported. When asked to clarify whether there were any adverse effects reported, Mr. Fishman stated that there were no adverse effects reported at all. On the basis of



but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. All compounding shall be done in compliance with the United States Pharmacopeia as defined by board of pharmacy rules.

II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

III. A pharmacist shall offer a compounded drug product to a practitioner for administration to an individual patient, in limited quantities. The compounded drug products are for practitioner administration only and shall not be re-dispensed. The pharmacist shall maintain records to indicate what compounded drug products were provided to the medical office or practice. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services, in accordance with state law and rules of the board, as well as applicable federal laws.

IV. Where a commercial drug shortage exists because a manufacturer is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, and the manufacturer cannot supply the drug product to the public or to practitioners for use, a pharmacist may compound a limited quantity using the active pharmaceutical ingredient and sell to a patient with a valid prescription from a valid prescriber. When the compounded drug product is sold to a medical office or practice it is for the practitioner to administer to patients, and shall not be for resale.

V. The board shall adopt rules under RSA 541-A concerning the regulation of compounding.

VI. Labeling requirements pursuant to paragraph II shall not apply when medication is dispensed to institutionalized patients as provided under RSA 318:47-b.

#### Ph 905.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or shall revoke a registration whenever the board determines that a mail-order pharmacy, its pharmacist-in-charge, owner(s) or corporate officer(s) has, after notice and opportunity for a hearing, except pursuant to (c) below, committed an act such as but not limited to:

(4) Failed to comply with RSA 318:37, II, the provisions of Ph 900, or both;

(6) Been found guilty of any violation of federal, state or local drug law or have entered into any agreement to resolve violations of such.

(c) Notwithstanding the above the board shall issue a registration or not revoke if:

- (1) No harm resulted from the actions of the applicant or registrant;
- (2) There was no intent to violate any provisions of RSA 318;
- (3) Corrective action has been taken by the registrant;
- (4) Remunerations have been made to the affected party(s); and
- (5) The board determines the action is unlikely to occur again.

place for so long. Mr. Fishman explained that the business changed hands in 2011, and he was not hired until 2014. Mr. Fishman stated that once he started at the company, he began establishing standard operating procedures, hitting the 797 standards or higher. Mr. Fishman explained that Wells had been working to improve its policies.

Commissioner Stout then asked about a citation in the NABP report concerning Wells shipping products for office use. Mr. Fishman explained that that citation was for veterinary products, and he stated that there was no regulation with this restriction for veterinary products. The Board clarified that here in New Hampshire, there is such a regulation, and stated that Wells is thus out of compliance with various Board statutes and rules.

Commissioner Rochefort asked Mr. Fishman about how Wells' pharmacists are trained on lyophilization, as it is not traditionally taught in schools. Mr. Fishman explained that Wells' head pharmacist had been Wells' pharmacist for 15 years, and he learned to lyophilize on the job. Mr. Fishman stated that after the lyophilized products are made, they are tested and verified. Commissioner Rochefort asked if this pharmacist had trained any others; Mr. Fishman answered that in the last three years the pharmacist has only trained two others.

### Relevant Law

#### RSA 318:1

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research, teaching, or chemical analysis, but not selling or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. "Compounding" shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring.

#### 318:14-a Compounding.

I. Products that are not commercially available may be compounded for hospital or office use

Mr. Fishman explained that after the remodel, the National Association of Boards of Pharmacy ("NABP") inspected the facilities. Mr. Fishman explained that Wells passed the NABP inspection. Shortly thereafter, NABP called the Texas Board of Pharmacy, and that board lifted the restrictions it had put on Wells' license. Shortly thereafter, the boards in both South Carolina and Arizona lifted the restrictions from Wells' license, as well.

With regard to lyophilization and pellets, Mr. Fishman stated that he is not a pharmacist so is not an expert, but told the Board that Wells uses the lyophilization process in order to keep the correct potency of the drugs. He stated that he understands that lyophilization can be difficult, particularly if a pharmacist does not have the correct equipment. Mr. Fishman stated that Wells will not lyophilize more than 250-500 vials at a time. Mr. Fishman explained that Wells does not produce pellets on site; the pellets are transferred from a 503(b) facility.

In response to Board questioning, Mr. Fishman admitted that once the mold was discovered, Wells failed to re-test frequently enough. Mr. Fishman stated that the individual who was responsible for overseeing quality at Wells is no longer with the company due to the unacceptable response to this incident.

Commissioner Stout stated that the standard operating procedures that Wells had provided in its packet to the Board were satisfactory. However, Commissioner Stout stated that the 2012 USP 797s, Compounding Standards, had wonderful guidance for operating procedures, and he asked why Wells failed to implement those. For instance, Commissioner Stout stated Wells had documented training deficiencies and cleaning deficiencies, and used to allow technicians to verify products for the final visual check. Commissioner Stout thus asked Mr. Fishman why the Board should be confident that Wells would comply with the satisfactory standard operating procedures it provided last week when it did not have sufficient procedures in

Mr. Fishman explained why the other states had disciplined Wells. According to Mr. Fishman, in February 2016 Wells staff tested one of Wells' compounding rooms for contamination and the room tested positive for airborne mold. Wells sent the sample to a lab and determined it was pennicilium. Wells disinfected and cleaned the facility, and a few weeks later there was no sign of the mold. Then, in late March 2016, the compounding room again tested positive for airborne mold. When Wells sent this sample for testing, they learned that there was both pennicilium and a different type of fungal growth present. Wells staff again disinfected and cleaned the facility. At some point in the future, Wells staff again determined there was an airborne mold in the compounding room, and Wells then shut that specific compounding room down.

Mr. Fishman explained that the company had already scheduled to demo the room to get it fully up to 797 standards and convert it to an 800 room. After the demo was started, Wells employees discovered the source of the mold — a small leak around a pipe that ran from the ceiling to about twenty feet above the ceiling tiles to the room. Mr. Fishman explained that no one had found that leak because no one had thought to pop the ceiling tiles.

Mr. Fishman explained that the room was completely remodeled to higher standards before being put back into use. He further explained that Wells worked with the Florida Board of Pharmacy and the FDA to recall their products, notifying the approximately 25,000 patients that were affected. He stated that throughout the recall process, there were zero adverse effects reported. Mr. Fishman further explained that Wells took all its products from its store room and sent them out for testing; there were zero concerns with sterility. He explained that Wells now tests the air continuously and tests for viables during batch time, which is every day.

Before the New Hampshire  
Board of Pharmacy  
Concord, NH 03301

In the Matter of:

Docket No: 2017-01

**Wells Pharmacy, NR0198**

(Show Cause Hearing for renewal of NRMO Pharmacy Application)

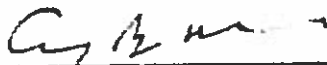
**ORDER OF DENIAL**

A show cause hearing commenced on April 19, 2017 to determine whether the Board properly denied the Renewal Application of Wells Pharmacy ("Wells") NR 0198, of Ocala, Florida. For the following reasons, the Board has voted to DENY Wells' application.

**Background**


Wells filed an application for renewal for a Non-Resident Pharmacy Permit which was accepted for filing on December 13, 2016. On or about February 15<sup>th</sup>, 2017, the Board issued an Order denying Wells' application but giving Wells the opportunity to request a hearing on the denial and show cause why it should be licensed. The Board's reason for the denial was twofold. First, the Board found that Wells' application packet documented recent disciplinary action taken by at least four different states. On that basis, the Board denied Wells' application pursuant to Ph 905.01(a)(6). Additionally, the Board stated that through Wells' application, the Board first became aware that Wells engages in the process of lyophilization and the process of producing pellets; the Board stated that if Wells wishes to continue doing so it must obtain a manufacturing or 503-B permit from the Board.

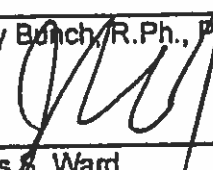
On or about March 15<sup>th</sup>, 2017, Wells requested a hearing on its denial, and on April 19, 2017, the Board held a show cause hearing on Wells' application. Kristopher Fishman, Senior Vice President of Operations, appeared on behalf of Wells.

  
\_\_\_\_\_  
Carey McRae, attorney for Wells Pharmacy  
Network, LLC

DONE this the \_\_\_\_\_ of \_\_\_\_\_ 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

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

any judicial review. Wells 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.

9. By execution of this Consent Order, Wells 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.

10. Wells acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wells 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 17<sup>th</sup> of May, 2017.

WELLS PHARMACY NETWORK, LLC  
PERMIT NO: 113948

BY: [Signature]

ITS: member / Secretary

[Signature]  
Carey McRae, attorney for Wells Pharmacy  
Network, LLC

WELLS PHARMACY NETWORK, LLC  
PERMIT NO: 113982

BY: [Signature]

ITS: member / Secretary

registration or similar authority issued by the Board or which seeks to conduct or engage in any activities regulated by the Board nor o in the future.

4. The provisions of Paragraphs 2 and 3 shall not apply to the permit of Wells Specialty Pharmacy, Inc., Permit No. 112752 upon the express condition that said pharmacy does not and shall not in the future engage in any compounding of any drug products or medications.

5. Wells agrees to pay costs to the Board in the amount of Ten Thousand and No/100 Dollars (\$10,000) 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.

6. Wells acknowledges and understands the Board is required to report this action to the National Practitioner Data Bank, which said reporting shall not include Robert Kilfeather who was mistakenly included in the charges involving Permit No. 113948.

7. Based expressly upon the representations and agreements set forth herein, the Board agrees to dismiss the pending charges against both Permit No. 113948 and Permit No. 113982 with prejudice.

8. Wells expressly waives 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



IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
WELLS PHARMACY NETWORK,	)	BOARD OF PHARMACY
LLC	)	
	)	CASE NO: 16-L-0120
Permit No. 113948	)	
	)	
and	)	
	)	
WELLS PHARMACY NETWORK,	)	
LLC	)	CASE NO: 16-L-0156
	)	
Permit No. 113982	)	

### CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a pending Statement of Charges and Notice of Hearing ("Statement") involving Wells Pharmacy Network, LLC (Wells), Permit No. 113948 located in Ocala, Florida and Permit No. 113982 located in Dyersburg, Tennessee.

Prior to the scheduled hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the parties through counsel have entered into an agreement the terms of which are set forth in this Consent Order as follows:


1. Wells agrees to voluntarily surrender Permit No. 113948 and Permit No. 113982.
2. Wells agrees to never apply for or seek any type, kind or description of any permit, license, registration or required authorization from the Board and further agrees that it shall never conduct or engage in any activities in the State of Alabama which the Board now or may in the future regulate.
3. The owners of Wells are correctly identified in the initial applications for the above identified permits or any renewals thereto and said owners agree and acknowledge they will not own in whole or part any entity which seeks any permit, license,

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.


(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.

  
 Scott Greenwell, President  
 Kentucky Board of Pharmacy

8 June 2017  
 Date

  
 Scott Greenwell, President  
 Wells Pharmacy Network LLC  
 Respondent

06/06/2017  
 Date

  
 Colleen Stacy Shapiro  
 Respondent's Attorney

06/06/17  
 Date

COMMONWEALTH OF KENTUCKY  
KENTUCKY BOARD OF PHARMACY  
Case No. 17-0171

IN RE: PERMIT NO. FL1685 HELD BY WELLS PHARMACY NETWORK LLC

*Agreed Order*

Come the parties, the Kentucky Board of Pharmacy ("the Board"), and Wells Pharmacy Network LLC ("Respondent"), and the parties having been fully informed regarding the matter set forth herein, state as follows:

- (1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.
- (2) Respondent is an out-of-state pharmacy licensed pursuant to KRS 315.0351, having been assigned permit no. FL1685.
- (3) (a) On or about June 21, 2016, Respondent submitted documentation that it had entered into a Consent Order with the Arizona Board of Pharmacy on June 9, 2015; Respondent submitted the corrective action it took as a result of the order. The Consent Order arose from a sterile compounding inspection conducted by the Arizona Board of Pharmacy on or about October 7 and 9, 2014, and the following violations were noted:
  - Compounding technician exited and re-entered the ante room without regarding; same technician later observed in ante room without gloves or mask.
  - Pharmacist failed to perform or document verification of components or weights prior to completion of finished preparation.
  - Discrepancies in compliance with sterility, endotoxin, and sterile filtration testing results records.

- Standard operating procedures were not observed for: patient counseling, sterilization, deprogramming, and pharmacist preparation of the first formulation of a complex preparation which is subsequently verified and approved by a pharmacist.
- Random review of prescriptions revealed failure to: maintain proper compounding records or quality assurance verification; document procedures for obtaining testing samples; document filter lot number/expiration date and bubble point testing in the compounding record; document the sampling plan for sterility/endotoxin testing; and follow procedures/protocols for sterility and endotoxin testing sampling.
- Records and documentation discrepancies, SOP compliance, and problems with testing/sampling/shipping procedures.

(b) On or about September 22, 2016, and pursuant to a joint investigation by the FDA and Florida Board of Pharmacy, Respondent, "out of an abundance of caution," issued a voluntary nationwide recall of all compounded sterile preparations between February 22 – September 14, 2016; 220 of 25,543 patients involved in the voluntary recall were from Kentucky.

(c) Respondent failed to disclose its Arizona discipline within thirty (30) days as required by KRS 315.121(3) and could be subject to suspension or revocation of its Kentucky permit.

(4) 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.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

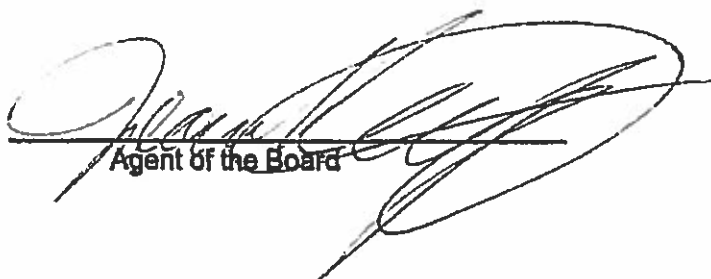
- (A) Respondent shall be fined \$11,000.00 payable by June 12, 2016. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.
- (B) By entering into this Agreed Order, Respondent expressly acknowledges that the

**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 18<sup>th</sup> day of May 2017, addressed as follows:

Wells Pharmacy Network, LLC  
Attn: Diane Raum  
1210 SW 33<sup>rd</sup> Ave.  
Ocala, FL 34474-2853  
Email: regulatoryaffairs@wellsrx.com

Victoria E. Lovato, Esq.  
Silver & DeBoskey, P.C.  
Email: lovatov@s-d.com



Agent of the Board

## ACCEPTED AND AGREED BY

## Respondent Pharmacy

Kristopher Fishman / Sr. VP of operations Dated: 03/31/2017  
 Authorized Representative / Title

Subscribed and sworn to before me in the County of Palm Beach,  
 State of Florida, this 31<sup>st</sup> day of March, 2017,  
 by Kristopher Fishman, authorized representative  
 of Wells Pharmacy Network, LLC.

My commission expires: 11/4/2018



BRET JONATHAN PHILLIPS  
 NOTARY PUBLIC  
 STATE OF FLORIDA  
 Comm# FF173681  
 Expires 11/4/2018

Bret Phillips  
 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 18<sup>th</sup> day of August, 2017.

## State Board of Pharmacy

BY: Wendy Anderson  
~~Chris Gasser~~ Wendy Anderson  
 Acting Program Director

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 Respondent Pharmacy to the sanctions imposed herein.

11. **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.
12. **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 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.
13. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
14. **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.
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 with the Board. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

acts in any other state that would subject him or her to disciplinary action in this state.

**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.

### **TERMS OF DISCIPLINE**

8. **Letter of Admonition.** This provision shall constitute a Letter of Admonition as set forth in Sections 12-42.5-124(6)(a), C.R.S. Respondent is hereby admonished for the acts and omissions described in the factual basis above. By entering this Order, Respondent agrees to waive the rights provided by Section 12-42.5-124(6)(b), C.R.S., to contest this Letter of Admonition.
9. **Other Requirements.** Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Pharmacy shall:
  - a. promptly pay all Respondent Pharmacy's 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 pharmacists and pharmaceuticals in the State of Colorado.
10. **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 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 Final Agency Order.

- a. Observation of a technician exiting and re-entering the ante room without re-garbing and later observation of the same technician working in the ante room without gloves or a mask.
  - b. The pharmacist in the general compounding area was not performing or documenting a verification of the components or weights prior to the completion of the finished product.
  - c. There were discrepancies with compliance with sterility, endotoxin, and sterile filtration testing results records.
  - d. A review of ten (10) random prescription orders from the Arizona report revealed a failure to maintain proper compounding records of quality assurance verification, documentation of procedures for obtaining samples for testing, documentation of filter lot number/expiration date and bubble point testing in the compounding record, documentation of the sampling plan for sterility/endotoxin testing, and failure to follow proper procedures/protocols for sterility and endotoxin testing sampling.
  - e. Discrepancies were noted regarding the records, documentation, compliance, standard operating procedures, testing procedures, sampling procedures, and shipping procedures involving six (6) prescriptions.
7. Respondent Pharmacy admits that its conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and provides ground 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[.]

(g) Had had his license or her license to practice pharmacy in another state revoked or suspended, or is otherwise disciplined or has committed



**BEFORE THE STATE BOARD OF PHARMACY**

**STATE OF COLORADO**

**Case No. 2015-2415**

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**STIPULATION AND FINAL AGENCY ORDER**

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**IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF WELLS PHARMACY NETWORK, REGISTRATION NO. OSP 6079,**

**Respondent Pharmacy.**

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**IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Wells Pharmacy Network, LLC ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Number 2015-2415, 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 August 8, 2012, being issued registration number OSP 6079, 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 1210 SW 33<sup>rd</sup> Ave., Ocala, Florida 34474-2853.**
- 4. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.**
- 5. On June 9, 2015, Respondent Pharmacy entered into a Consent Order with the Arizona Board of Pharmacy due to deficiencies found during the course of an October 2014 inspection conducted by the Arizona Board.**
- 6. Some of the deficiencies outlined in the October 2014 inspection, as detailed below, would be grounds for discipline in Colorado under Board Rule 21.00.00:**



STATE OF ALASKA  
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT  
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING  
BEFORE THE BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE

Case # 2016-001006

Wells Pharmacy Network, LLC, admits and agrees the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of their license in Alaska and over this Imposition of Civil Fine.

1. On June 9, 2014, Wells Pharmacy Network submitted a Biennial Out-of-State Pharmacy License Renewal for Alaska License # PHAO1183.
2. Wells Pharmacy Network neglected to reveal derogatory information concerning criminal convictions of employees, as well as disciplinary action of an employee.
3. On May 10, 2016, Wells Pharmacy Network submitted a Biennial Out-of-State Pharmacy License Renewal for Alaska License # PHAO1183.
4. Wells Pharmacy Network neglected to reveal derogatory information concerning a 2014 disciplinary action by the Maine Board of Pharmacy for failure to notify the Board of the Pharmacist-In-Charge change as required. Wells Pharmacy also failed to disclose criminal convictions of employees.
5. Wells Pharmacy Network admitted an error in failing to disclose criminal convictions and disciplinary actions of the pharmacy and employees.

Wells Pharmacy Network admits that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.260(a)(1), and 12 AAC 52.920(a)(13). Wells Pharmacy Network is agreeing to this Imposition of a Civil Fine of one thousand dollars (\$1,000) in cash, certified check, or money order payable to the "State of Alaska" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

Wells Pharmacy Network has the right to consult with an attorney and a right to an administrative hearing on the facts in this case. Wells Pharmacy Network understands and agrees by voluntarily signing this Imposition of Civil Fine, Wells Pharmacy Network is waiving their rights to counsel and to a hearing on this matter.

12/28/16

For Wells Pharmacy Network, LLC

Date

Colleen S. Shapiro, Secretary

Authorized Representative Name / Title

ORDER

The Alaska Board of Pharmacy hereby adopts the Imposition of Civil Fine in this matter. The Board has determined that this is a technical violation of professional licensing statutes and regulations not related to the delivery of patient care and, therefore, this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 4<sup>th</sup> day of May, 2017, at Anchorage, Alaska.

BOARD OF PHARMACY

By:

Board Chair

AMK

IMPOSITION OF CIVIL FINE and ORDER  
Wells Pharmacy Network, LLC  
2016-001006




of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.


6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

  
 Wells Pharmacy Network LLC, Respondent  
 Melissa Stefko  
 1210 SW 33<sup>rd</sup> Avenue  
 Ocala, FL 34474  
 License no. 805-43

14 Aug 17  
 Date

  
 Gretchen Mrozinski, Prosecuting Attorney  
 Department of Safety and Professional Services  
 Division of Legal Services and Compliance  
 P.O. Box 7190  
 Madison, WI 53707-7190

8-21-17  
 Date

Tracking # for payment: EV86891828805

STATE OF WISCONSIN  
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY  
PROCEEDINGS AGAINST

WELLS PHARMACY NETWORK LLC,  
RESPONDENT.

STIPULATION

0005454

Division of Legal Services and Compliance Case No. 16 PHM 159

Respondent Wells Pharmacy Network LLC., and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

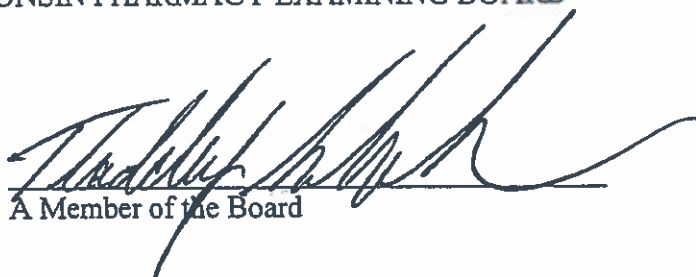
5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division

2. Respondent Wells Pharmacy Network LLC, is REPRIMANDED.
3. Within ninety (90) days from the date of this Order, Respondent Wells Pharmacy Network LLC, shall pay COSTS of this matter in the amount of 468.00.
4. Payment of costs (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:
 

Department Monitor  
 Division of Legal Services and Compliance  
 Department of Safety and Professional Services  
 P.O. Box 7190, Madison, WI 53707-7190  
 Telephone (608) 267-3817; Fax (608) 266-2264  
[DSPSMonitoring@wisconsin.gov](mailto:DSPSMonitoring@wisconsin.gov)
5. In the event that Respondent violates any term of this Order, Respondent's out-of-state pharmacy license (no. 805-43) in the state of Wisconsin, may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of the Order. The Board may, in addition and/or in the alternative refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.
6. This Order is effective on the date of its signing.

**WISCONSIN PHARMACY EXAMINING BOARD**

by:

  
 A Member of the Board

9/21/17  
 Date

3. On September 27, 2016, Respondent entered into a voluntary agreement (FL Agreement) with the State of Florida, Department of Health (FL Board) to restrict practice of sterile compounding, which states in part as follows:

- a. Respondent shall immediately cease compounding sterile products, and cease dispensing or shipping sterile products it has previously compounded;
- b. Respondent agreed with the United States Food and Drug Administration (FDA) to cease sterile compounding until necessary corrective actions can be implemented to address the FDA's alleged concerns;
- c. Respondent shall, under separate cover, submit to the Florida Board each of the corrective actions taken as well as any subsequent testing confirming the corrective actions to successfully resolve and address the FDA's alleged concerns and demonstrate compliance with the Florida Administrative Code; and
- d. Respondent shall give the FL Board 72-hour advance notice of its intent to resume sterile compounding.

4. The FL Agreement of Respondent with the FL Board was based on the allegation that Respondent may have compounded sterile products without being in compliance with the standards of practice for compounding sterile products per Florida Administrative Code.

5. On November 4, 2016, the restrictions on Respondent's Florida license were lifted.

6. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

#### CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Respondent engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having been subject to other disciplinary action by the State of Florida Board of Pharmacy.

3. As a result of the above violations, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

#### ORDER

1. The attached Stipulation is accepted.



STATE OF WISCONSIN  
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY	:	
PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
WELLS PHARMACY NETWORK LLC,	:	
RESPONDENT.	:	0005454

Division of Legal Services and Compliance Case No. 16 PHM 159

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Wells Pharmacy Network LLC  
1210 SW 33<sup>rd</sup> Avenue  
Ocala, FL 34474

Wisconsin Pharmacy Examining Board  
P.O. Box 8366  
Madison, WI 53708-8366

Division of Legal Services and Compliance  
Department of Safety and Professional Services  
P.O. Box 7190  
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent Wells Pharmacy Network LLC, is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 805-43, first issued on August 9, 2012, and current through May 31, 2018. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 1210 SW 33<sup>rd</sup> Avenue, Ocala, Florida 34474.

2. Respondent is an out-of-state pharmacy located in Ocala, Florida.

# CERTIFICATE OF SERVICE

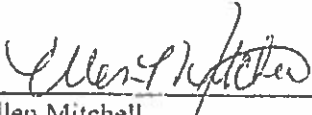
I HEREBY CERTIFY that on this 27<sup>th</sup> day of October, 2017, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER by the following method to:

Jed W. Manwaring  
Christy A. Kaes  
Evans Keane, LLP  
1161 West River Street, Suite 110  
Boise, ID 83702

- ☒ U.S. Mail
- ☐ Hand Delivery
- ☒ Certified Mail, Return Receipt Requested
- ☐ Overnight Mail
- ☐ Facsimile:

Steven L. Olsen  
Deputy Attorney General  
Civil Litigation Division  
P. O. Box 83720  
Boise, ID 83720-0010

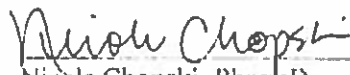
- ☐ U.S. Mail
- ☐ Hand Delivery
- ☐ Overnight Mail
- ☐ Facsimile:
- ☒ Email: steven.olsen@ag.idaho.gov  
colleen.funk@ag.idaho.gov

  
\_\_\_\_\_  
Ellen Mitchell  
Investigations Support Coordinator

**ORDER**

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order, and it is hereby ordered that Respondent comply with said terms and conditions.

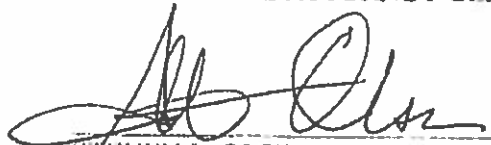
DATED this 26<sup>th</sup> day of October, 2017.

  
\_\_\_\_\_  
Nicole Chopski, PharmD  
Board Chair

I concur in this stipulation and order and recommend that the Board adopt the same.

DATED this 17 day of October, 2017.

STATE OF IDAHO  
OFFICE OF THE ATTORNEY GENERAL

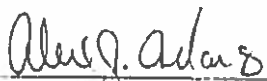


STEVEN L. OLSEN  
Deputy Attorney General

I also concur in this stipulation and order and recommend the Board adopt the same.

DATED this 17<sup>th</sup> day of October, 2017.

IDAHO BOARD OF PHARMACY

By: 

Alex J. Adams, PharmD, MPH  
Executive Director

DATED this 18<sup>th</sup> day of October, 2017.

WELLS PHARMACY NETWORK, LLC

By: [Signature]

Its: Secretary  
Authorized Representative for Respondent

DATED this 16 day of October, 2017.

EVANS KEANE, LLP

[Signature]  
Jed W. Manwaring  
Attorneys for Respondent

*[The remainder of this page is intentionally blank.]*

submitted to the Board. .

6. In the event this Stipulation is rejected by the Board, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative action based on the fact that the Board has considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation and Consent Order to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a public record.

9. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise.

10. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board at the next regularly-scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member executes the attached Order incorporating this Stipulation.

12. Subsequent to the Board executing this Stipulation and Consent Order below, the Board shall not pursue an administrative complaint or disciplinary action against Respondent for any alleged violations predating the date of the Board's execution.

### E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

1. Respondent understands these allegations constitute cause for disciplinary terms upon its license. Respondent agrees the Board has jurisdiction to proceed in this matter with its consent as indicated by signature on its behalf hereto.

2. Respondent has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by its terms it is waiving certain rights provided under Idaho law.

3. Respondent understands that it has, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on its own behalf; the right to reconsideration; the right to appeal this matter to district court; and all rights provided by the Idaho Administrative Procedure Act and the laws and rules governing the practice of pharmacy in Idaho. Respondent hereby freely and voluntarily waives these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein.

4. Respondent understands that in signing this Stipulation, it is enabling the Board to impose disciplinary terms upon its license as set forth in Section C without further process.

5. Respondent understands the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondent understands that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the aforementioned terms, and Respondent hereby agrees to the above Stipulation for settlement. If the Board rejects this proposed Stipulation and Consent Order, this Stipulation and Consent Order will not have any effect and a new proposed Stipulation and Consent Order may be proposed and

4. Upon receipt of full payment of the agreed-upon fine herein, the Board shall move for dismissal of the Amended Administrative Complaint filed in the pending administrative action. Each party shall bear its own attorneys' fees and costs incurred in the course of prosecuting or defending the administrative action.

5. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional action being taken against Respondent's mail service pharmacy license.

6. All costs associated with Respondent's compliance with the terms of this Stipulation and Order shall be borne solely by Respondent.

#### **D. COMPLIANCE WITH STIPULATION AND CONSENT ORDER**

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and its attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on the administrative complaint, any allegations of non-compliance will be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section.

3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be borne solely by Respondent.



6. Pursuant to Idaho Code § 37-2723, no person shall fill, compound or dispense a prescription for a controlled substance unless it is in compliance with applicable federal law; including but not limited to Title 21, Chapter 13, U.S. Code, and 21 C.F.R. § 1306.04(a).

7. Respondent, in lieu of proceeding with a formal disciplinary hearing, hereby stipulates that the Board may enter a final order against its license as set forth in Section C below. By entering this stipulation, Respondent is not admitting to any violations or wrongdoing but rather simply seeks a settlement with compliance of the Board's demands going forward.

### **C. STIPULATED SETTLEMENT**

1. The Board has authority pursuant to Idaho Code § 54-1728(c) to impose conditions restricting Respondent's license, and pursuant to § 54-1728(f) to impose administrative fines not to exceed \$2,000 per violation, plus attorneys' fees and administrative costs. Respondent agrees to pay the Board \$10,000 for the alleged violations outlined above in Section B(6). This fine shall become due only after the Board approves and executes the Order incorporating this Stipulation and shall be paid to the Board within 180 days of the date the Order is executed.

2. Going forward from the date the Order incorporating this Stipulation is executed, Respondent shall verify the appropriate Idaho medical or prescriber licenses and controlled substance registrations for all prescribers issuing prescriptions to Idaho residents. Documentation of such verifications shall be retained by Respondent for two years from the date they are obtained and shall be provided to the Board upon its written request.

3. Respondent shall designate a representative of its management to whom the Board should direct its communications and inquiries and who will be responsible for responding to such inquiries. This representative shall be designated in writing within thirty days of the date the Order incorporating this Stipulation is executed.

laws and rules of the state of Idaho. Respondent denies these allegations and contends that: it requires prescriber-physicians to comply with all state and federal statutes; it cannot interfere with the patient-physician relationship; and the Board should seek to administratively discipline the physicians if they are in violation rather than vicariously seek to punish the Respondent pharmacy which has no control over the physician's license and relationship with patients.

6. The Board has authority and jurisdiction to discipline violations of the laws and rules governing the practice of pharmacy and controlled substances in the state of Idaho as follows:

- a. Pursuant to Idaho Code §§ 54-1726(1) and 54-1728(1), the Board may suspend, revoke or restrict the license or registration of any person, and may impose an administrative fine and collect the costs of prosecution, upon the grounds of unprofessional conduct as defined by Board rule, or the grounds of violation of any provision of Title 54; Chapter 17;
- b. Pursuant to IDAPA 27.01.01.501, the Board may suspend, revoke or restrict the registration of an individual on one or more of the grounds provided in Idaho Code § 54-1726;
- c. Pursuant to IDAPA 27.01.01.500.01, negligence and dishonest dealings constitute unethical conduct;
- d. Pursuant to IDAPA 27.01.01.500.04, supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows for the circumvention of laws pertaining to the legal sale of these articles constitutes diversion of drug products;
- e. Pursuant to Idaho Code § 54-1733(5)(b), to knowingly dispense a legend drug pursuant to an invalid prescription drug order is a violation of this chapter;

Enforcement Agency ("DEA") registration for controlled substances in Idaho. In addition, V.D. has been disciplined by the Idaho Board of Medicine for treating and prescribing to Idaho residents in violation of the Idaho Telehealth Access Act.

4. Respondent issued prescription drugs, including Schedule III controlled substances, under which the Board alleges were invalid prescriptions. These allegations are based upon the Board's position that the prescriptions were invalid because they were issued by physicians who claimed to be treating patients via telehealth but were not complying with the Idaho Telehealth Access Act, Title 54, Chapter 56, Idaho Code, nor complying with United States Code, Title 21, Section 802(54). Specifically, the Board alleges that: Idaho Code § 54-5703(4) requires telehealth providers to be licensed in the state of Idaho; Idaho Code § 54-5707(1) requires telehealth providers to have an established provider-patient relationship in order to issue prescription drug orders; and 21 U.S.C. § 802(54) requires telemedicine providers to possess a DEA controlled substance registration and a state controlled substance registration in the state where the patient is located. The Respondent denies these allegations and contends that: it requires prescriber-physicians to comply with all state and federal statutes; Idaho Code §54-5703(4) is ambiguous as to whether it requires physicians practicing telemedicine to be licensed in Idaho; and that all physicians requesting prescriptions from Respondent have a DEA controlled substance registration.

5. The Board alleges that Respondent had a duty to confirm the validity of the prescriptions it filled for the patients of its associated physicians. Specifically, the Board alleges that: Respondent failed to verify the information provided to it by its associated physicians with regard to (1) those physicians' licensing status in the states in which they prescribed drugs and controlled substances; (2) the patient-physician relationships that must exist; and (3) whether the actions taken by the physicians in treating their patients via telehealth complied with applicable

b. Patient M.H. received ten prescriptions for Schedule III controlled substances from three prescribers located in Florida, only one of whom was licensed to practice medicine in Idaho, none of whom were registered for controlled substances in Idaho. The Board alleges that: Patient M.H. did not have an existing relationship with the prescribers; and had no face-to-face interaction with the prescribers. Patient M.H. did not have any contact with Respondent other than receiving the prescribed medications by mail.

c. Patient B.M. received eight prescriptions for Schedule III controlled substances from two prescribers located in Maine and California, neither of whom were licensed to practice medicine nor registered for controlled substances in Idaho. The Board alleges that: Patient did not have an existing relationship with the prescribers; had no face-to-face interaction with the prescribers; and he had no telephone interaction with the prescribers, only with a representative. Respondent denies these allegations. Patient B.M. did not have any contact with Respondent other than receiving the prescribed medications by mail.

d. Patient R.W. received five prescriptions for Schedule III controlled substances from three prescribers located in Florida and Virginia, none of whom were licensed to practice nor registered for controlled substances in the state of Idaho. The Board alleges that: Patient R.W. did not have an existing relationship with the prescribers and had no face-to-face interaction with the prescribers, but did speak with two of them by telephone. Respondent denies these allegations. Patient R.W. did not have any contact with Respondent other than receiving the prescribed medications by mail.

3. In the course of its investigation of Respondent, the Board also found that at least one of Respondent's prescribers, V.D., is a licensed medical provider in the state of Idaho but does not have a valid Idaho Board of Pharmacy Controlled Substance Registration, nor a federal Drug

## B. STIPULATED FACTS

1. In March 2015, Board staff reviewed its Prescription Monitoring Program ("PMP") and became concerned about Respondent's activity. In July 2016, Board staff prepared and reviewed a PMP dispensing report regarding Respondent for the time period of April 4, 2014, through July 5, 2016. This PMP dispensing report showed medications prescribed to Idaho residents by medical providers located in Arizona, California, Florida, Illinois, Maine, Massachusetts, and Virginia.

2. The Board requested and timely received prescription records from Respondent's Director of Quality Assurance. Board staff's review of the provided records revealed that Respondent issued prescription drugs to at least four residents of the state of Idaho which were the result of patient-doctor "Telehealth Service" consultations in which the prescriber/doctor was not licensed in Idaho. The Board alleges that these prescriber-doctors not licensed in Idaho was a violation of Idaho Code §54-5703(4), which interpretation of said statute, Respondent denies as not being clear in the statute's wording. Regardless, the Board alleges that these prescriptions were filled by Respondent in violation of Idaho Code, Title 54, Chapter 57 (the Idaho Telehealth Access Act), as follows:

a. Patient D.D. received six prescriptions for Schedule III controlled substances from two prescribers located in Maine and California, neither of whom were licensed to practice medicine nor registered for controlled substances in Idaho. The Board alleges that: Patient D.D. did not have an existing relationship with the prescribers; had no face-to-face interaction with the prescribers; and had no telephone interaction with the prescribers, only with a representative. Respondent denies these allegations. Patient D.D. did not have any contact with Respondent other than emails and receiving the prescribed medications by mail.

## BEFORE THE BOARD OF PHARMACY

## STATE OF IDAHO

In the Matter of the License and Registration of:	)	
	)	Case No. BOP 16-071
	)	
WELLS PHARMACY NETWORK, LLC,	)	
Mail Service Pharmacy License No. 19765MS,	)	<b>STIPULATION AND</b>
	)	<b>CONSENT ORDER</b>
Respondent.	)	
_____	)	

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that constitutes sufficient grounds for administrative action against Wells Pharmacy Network, LLC ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board.

NOW, THEREFORE, it is hereby stipulated and agreed between the Board and Respondent that this matter shall be settled and resolved upon the following terms:

**A. JURISDICTION OF THE BOARD**

1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

2. Respondent has been an active licensee of the Board since September 2012 and currently holds Mail Service Pharmacy License No. 19765MS. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

STIPULATION AND CONSENT ORDER



Pursuant to Sections 67-5270 and 67-5272, Idaho Code, if this preliminary order becomes final, any party aggrieved by the final order or orders previously issued in this case may appeal the final order and all previously issued orders in this case to district court by filing a petition in the district court of the county in which a hearing was held; the final agency action was taken; the party seeking review of the order resides, or operates its principal place of business in Idaho, or; the real property or personal property that was the subject of the agency action is located.

This appeal must be filed within twenty-eight (28) days of this preliminary order becoming final. See Section 67-5273, Idaho Code. The filing of an appeal to district court does not itself stay the effectiveness or enforcement of the order under appeal.

\* \* \* \* \*

### CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 6th day of November, 2017, I caused to be served a true and correct copy of the foregoing by the following method to:

Jed Manwaring  
EVANS KEANE LLP  
1161 W. River St., Suite 100  
PO Box 959  
Boise, ID 83701  
[jmanwaring@evanskeane.com](mailto:jmanwaring@evanskeane.com)  
[ckaes@evanskeane.com](mailto:ckaes@evanskeane.com)

☐ U.S. Mail  
☐ Hand Delivery  
☐ Facsimile:  
☒ Email

Steven Olsen  
Deputy Attorney General  
Civil Litigation Division  
PO Box 83720  
Boise, ID 83720  
[steven.olsen@ag.idaho.gov](mailto:steven.olsen@ag.idaho.gov)

☐ U.S. Mail  
☐ Hand Delivery  
☐ Facsimile:  
☒ Email

Alex J. Adams  
Executive Director  
Idaho Board of Pharmacy  
1199 Shoreline Ln., Suite 303  
Boise, ID 83702  
[alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov)

☐ U.S. Mail  
☐ Hand Delivery  
☐ Facsimile:  
☒ Email

  
\_\_\_\_\_  
SAM SEEVERS, PARALEGAL  
FAIR HEARINGS UNIT

IT IS SO ORDERED.

DATE: November 6, 2017.

STATE OF IDAHO  
OFFICE OF THE ATTORNEY GENERAL

By   
LINCOLN STRAWN  
HEARING OFFICER

\* \* \* \* \*

PRELIMINARY ORDER (IDAPA 04.11.01.730):

This is a preliminary order of the hearing officer. It can and will become final without further action of the agency unless any party petitions for reconsideration before the hearing officer issuing it or appeals to the hearing officer's superiors in the agency. Any party may file a motion for reconsideration of this preliminary order with the hearing officer issuing the order within fourteen (14) days of the service date of this order. The hearing officer issuing this order will dispose of the petition for reconsideration within twenty-one (21) days of its receipt, or the petition will be considered denied by operation of law. Idaho Code 67-5243(3).

Within fourteen (14) days after (a) the service date of this preliminary order, (b) the service date of the denial of a petition for reconsideration from this preliminary order, or (c) the failure within twenty-one (21) days to grant or deny a petition for reconsideration from this preliminary order, any party may in writing appeal or take exceptions to any part of the preliminary order and file briefs in support of the party's position on any issue in the proceeding to the agency head (or designee of the agency head). Otherwise, this preliminary order will become a final order of the agency.

If any party appeals or takes exceptions to this preliminary order, opposing parties shall have twenty-one (21) days to respond to any party's appeal within the agency. Written briefs in support of or taking exceptions to the preliminary order shall be filed with the agency head (or designee). The agency head (or designee) may review the preliminary order on its own motion.

If the agency head (or designee) grants a petition to review the preliminary order, the agency head (or designee) shall allow all parties an opportunity to file briefs in support of or taking exceptions to the preliminary order and may schedule oral argument in the matter before issuing a final order. The agency head (or designee) will issue a final order within fifty-six (56) days of receipt of the written briefs or oral argument, whichever is later, unless waived by the parties or for good cause shown. The agency head (or designee) may remand the matter for further evidentiary hearings if further factual development of the record is necessary before issuing a final order.



LAWRENCE G. WASDEN  
ATTORNEY GENERAL

S. KAY CHRISTENSEN  
CHIEF OF CONTRACTS AND ADMINISTRATIVE LAW

LINCOLN STRAWHUN, ISB #8925  
REBECCA OPHUS, ISB #7697  
Deputy Attorneys General  
Fair Hearings Unit  
Contracts and Administrative Law  
Office of the Attorney General  
954 W. Jefferson, 2<sup>nd</sup> Floor  
P. O. Box 83720  
Boise, ID 83720-0010  
Telephone: (208) 334-4555  
Fax: (208) 854-8070

**BEFORE THE BOARD OF PHARMACY STATE OF IDAHO**

In the Matter of the License of:	)	
	)	Case No. BOP 16-071
	)	
WELLS PHARMACY NETWORK, LLC	)	
Mail Service Pharmacy License No. 19765MS	)	<b>PRELIMINARY ORDER</b>
	)	
Respondent.	)	
	)	
	)	
	)	

Per IDAPA 04.11.01.280, the above appeal is resolved, without a hearing on the merits of the appeal, by a Stipulation and Consent Order between the parties. The stipulation is attached (Exhibit A) and incorporated into this Order.



GARY R. HERBERT  
Governor  
SPENCER J. COX  
Lieutenant Governor

State of Utah

## Department of Commerce

Division of Occupational and Professional Licensing

FRANCINE A. GIANI  
Executive Director

MARK B. STEINAGEL  
Division Director

Date: 4-16-2018

Dear Respondent,

You have been ordered to pay a fine to the Division of Occupational and Professional Licensing:

Your fine of 500. is due 4-16-2018.\*

Your case number is DOPL- 2018-15 Wells Pharmacy Network LLC

\*If you are unable to pay the fine as indicated in your Order or your Order indicates other arrangements, you must contact me or my co-worker Carol Inglesby within ten (10) days from the date of this letter. No special considerations will be granted for failure to contact us within the ten (10) day limit.

Make check(s) payable to DOPL and remit to:

DOPL  
Attn: Disciplinary Files  
P O Box 146741  
Salt Lake City UT 84114-6741

Or you may pay with a Visa/Mastercard/American Express. Please mail your card number and expiration date to the above address or call (801)530-6088 and leave the information. Ms. Inglesby's phone number is (801)530-6626.

Please be sure to include your case number on any correspondence you send us.

Thank you,

Kim Lesh

Kim Lesh  
Administrative Secretary

Disp/Fine letter 6/3/06

## CERTIFICATE OF SERVICE

I hereby certify that on the 16 day of January, 2018, a true and correct copy of the foregoing STIPULATION AND ORDER has been served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

WELLS PHARMACY NETWORK LLC  
450 US HWY 51 BYPASS N  
DYERSBURG TN 38024

and caused a copy to be electronically mailed to:

L. Mitchell Jones, Assistant Attorney General  
([mitchelljones@agutah.gov](mailto:mitchelljones@agutah.gov))

(Signature)  
Carol Inglesby  
Administrative Assistant  
Division of Occupational  
and Professional  
Licensing

1 pyrogens of batch-produced sterile injectable drug products compounded from one or more non-  
 2 sterile ingredients. The circumstances are as follows:

3 14. Between May 2015 and March 2016, Respondent shipped about 2,890 batch-  
 4 produced non-sterile to sterile compounded injectable drug products into California without  
 5 documentation of end product sterility or pyrogen testing.<sup>2</sup>

6 PRAYER

7 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
 8 and that following the hearing, the Board of Pharmacy issue a decision:

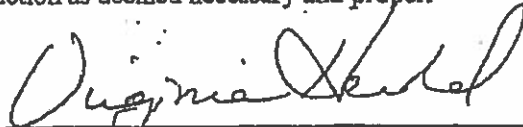
9 1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1325, issued to  
 10 Wells Pharmacy Network LLC;

11 2. Revoking or suspending Non-Resident Pharmacy Permit Number NSC 99824, issued  
 12 to Wells Pharmacy Network LLC;

13 3. Ordering Wells Pharmacy Network LLC to pay the Board of Pharmacy the reasonable  
 14 costs of the investigation and enforcement of this case, pursuant to Business and Professions Code  
 15 section 125.3; and,

16 4. Taking such other and further action as deemed necessary and proper.

17  
 18 DATED: 10/14/16

  
 VIRGINIA HEROLD  
 Executive Officer  
 Board of Pharmacy  
 Department of Consumer Affairs  
 State of California  
 Complainant

22  
 23 SA2016102809  
 12442799.doc

24  
 25  
 26  
 27  
 28 <sup>2</sup> A pyrogen is any substance or agent that causes fever.

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

5/23/2017

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
KENT D. HARRIS  
Supervising Deputy Attorney General



DAVID E. BRICE  
Deputy Attorney General  
*Attorneys for Complainant*

SA2016102809  
12687933.docx



1       14. This Stipulated Settlement and Disciplinary Order for Public Reapproval is intended by  
2 the parties to be an integrated writing representing the complete, final, and exclusive embodiment  
3 of their agreement. It supersedes any and all prior or contemporaneous agreements,  
4 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated  
5 Settlement and Disciplinary Order for Public Reapproval may not be altered, amended, modified,  
6 supplemented, or otherwise changed except by a writing executed by an authorized representative  
7 of each of the parties.

8       15. In consideration of the foregoing admissions and stipulations, the parties agree that  
9 the Board may, without further notice or formal proceeding, issue and enter the following  
10 Disciplinary Order:

11                                   **DISCIPLINARY ORDER**

12       IT IS HEREBY ORDERED that both Non-Resident Pharmacy Permit No. NRP 1325 and  
13 Non-Resident Sterile Compounding Permit No. NSC 99824 issued to Respondent Wells  
14 Pharmacy Network LLC shall be publicly reprovved by the Board of Pharmacy under Business  
15 and Professions Code section 495 in resolution of Accusation No. 5887, attached as exhibit A.

16       **Cost Recovery.** Respondent shall pay \$6,155.25 to the Board for its costs associated with  
17 the investigation and enforcement of this matter. Respondent shall be permitted to pay these  
18 costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as  
19 ordered, Respondent shall not be allowed to renew its Non-Resident Pharmacy Permit or its Non-  
20 Resident Sterile Compounding Permit until Respondent pays costs in full.

21       ///

22       ///

23       ///

1           8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and  
2 every right set forth above.

3                                   CULPABILITY

4           9. Respondent understands and agrees that the charges and allegations in Accusation  
5 No. 5887, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident  
6 Pharmacy Permit and its Non-Resident Sterile Compounding Permit.

7           10. For the purpose of resolving the Accusation without the expense and uncertainty of  
8 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual  
9 basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest  
10 those charges.

11           11. Respondent agrees that its Non-Resident Pharmacy Permit and its Non-Resident  
12 Sterile Compounding Permit are subject to discipline and agrees to be bound by the Disciplinary  
13 Order below.

14                                   CONTINGENCY

15           12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent  
16 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may  
17 communicate directly with the Board regarding this stipulation and settlement, without notice to  
18 or participation by Respondent or its counsel. By signing the stipulation, Respondent understands  
19 and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the  
20 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its  
21 Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall  
22 be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action  
23 between the parties, and the Board shall not be disqualified from further action by having  
24 considered this matter.

25           13. The parties understand and agree that Portable Document Format (PDF) and facsimile  
26 copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including  
27 Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and  
28 effect as the originals.



JURISDICTION

3. On or about May 28, 2013, the Board issued Original Non-Resident Pharmacy Permit No. NRP 1325 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

4. On or about July 1, 2013, the Board issued Original Non-Resident Sterile Compounding Permit Number NSC 99824 to Respondent to compound injectable sterile drug products. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

5. Accusation No. 5887 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 21, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5887 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5887. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

///

EXHIBIT A

1 XAVIER BECERRA  
 Attorney General of California  
 2 KENT D. HARRIS  
 Supervising Deputy Attorney General  
 3 DAVID E. BRICE  
 Deputy Attorney General  
 4 State Bar No. 269443  
 1300 I Street, Suite 125  
 5 P.O. Box 944255  
 Sacramento, CA 94244-2550  
 6 Telephone: (916) 324-8010  
 Facsimile: (916) 327-8643  
 7 E-mail: David.Brice@doj.ca.gov  
 Attorneys for Complainant

8  
 9 **BEFORE THE**  
**BOARD OF PHARMACY**  
**DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5887

12 **WELLS PHARMACY NETWORK LLC**  
 13 **450 US Hwy 51 Bypass N**  
**Dyersburg, TN 38024**

OAH No. 2017011087

14 **Non-Resident Pharmacy Permit No. NRP**  
 15 **1325**  
**Non-Resident Sterile Compounding Permit**  
 16 **No. NSC 99824**

**STIPULATED SETTLEMENT AND**  
**DISCIPLINARY ORDER FOR PUBLIC**  
**REPROVAL**

[Bus. & Prof. Code § 495]

17 Respondent.

18  
 19 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
 20 entitled proceedings that the following matters are true:

21 **PARTIES**

22 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy  
 23 (Board). She brought this action solely in her official capacity and is represented in this matter by  
 24 Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney  
 25 General.

26 2. Wells Pharmacy Network LLC (Respondent) is represented in this proceeding by  
 27 attorneys Steven L. Simas and Daniel Tatick, whose address is: Simas and Associates, 3835  
 28 North Freeway Blvd., Suite 228, Sacramento, CA 95834.

EX A

ORDER

THE ABOVE STIPULATION, in the matter of WELLS PHARMACY NETWORK, LLC, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 16 day of January, 2018

DIVISION OF OCCUPATIONAL AND  
PROFESSIONAL LICENSING

  
MARK B. STEINAGEL  
Director

Investigator: Sharilee McIntyre

DIVISION OF OCCUPATIONAL &  
PROFESSIONAL LICENSING

BY: Jennifer Zaelit  
JENNIFER ZAELIT  
Bureau Manager

DATE: 1/12/2019

SEAN D. REYES  
UTAH ATTORNEY GENERAL

BY: L. Mitchell Jones  
L. MITCHELL JONES  
Counsel for the Division

DATE: 16 Jan 19

RESPONDENT

BY: Stacy Shapiro  
STACY SHAPIRO

DATE: 1/8/19

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:

- a. Respondent was first licensed to operate as a pharmacy and to dispense controlled substances in the State of Utah on or about November 26, 2012.
- b. On or about May 23, 2017, Respondent entered into a "Stipulated Settlement and Disciplinary Order for Public Reproval" with the Board of Pharmacy of the State of California, a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit A, sanctioning Respondent's California pharmacy license. Exhibit A also contains an "Accusation" which describes the allegations of misconduct against Respondent.
- c. The allegations contained in Exhibit A would constitute misconduct in the State of Utah.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a) and (d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

- (a) Respondent shall pay a fine to the Division in the amount of \$500.00 (five hundred dollars), pursuant to Utah Code Ann. § 58-17b-401(6), § 58-17b-504(5), and Utah Administrative Code R156-17b-402, within 90 days of the effective date of this Stipulation and Order.
  - (b) Respondent's license shall be publicly reprimanded for the conduct described above.
  - (c) Respondent shall successfully complete all the requirements of Exhibit A.
9. Upon approval by the Director of the Division this Stipulation and Order shall be the

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to a hearing, the right to call witnesses on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-4-901 through R151-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation



L. MITCHELL JONES (U.S.B. 5979)  
 Assistant Attorney General  
 SEAN D. REYES (U.S.B. 7969)  
 Utah Attorney General  
 Commercial Enforcement Division  
 Heber M. Wells Building  
 Box 140872  
 Salt Lake City, UT 84114-6741  
 Telephone: (801) 366-0310

---

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING  
 OF THE DEPARTMENT OF COMMERCE  
 OF THE STATE OF UTAH

---

IN THE MATTER OF THE LICENSES OF	)	
WELLS PHARMACY NETWORK, LLC	)	STIPULATION AND ORDER
UTAH LICENSE #8473516-1708 & 8913	)	
TO OPERATE AS A PHARMACY	)	CASE NO. DOPL
AND TO DISPENSE	)	
CONTROLLED SUBSTANCES	)	
IN THE STATE OF UTAH	)	

2018-15

---

WELLS PHARMACY NETWORK, LLC ("Respondent") and the DIVISION OF  
 OCCUPATIONAL AND PROFESSIONAL LICENSING of the Department of Commerce of  
 the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Stacy Shapiro is an officer of Respondent pharmacy and is authorized to act as agent for and enter into binding agreements on behalf of Respondent pharmacy.



State of Utah  
Department of Commerce

Division of Occupational and Professional Licensing

GARY R. HERBERT  
Governor

SPENCER J. COX  
Lieutenant Governor

FRANCINE A. GIANI  
Executive Director

MARK B. STEINAGEL  
Division Director

Date: 1-16-2018

Dear Respondent,

You have been ordered to pay a fine to the Division of Occupational and Professional Licensing:

Your fine of 500.00 is due 4-16-2018.\*

Your case number is DOPL-2018-14 Wells Pharmacy Network

\*If you are unable to pay the fine as indicated in your Order or your Order indicates other arrangements, you must contact me or my co-worker Carol Inglesby within ten (10) days from the date of this letter. No special considerations will be granted for failure to contact us within the ten (10) day limit.

Make check(s) payable to DOPL and remit to:

DOPL  
Attn: Disciplinary Files  
P O Box 146741  
Salt Lake City UT 84114-6741

Or you may pay with a Visa/Mastercard/American Express. Please mail your card number and expiration date to the above address or call (801)530-6088 and leave the information. Ms. Inglesby's phone number is (801)530-6626.

Please be sure to include your case number on any correspondence you send us.

Thank you,

Kim Lesh

Kim Lesh  
Administrative Secretary

Disc/Fine letter 03/06


## CERTIFICATE OF SERVICE

I hereby certify that on the 16 day of January, 2018, a true and correct copy of the foregoing STIPULATION AND ORDER has been served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

WELLS PHARMACY NETWORK  
1210 SW 33RD AVENUE  
OCALA FL 34474

and caused a copy to be electronically mailed to:

L. Mitchell Jones, Assistant Attorney General  
([mitchelljones@agutah.gov](mailto:mitchelljones@agutah.gov))

  
\_\_\_\_\_  
Carol Inglesby  
Administrative Assistant  
Division of Occupational  
and Professional  
Licensing

1 COPY OF THE FOREGOING MAILED  
2 this *09* day of *June*, ~~2014~~ to: *2015*

3 Montgomery Lee  
4 Assistant Attorney General  
5 1275 W. Washington Street, CIV/LES  
6 Phoenix, Arizona 85007  
7 Attorney for the State of Arizona

8  
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Doc #4200554

1 required unannounced random inspection in paragraph 4 of this Order prior to the  
 2 expiration of the one (1) year probationary period, Respondent may petition the Board for  
 3 early termination of the probation by submitting such a request in writing and appearing  
 4 before the Board at a regularly scheduled meeting.

5 6. If Respondent violates this Order in any way or fails to fulfill the  
 6 requirements of this Order, the Board, after giving the Respondent notice and the  
 7 opportunity to be heard, make take disciplinary action against Respondent's permit. The  
 8 issue at such a hearing will be limited solely to whether this Order has been violated.

9  
 10 DATED this 09 day of June, 2014. 2015

11 ARIZONA STATE BOARD OF PHARMACY

12 (Seal)

13  
 14  
 15  
 16 By: 

KAMLESH GANDHI  
 EXECUTIVE DIRECTOR

17  
 18 ORIGINAL OF THE FOREGOING FILED  
 19 this 09 day of June, 2014 with:  
 20 2015

21 Arizona State Board of Pharmacy  
 1616 W. Adams St.  
 Phoenix, Arizona 85007

22 COPY OF THE FOREGOING MAILED  
 23 BY CERTIFIED MAIL  
 24 this 09 day of June, 2014  
 2015

25 Wells Pharmacy Network  
 1210 SW 33<sup>rd</sup> Ave.  
 Ocala, Florida 34474  
 26 Respondent

4. The conduct and circumstances described above constitute unethical conduct pursuant to A.R.S. § 32-1901.01 (A) (5) by violating A.A.C. R4-23-402 (I), R4-23-410 (I) (2) (a) and (b), A.A.C. R4-23-410 (I) (5), A.A.C. R4-23-410 (J) (1) (d) and A.A.C. R4-23-670 (C) (1).

Based upon the above Findings of Fact and Conclusions of Law, the Board issues the following Order:

1. Respondent's permit no. Y005709 is placed on probation for a period of one (1) year.

2. Respondent shall pay a civil penalty of \$9,000.00 within 90 days of the effective date of this Order.

3. Respondent shall pay for the costs of the inspection conducted by Board compliance officers in October 2014 in the amount of \$2,345.37 within 90 day of the effective date of this Order.

4. Respondent shall to submit to and pass one (1) unannounced random inspection by Board compliance officers within one (1) year of the effective date of this Order and shall pay for the costs of this inspection in an amount not to exceed \$3,000.00. Respondent shall pay for the costs of this inspection within 90 days of receiving written notification from Board staff of the incurred costs.

5. If Respondent pays the civil penalty in paragraph 2 of this Order, pays the costs of the October 2014 inspection in paragraph 3 of this Order, submits to and passes the unannounced random inspection in paragraph 4 of this Order and pays the costs of the

1 complex preparation which is then verified and approved by a pharmacist (quality  
2 manager).

3 10. At the October 7 and 8, 2014 inspection Board compliance officers  
4 reviewed ten (10) random prescription/orders from the Arizona report which revealed  
5 Respondent failed to maintain proper compounding records of quality assurance  
6 verification, documentation of procedures for obtaining samples for testing,  
7 documentation of filter lot number/expiration date and bubble point testing in the  
8 compounding record, documentation of the sampling plan for sterility/endotoxin testing  
9 and failure to follow proper procedures/protocols for sterility and endotoxin testing  
10 sampling.  
11

12 11. Board compliance officers reviewed additional documents requested from  
13 Respondent and received on or about October 15, 2014 which revealed additional  
14 discrepancies regarding the records, documentation, compliance with standard operating  
15 procedures, testing procedures, sampling procedures and shipping procedures involving  
16 Rx 6009925, Rx 6038319, Rx 6038321, Rx 6021313, Rx 605 1741 and Rx 6004621 as  
17 more fully set forth in the compliance officers' report dated October 15, 2014, a copy of  
18 which is attached and is incorporated by this reference.  
19

#### 20 CONCLUSIONS OF LAW

21 1. The Board possesses jurisdiction over the subject matter and over  
22 Respondent pursuant to A.R.S. § 32-1901 *et seq.*  
23

24 2. The Board may discipline permit holder if the Board determines that the  
25 permittee or the permittee's employee has engaged in unethical conduct. A.R.S. § 32-  
26 1927.02(A)(1).

1 October 10, 2014 requested additional documents which were provided by Respondent  
2 on October 15, 2014.

3 5. At the October 7 and 8, 2014 inspection Board compliance officers  
4 observed a technician working at Respondent's facility exiting and re-entering the ante  
5 room without re-garbing and later observed the same technician working in the ante room  
6 without gloves or a mask both activities were not in compliance with Respondent's  
7 standard operating procedures.  
8

9 6. At the October 7 and 8, 2014 inspection Board compliance officers noted  
10 that the pharmacist in the general compounding area was not performing or documenting  
11 a verification of the components or weights prior to the completion of the finished  
12 product.  
13

14 7. At the October 7 and 8, 2014 inspection Board compliance officers  
15 conducted a random sampling of the compounding records regarding the "Beyond Use  
16 Date" (BUD) for several lots of Trimix injectable.  
17

18 8. At the October 7 and 8, 2014 inspection Board compliance officers  
19 observed discrepancies in Respondent's compliance with sterility, endotoxin and sterile  
20 filtration testing results records.

21 9. At the October 7 and 8, 2014 inspection Board compliance officers  
22 observed that Respondent's employees were not following Respondent's standard  
23 operating procedures regarding patient counseling of compounded preparations,  
24 sterilization and depyrogenation and pharmacist preparation of the first formulation of a  
25  
26



1 ACCEPTED AND AGREED BY RESPONDENT

2  
3 Wells Pharmacy Network

Dated: 3/31/15

4 by Ben David, CEO on behalf of Wells Pharmacy Network

5  
6 Subscribed and sworn to before me in the County of Palm Beach, State of  
7 Florida, this 31st day of March, 2014, by  
8 Ben David, on behalf of Wells Pharmacy Network. 2015



BRET JONATHAN PHILLIPS  
NOTARY PUBLIC  
STATE OF FLORIDA  
Comm# FF173681  
Expires 11/4/2018

Bret J Phillips  
NOTARY PUBLIC

9  
10 My Commission expires: 11/4/2018

### 11 FINDINGS OF FACT

- 12 1. The Board is the duly constituted authority for licensing and regulating the  
13 practice of pharmacy in the State of Arizona.
- 14 2. Respondent is the holder of Pharmacy Permit Number Y005709.
- 15 3. From February 21, 2014 through March 7, 2014 representatives of the  
16 United States Food and Drug Administration ("FDA") conducted an inspection of  
17 Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala, Florida. As a result of that  
18 inspection, the FDA issued a report on March 7, 2014 which contained eleven (11)  
19 observations detailing potential violations. Based upon its concerns regarding the  
20 observations identified in the FDA report the Board directed its staff to conduct an  
21 inspection of Respondent's facility in Ocala, Florida.
- 22 4. On or about October 7 and 8, 2014 Board compliance officers conducted an  
23 inspection of Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala Florida and on  
24  
25  
26

1        8. Respondent acknowledges and agrees that, upon signing this Consent  
2 Agreement and returning this document to the Board's Executive Director, it may not  
3 revoke its acceptance of the Consent Agreement or make any modifications to the  
4 document regardless of whether the Consent Agreement has been signed by the  
5 Executive Director. Any modification to this original document is ineffective and void  
6 unless mutually agreed by the parties in writing.

7        9. This Consent Agreement is subject to the approval of the Board and is  
8 effective only when accepted by the Board and signed by the Board's Executive Director.  
9 In the event that the Board does not approve this Consent Agreement, it is withdrawn and  
10 shall be of no evidentiary value and shall not be relied upon nor introduced in any action  
11 by any party, except that the parties agree that should the Board reject this Consent  
12 Agreement and this case proceeds to hearing, Respondent shall assert no claim that the  
13 Board was prejudiced by its review and discussion of this document or any records  
14 relating thereto.

15        10. If a court of competent jurisdiction rules that any part of this Consent  
16 Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement  
17 shall remain in full force and effect.

18        11. Respondent understands that this Consent Agreement is a public record that  
19 may be publicly disseminated as a formal action of the Board and may be reported as  
20 required by law to the National Practitioner Data Bank and the Healthcare Integrity and  
21 Protection Data Bank.

22        12. Respondent understands that any violation of this Consent Agreement  
23 constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-  
24 1901.01(A) and A.R.S. § 32-1927.02(A).

25        13. Respondent agrees that the Board will adopt the following Findings of Fact,  
26 Conclusions of Law and Order.

RECITALS

1  
2       1.     Respondent has read and understands this Consent Agreement and has had  
3 the opportunity to discuss this Consent Agreement with an attorney, or has waived the  
4 opportunity to discuss this Consent Agreement with an attorney.

5       2.     Respondent understands that it has a right to a public administrative hearing  
6 concerning the above-captioned matter, at which hearing it could present evidence and  
7 cross examine witnesses. By entering into this Consent Agreement, Respondent  
8 knowingly and voluntarily relinquishes all right to such an administrative hearing, as well  
9 as rights of rehearing, review, reconsideration, appeal, judicial review or any other  
10 administrative and/or judicial action, concerning the matters set forth herein.

11       3.     Respondent affirmatively agrees that this Consent Agreement shall be  
12 irrevocable.

13       4.     Respondent understands that this Consent Agreement or any part of the  
14 agreement may be considered in any future disciplinary action by the Board.

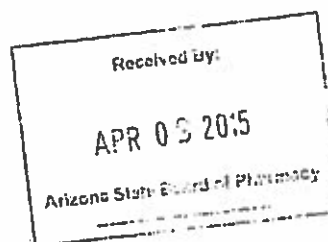
15       5.     Respondent understands this Consent Agreement deals with Board  
16 Complaint No. 4338 involving allegations of unethical conduct against Respondent. The  
17 investigation into these allegations against Respondent shall be concluded upon the  
18 Board's adoption of this Consent Agreement.

19       6.     Respondent understands that this Consent Agreement does not constitute a  
20 dismissal or resolution of any other matters currently pending before the Board, if any,  
21 and does not constitute any waiver, express or implied, of the Board's statutory authority  
22 or jurisdiction regarding any other pending or future investigation, action or proceeding.

23       7.     Respondent also understands that acceptance of this Consent Agreement  
24 does not preclude any other agency, subdivision, or officer of this State from instituting  
25 any other civil or criminal proceedings with respect to the conduct that is the subject of  
26 this Consent Agreement.

1 THOMAS C. HORNE  
 2 Attorney General  
 (Firm State Bar No. 14000)

3 MONTGOMERY LEE  
 4 Assistant Attorney General  
 State Bar No. 005658  
 5 1275 W. Washington, CIV/LES  
 Phoenix, Arizona 85007-2997  
 Tel: (602) 542-7980  
 6 Fax: (602) 364-3202



7  
 8 Attorneys for the Arizona State Board of Pharmacy

9  
 10 **BEFORE THE ARIZONA STATE BOARD OF PHARMACY**

11  
 12 In the Matter of

13 Wells Pharmacy Network,  
 14

15 Holder of Pharmacy Permit No. Y005709  
 16 in the State of Arizona.

Board Case No. 14-0019-PHR

**CONSENT AGREEMENT FOR  
 PROBATION, CIVIL PENALTY,  
 COSTS AND INSPECTION**

17  
 18  
 19 In the interest of a prompt and judicious settlement of this case, consistent with the  
 20 public interest, statutory requirements and the responsibilities of the Arizona State Board  
 21 of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Wells Pharmacy Network,  
 22 holder of Pharmacy Permit Number Y005709 in the State of Arizona ("Respondent"),  
 23 and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law  
 24 and Order ("Consent Agreement") as a final disposition of this matter.  
 25  
 26

EX A

ORDER

THE ABOVE STIPULATION, in the matter of WELLS PHARMACY NETWORK, LLC, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 16 day of January 2018

DIVISION OF OCCUPATIONAL AND  
PROFESSIONAL LICENSING

  
\_\_\_\_\_  
MARK B. STEINAGEL  
Director

Investigator: Sharilee McIntyre

DIVISION OF OCCUPATIONAL &  
PROFESSIONAL LICENSING

BY: Jennifer Zaelit  
JENNIFER ZAELIT  
Bureau Manager

DATE: 1/12/2019

SEAN D. REYES  
UTAH ATTORNEY GENERAL

BY: L. Mitchell Jones  
L. MITCHELL JONES  
Counsel for the Division

DATE: 16 Jan 18

RESPONDENT

BY: Stacy Shapiro  
STACY SHAPIRO

DATE: 1/9/18

subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

9. Upon approval by the Director of the Division this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may



and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:

- a. Respondent was first licensed to operate as a pharmacy and to dispense controlled substances in the State of Utah on or about November 26, 2012.
- b. On or about March 31, 2015, Respondent entered into a "Consent Agreement for Probation, Civil Penalty, Costs, and Inspection" with the Board of Pharmacy of the State of Arizona, a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit A, sanctioning Respondent's Arizona pharmacy license.
- c. The allegations contained in Exhibit A would constitute misconduct in the State of Utah.
- d. Respondent shipped compounded drugs to Utah during the time period described in Exhibit A.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a) and (d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

- (a) Respondent shall pay a fine to the Division in the amount of \$500.00 (five hundred dollars), pursuant to Utah Code Ann. § 58-17b-401(6), § 58-17b-504(5), and Utah Administrative Code R156-17b-402, within 90 days of the effective date of this Stipulation and Order.
- (b) Respondent's license shall be publicly reprimanded for the conduct described above.
- (c) Respondent shall successfully complete all the requirements of Exhibit A.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to a hearing, the right to call witnesses on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-4-901 through R151-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation

L. MITCHELL JONES (U.S.B. 5979)  
 Assistant Attorney General  
 SEAN D. REYES (U.S.B. 7969)  
 Utah Attorney General  
 Commercial Enforcement Division  
 Heber M. Wells Building  
 Box 140872  
 Salt Lake City, UT 84114-6741  
 Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING  
 OF THE DEPARTMENT OF COMMERCE  
 OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF	)	
WELLS PHARMACY NETWORK	)	STIPULATION AND ORDER
UTAH LICENSE #8392997-1708 & 8913	)	
TO OPERATE AS A PHARMACY	)	CASE NO. DOPL
AND TO DISPENSE	)	
CONTROLLED SUBSTANCES	)	
IN THE STATE OF UTAH	)	

2018-14

WELLS PHARMACY NETWORK, LLC ("Respondent") and the DIVISION OF  
 OCCUPATIONAL AND PROFESSIONAL LICENSING of the Department of Commerce of  
 the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the  
 subject matter of this action. Stacy Shapiro is an officer of Respondent pharmacy and is  
 authorized to act as agent for and enter into binding agreements on behalf of Respondent  
 pharmacy.

RECITALS

1  
2 1. Respondent has read and understands this Consent Agreement and has had  
3 the opportunity to discuss this Consent Agreement with an attorney, or has waived the  
4 opportunity to discuss this Consent Agreement with an attorney.

5 2. Respondent understands that it has a right to a public administrative hearing  
6 concerning the above-captioned matter, at which hearing it could present evidence and  
7 cross examine witnesses. By entering into this Consent Agreement, Respondent  
8 knowingly and voluntarily relinquishes all right to such an administrative hearing, as well  
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12 irrevocable.

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14 agreement may be considered in any future disciplinary action by the Board.

15 5. Respondent understands this Consent Agreement deals with Board  
16 Complaint No. 4338 involving allegations of unethical conduct against Respondent. The  
17 investigation into these allegations against Respondent shall be concluded upon the  
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26 this Consent Agreement.

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PROFESSIONAL  
LIBRARIAN DIVISION

1           8.     Respondent acknowledges and agrees that, upon signing this Consent  
2 Agreement and returning this document to the Board's Executive Director, it may not  
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4 document regardless of whether the Consent Agreement has been signed by the  
5 Executive Director. Any modification to this original document is ineffective and void  
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11 by any party, except that the parties agree that should the Board reject this Consent  
12 Agreement and this case proceeds to hearing, Respondent shall assert no claim that the  
13 Board was prejudiced by its review and discussion of this document or any records  
14 relating thereto.

15          10.    If a court of competent jurisdiction rules that any part of this Consent  
16 Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement  
17 shall remain in full force and effect.

18          11.    Respondent understands that this Consent Agreement is a public record that  
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20 required by law to the National Practitioner Data Bank and the Healthcare Integrity and  
21 Protection Data Bank.

22          12.    Respondent understands that any violation of this Consent Agreement  
23 constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-  
24 1901.01(A) and A.R.S. § 32-1927.02(A).

25          13.    Respondent agrees that the Board will adopt the following Findings of Fact.  
26 Conclusions of Law and Order

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LICENSING DIVISION

1 ACCEPTED AND AGREED BY RESPONDENT

2  
3 Wells Pharmacy Network

Dated: 2/2/14

4 by Ben Daniel, CEO on behalf of Wells Pharmacy Network

5  
6 Subscribed and sworn to before me in the County of Palm Beach, State of  
7 Florida, this 31<sup>st</sup> day of March, 2014, by  
8 Ben Daniel, on behalf of Wells Pharmacy Network. 2014



BRET JONATHAN PHILLIPS  
NOTARY PUBLIC  
STATE OF FLORIDA  
Comm# FF173681  
Expires 11/4/2018

Bret J Phillips  
NOTARY PUBLIC

10 My Commission expires: 11/4/2018

### 11 FINDINGS OF FACT

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13 practice of pharmacy in the State of Arizona.

14 2. Respondent is the holder of Pharmacy Permit Number Y005709.

15 3. From February 21, 2014 through March 7, 2014 representatives of the  
16 United States Food and Drug Administration ("FDA") conducted an inspection of  
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18 inspection, the FDA issued a report on March 7, 2014 which contained eleven (11)  
19 observations detailing potential violations. Based upon its concerns regarding  
20 observations identified in the FDA report the Board directed its staff to conduct  
21 inspection of Respondent's facility in Ocala, Florida.  
22  
23  
24

25 4. On or about October 7 and 8, 2014 Board compliance officers conducted an  
26 inspection of Respondent's facility located at 1210 SW 33<sup>rd</sup> Ave., Ocala Florida and on

3. The conduct and circumstances described above constitute unethical conduct pursuant in violation of A.R.S. § 32-1901.01(A) (5) (Violating a federal or state law or administrative rule relating to the manufacture, sale or distribution of drugs, devices, poisons, hazardous substances or precursor chemicals).

4. The conduct and circumstances described above constitute unethical conduct pursuant to A.R.S. § 32-1901.01 (A) (5) by violating A.A.C. R4-23-402 (I), R4-23-410 (I) (2) (a) and (b), A.A.C. R4-23-410 (I) (5), A.A.C. R4-23-410 (J) (I) (d) and A.A.C. R4-23-670 (C) (1).

### ORDER

Based upon the above Findings of Fact and Conclusions of Law, the Board issues the following Order:

1. Respondent's permit no. Y005709 is placed on probation for a period of one (1) year.

2. Respondent shall pay a civil penalty of \$9,000.00 within 90 days of the effective date of this Order.

3. Respondent shall pay for the costs of the inspection conducted by Board compliance officers in October 2014 in the amount of \$2,345.37 within 90 day of the effective date of this Order.

4. Respondent shall to submit to and pass one (1) unannounced random inspection by Board compliance officers within one (1) year of the effective date of this Order and shall pay for the costs of this inspection in an amount not to exceed \$3,000.00. Respondent shall pay for the costs of this inspection within 90 days of receiving written notification from Board staff of the incurred costs.

5. If Respondent pays the civil penalty in paragraph 2 of this Order, pays the costs of the October 2014 inspection in paragraph 3 of this Order, submits to and passes the unannounced random inspection in paragraph 4 of this Order and pays the costs of the

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OCT 1 2014

required unannounced random inspection in paragraph 4 of this Order prior to the expiration of the one (1) year probationary period, Respondent may petition the Board for early termination of the probation by submitting such a request in writing and appearing before the Board at a regularly scheduled meeting.

6. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, make take disciplinary action against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 09 day of June, 2014. 2015

ARIZONA STATE BOARD OF PHARMACY

(Seal)

By:

  
KAMLESH GANDHI  
EXECUTIVE DIRECTOR

ORIGINAL OF THE FOREGOING FILED  
this 09 day of June, 2014 with:  
2015

Arizona State Board of Pharmacy  
1616 W. Adams St.  
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED  
BY CERTIFIED MAIL

this 09 day of June, 2014  
2015

Wells Pharmacy Network  
1210 SW 33<sup>rd</sup> Ave.  
Ocala, Florida 34474  
Respondent

15 DEC 16 P 4:05

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PROF & VOCATIONAL  
LICENSING DIVISION



1 COPY OF THE FOREGOING MAILED  
2 this *09* day of *June*, ~~2014~~ to  
3 *2015*

3 Montgomery Lee  
4 Assistant Attorney General  
5 1275 W. Washington Street, CIV/LES  
6 Phoenix, Arizona 85007  
7 Attorney for the State of Arizona

6 Doc #4200554  
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LICENSING DIVISION

15 DEC 18 PM 15

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 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: TruMobility Inc.

Physical Address: 3100 E. Charleston #103  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: same

City: Las Vegas State: NV Zip Code: 89104

Telephone: 702 823 2834 Fax: 702 922 3498

E-mail: clarry@tru-mobility-inc.com Website: \_\_\_\_\_

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9 to 4 Tue: 9 to 4 Wed: 9 to 4 Thu: 9 to 4  
Fri: 9 to 4 Sat: closed to Sun: closed to Holidays: closed to

### MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: Danny Lumpkin

### 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>custom 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: N/A Telephone: N/A

## 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:

Medicare      7484130001      \_\_\_\_\_  
Ut Medicaid      1497126486      \_\_\_\_\_  
 \_\_\_\_\_      \_\_\_\_\_      \_\_\_\_\_

- 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.

- ☐ 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.

**APPLICATION FOR NEVADA MDEG LICENSE**

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 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.

Danny Lumpkin

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

Danny Lumpkin  
Print Name of Authorized Person

5-17-18  
Date

Board Use Only

Received: \_\_\_\_\_

Amount: \$500.00

**APPLICATION FOR NEVADA MDEG LICENSE****OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION**

State of Incorporation: Utah  
 Parent Company if any: none  
 Corporation Name: TruMobility Inc.  
 Mailing Address: 272 S. 671 W.  
 City: Pleasant Grove State: UT Zip: 84062  
 Telephone: 801 607 1050 Fax: 801 772 2710  
 Contact Person: Danny Lumpkin

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>Danny Lumpkin</u>	<u>W. Centennial Cedar Hills</u>	<u>UT</u>
	Name	Address	84062
b)	<u>Vernon Evans</u>	<u>W. 1300 S. Spanish Fork</u>	<u>UT 84660</u>
	Name	Address	
c)	<u>N/A</u>		
	Name	Address	
d)	<u>N/A</u>		
	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  
 3) What was the price paid per share? 0  
 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

attached

## APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 5-17-18

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 Durale Medical Equipment Supplier

Nature of MDEG

Tru Mobility Inc. 3100 E Charleston #103 Las Vegas NV 89104

Name and Address of Business for Which MDEG Administrator Is Requested

N/A

If applicable, Name Under Which It Is Now Operated



## 1. PERSONAL INFORMATION:

Lumpkin Danny Paul  
Last Name First Name Middle Name

NA

---

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Centennial Dr. ~~Plaza~~ Cedar Hills UT 84062

225 671 W  
Present Business Address

Dates 1/18 to present  
City

Pleasant Grove UT 84062  
State/Zip

President Dates 2/15 to present

---

Present Position with the MDEG

Phone: 801 627 1050 Fax: 801 772 2710

Email address: danny@translilityinc.com

                     Victorville CA  
Date of Birth Place of Birth (City, County, State)

43 \_\_\_\_\_ m \_\_\_\_\_  
Age Social Security Number Sex

<u>Blue</u>	<u>Blonde</u>	<u>185</u>	<u>6'2"</u>
Color of Eyes	Color of Hair	Weight	Height

Scars, tattoos or distinguishing marks and/or characteristics NA

Are you a citizen of the United States? Yes ☒ No ☐

If alien, registration No NA

If naturalized, certificate No NA Date NA

Place NA (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.

*Tru Mobility*

*7/15 to present 272 S. 671 W. Pleasant Grove UT 84062 6240 hrs*

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

<i>President / ATP</i>	<i>OME company management provision</i>	<i>self</i>
<i>Title</i>	<i>Description of Duties</i>	<i>Name of Supervisor</i>

*Britkare of custom wheelchairs*

*1/11 to 6/15 Amarillo TX 9360*

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

<i>Relat manager</i>	<i>provision of OME / custom</i>	<i>Josh Britten</i>
<i>Title</i>	<i>Description of Duties</i>	<i>Name of Supervisor</i>

*wheelchairs*

*NA*

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

*NA*

<i>Title</i>	<i>Description of Duties</i>	<i>Name of Supervisor</i>
--------------	------------------------------	---------------------------

*NA*

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

*NA*

<i>Title</i>	<i>Description of Duties</i>	<i>Name of Supervisor</i>
--------------	------------------------------	---------------------------

*NA*

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

*NA*

<i>Title</i>	<i>Description of Duties</i>	<i>Name of Supervisor</i>
--------------	------------------------------	---------------------------

*NA*

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
----------------	------------------------------------	----------------------

*NA*

<i>Title</i>	<i>Description of Duties</i>	<i>Name of Supervisor</i>
--------------	------------------------------	---------------------------

*LR*



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: State: NA

b) Date: NA

Case Number: NA

c) Criminal Action: State: NA

Date: NA

Case Number: NA

County: NA

Court: NA

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.

I will be at the Las Vegas  
location at least 2  
weeks per month. No  
drugs or medical gases  
will be supplied by  
Transubility.

ATTACH P

TAKEN V

30 DAY



Date of photograph 5-17-18

OR

I, Danny Leemkin, 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

*[Handwritten signature]*

# PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 5-21-18

## 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  
Tru Motility Inc. 3100 E. Charleston #107 Las Vegas NV 89104  
N/A  
 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:

Lumpkin Danny P  
 Last Name First Name Middle Name  
N/A

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Centennial Cedar Hills UT 84062  
 Present Residence Address-Street or RFD City State/Zip

272 S 671 W Mar 2017 Pleasant Grove UT 84062  
 Present Business Address Dates City State/Zip

Owner - DME 7/15-present  
 Occupation Dates

Phone:  
 Residence  
 Business 801 607 1050

Victorville CA  
 Date of Birth Place of Birth (City, County, State)

43 M  
 Age Sex

Blue Blonde N/A 185 Med 6'2"  
 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 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 [Signature]  
 Page 1

## MARITAL INFORMATION-Continued

A. **Current Marriage** Dec 1996 Denton TX  
 Spouse's full name (Maiden) Angele Ensign NA  
 Date of Birth \_\_\_\_\_ Place of Birth UT  
 Resident address same \_\_\_\_\_  
 Telephone: Residence same Business NA  
 Spouse's employer NA Occupation NA  
 Address of employer NA \_\_\_\_\_

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>Turner Lumpkin</u>		<u>Amarillo TX</u>	<u>same</u>
<u>Jordan Lumpkin</u>		<u>Pland TX</u>	<u>same</u>
<u>Bieke Lumpkin</u>		<u>Amarillo TX</u>	<u>same</u>
<u>Carter Lumpkin</u>		<u>Lehi UT</u>	<u>same</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 RE

**FAMILY INFORMATION-Continued**

District attorney or public agency responsible for enforcing the child support order:

Name N/A  
 Address N/A  
 Contact 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			
Jim Lumpkin		clovis CA	
Mother			
Rita Lumpkin		Hereford TX	
Father-in-Law			
Mark Ensign		Draper UT	
Mother-in-Law			
Brenda Ensign		Draper UT	

**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
Katie Lumpkin		Amarillo TX	NA
Spouse			
Chris Lumpkin		Amarillo TX	mechanic
Spouse			
Corrinne Lumpkin		Hereford TX	NA
Spouse			
Spouse			

**4. EDUCATION:**

Name of School	Location	Dates Attended	Graduate
Grammar School	St. Marys	Amarillo TX	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	Caprock H.S.	Amarillo TX 88-92	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	Amarillo College	Amarillo TX	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	Univ. of W. Texas	Odenton TX	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	WTAMU	Canyon TX 1999	Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any BSCollege or university where obtained WTAMUApplicant's initial LD

**5 MILITARY INFORMATION:**

A. Have you ever served in any armed forces?

Yes ☐ No ☒Branch NA Date of entry-active service NADate of separation NA Type of discharge NARating at separation NA Serial number NA

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 Randall State TX Date registered 1992**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? \_\_\_\_\_ 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
<u>N/A</u>				

Applicant's initial LS

**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
July 2017 - present	Centennial	Cedar Hills	UT
7/16-7/17	10474 Sage Vista	Cedar Hills	UT
8/15-7/16	97 Steep Mtn	Draper	UT
1/10-8/15	11411 Looby Ln	Amarillo	TX
10/07-12/09	290 E. 1270 N	Springville	UT

Applicant's initial



**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
7/15 - present	Tru Mobility Inc Pleasant Grove UT	
Title	Description of Duties	Name of Supervisor
Owner	operations	none
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1/12 - 7/15	Briticare Home Medical And TX	moved
Title	Description of Duties	Name of Supervisor
ATP	Assistive Technology Professional	Josh Britten
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
3/08 / 12/09	Alpine Home Medical LLC UT	moved
Title	Description of Duties	Name of Supervisor
ATP	same	Scott Naylor
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
9/07 - 3/08	Intermountain Home Care	job change
Title	Description of Duties	Name of Supervisor
ATP	same	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
7/07 - 8/07	TRACS DME Cleburne TX	job change
Title	Description of Duties	Name of Supervisor
ATP	same	Tom Hafford
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 LSZ



## 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>Chris Williams</u>	Home	<u>McKinney</u>	<u>TX</u>		<u>214 566 5875</u>	<u>10</u>
Employer <u>N/A</u>		Business				
Name <u>Mike Torres</u>	Home	<u>Port Worth</u>	<u>TX</u>		<u>682 234 9128</u>	<u>10</u>
Employer <u>NSM</u>		Business	<u>Custom W/L</u>			
Name <u>Robin Kidd</u>	Home	<u>Port Worth</u>	<u>TX</u>		<u>682 554 5824</u>	<u>10</u>
Employer <u>UPS</u>		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
<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

N/A

12. 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.

Transability Inc. Pleasant Grove UT

Vernon Evans - business partner

State of Utah

Applicant's initial

LD

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:

UT pharmacy license for DME company

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 5-31-18

Applicant's initial LR

STATE OF Utah

ss.

COUNTY OF Utah

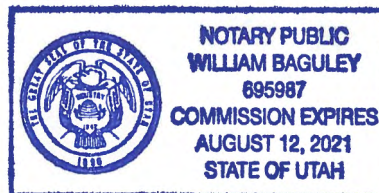
I, Danny Lungkin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation 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 1st day of

June, 2018  
William Baguley  
Notary Public



(seal)

Applicant's initial [Signature]

# PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 5-21-2018

## 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.

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Application for MDEG  
Tru Mobility Inc. 3100 E Charleston #103 Las Vegas NV 89104  
 Nature of License  
 Name and Address of Establishment for Which License Is Requested  
N/A  
 If applicable, Name Under Which It Is Now Operated

### 1. PERSONAL INFORMATION:

Evans Vernon E  
 Last Name First Name Middle Name  
N/A  
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)  
W 1300 S Spanish Fork UT 84660  
 Present Residence Address-Street or RFD City State/Zip  
272 S. 671 W Dates 1-18-present Pleasant Grove UT 84062  
 Present Business Address City State/Zip  
Owner - Custom Wheelchairs Dates 7-15-present  
 Occupation  
 Phone:  
 Residence  
 Business 801 607 1050  
Altus, OK  
 Date of Birth Place of Birth (City, County, State)  
43 M  
 Age Social Security Number Sex  
H2L Brown N/A 175 lbs N/A 5'8"  
 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 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 EV

## MARITAL INFORMATION-Continued

A. **Current Marriage** 4-22-95 Amarillo, TX  
Date City, County and State  
 Spouse's full name (Maiden) Kathryn L. Heym N/A  
S.S. No  
 Date of Birth \_\_\_\_\_ Place of Birth Puyallup, WA  
 Resident address Same as mine  
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
----------------	-------------------------	---------------------------	------------------	-----------------------

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>Alvin Evans</u>		<u>Puyallup, WA</u>	<u>Same as mine</u>
<u>Zoe Evans</u>		<u>Amarillo TX</u>	<u>Same as mine</u>
<u>Kelby Evans</u>		<u>Amarillo TX</u>	<u>Same as mine</u>
<u>Conner Evans</u>		<u>Orlando, FL</u>	<u>Same as mine</u>

B. **Child Support Information:**

Please mark the appropriate response:

- ☒ I am not subject to a court order for <sup>any</sup> 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 JE

**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
Michael Evans		Amarillo, TX	UPS driver
Spouse			
Spouse			
Spouse			
Spouse			

**4. EDUCATION:**

Name of School	Location	Dates Attended	Graduate
Grammar School	Oak Dale	Amarillo TX	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	Caprock	Amarillo TX	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	Amarillo College	Amarillo TX	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Other			Yes <input type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any N/A

College or university where obtained N/A

Applicant's initial

**5 MILITARY INFORMATION:**

A. Have you ever served in any armed forces?

Yes ☐ No ☒Branch N/A Date of entry-active service N/ADate of separation N/A Type of discharge N/ARating 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 Potter State TX Date registered 1993**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? \_\_\_\_\_ 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
<u>N/A</u>				

Applicant's initial BT

**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
12-16 - Current	W 1300 S	Spanish Fork	UT
10-14 - 12-16	1740 N 440 E	Provo	UT
7-13 10-14	1738 Cobblestone Dr	Provo	UT
5-07 7-13	2425 Columbine Dr	Philomath	OR
1975 5-07	3202 S. Regency	Amarillo TX	TX

Applicant's initial





**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.

7-2015 - Current		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Owner	Tru Mobility 272 S. 671 W Pleasant Grove UT	N/A
Title	Description of Duties	Name of Supervisor
	All of them	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
7/14 7/15	Rehab Medical	opened business
Title	Description of Duties	Name of Supervisor
ATP	Area Manager - Sales	Jimmy Hebdan
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
6-11 7-14	Otto Back	Closed
Title	Description of Duties	Name of Supervisor
ATP/Sales	Sales	Chris Williams
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1993 - Current	Custom Ships in Bottles	N/A
Title	Description of Duties	Name of Supervisor
owner	Make & Sale ships in Bottles	Self
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 <u>Todd Stoct</u>	Home	?			801 558 6302	10+
Employer <u>self employed</u>	Business					
Name <u>Bredd Spammers</u>	Home	?			253-310-8800	20+
Employer <u>retired</u>	Business					
Name <u>Todd Vanderhust</u>	Home	?			509-222-9948	7+
Employer <u>Self</u>	Business					
Name <u>Wayne Whaley</u>	Home	?			801-863-8607	10+
Employer <u>Professor UNV</u>	Business					
Name <u>John Skoggs</u>	Home	?			210-367 2880	20+
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

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.

Tru Mobile, UT presently Danny Lumpkin - Partner

Applicant's initial JS

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 ☐

*Utah Pharmacy License*

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 5-10-18

Applicant's initial JS

STATE OF Utah

ss.

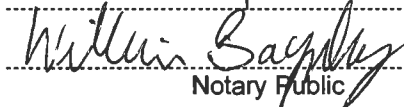
COUNTY OF Utah

I, Vernon Evans, 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,

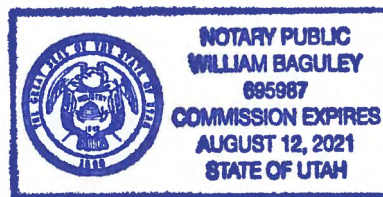
I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their 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 30<sup>th</sup> day ofMay


Notary Public



(seal)

Applicant's initial EV

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (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 NO 2759)  
 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: Ken's Professional Compounding Pharmacy  
 Physical Address: 2202 W Charleston Blvd, Ste #13  
 City: Las Vegas State: NV Zip Code: 89102  
 Telephone: 702-384-3784 Fax: 702-384-3796  
 Toll Free Number: N/A E-mail: N/A  
 Website: N/A  
 Managing Pharmacist: Eileen Kennedy License Number: 19576

**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

Eileen Kennedy  
Print Name of Authorized Person

6/7/18  
Date

Board Use Only

Date Processed: \_\_\_\_\_

Amount: \_\_\_\_\_



# APPLICATION FOR NEVADA PHARMACY LICENSE

**OWNERSHIP IS A NON PUBLICY TRADED CORPORATION**

State of Incorporation: Nevada

Parent Company if any: N/A

Mailing Address: 200 Sunday Grace Drive

City: Henderson State: NV Zip: 89052

Telephone: 323-360-2060 Fax: N/A

Contact Person: Eileen 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) Eileen Kennedy Sunday Grace Dr, Henderson NV 89052  
Name Business Address

b) Chris Kennedy in - Sunday Grace Dr, Henderson NV 89052

[illegible]

d) \_\_\_\_\_

Name	Business Address
------	------------------

- 2) Provide the number of shares issued by the corporation. 100

- 3) What was the price paid per share? 700

List any physician shareholders and percentage of ownership.

Name: N/A %: \_\_\_\_\_

Name: \_\_\_\_\_ %: \_\_\_\_\_

**Hours of Operation for the pharmacy:**

Monday thru Friday 9:00 am 5:30 pm

Saturday 10:00am 2:00pm

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: NV20181354781

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy  
FOR Corporations, Partnership or Sole Owners

I, Eileen Kennedy

Responsible Person of Kennedy Pharmacy Group LLC, dba Ken's 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

Eileen Kennedy

Print Name of Authorized Person

6/7/18

Date



## Managing Pharmacist

 Pharmacist Name: Eileen Kennedy

 License #: 19576

 Pharmacy Name: Ken's 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 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

6/7/18

Kennedy Pharmacy Group LLC

List of Officers and Directors

President – Eileen Kennedy, : ' Sunday Grace Drive, Henderson, NV 89052

Vice President – Christopher Kennedy, : ' Sunday Grace Drive, Henderson, NV 89052

# PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

 Date 6/6/18

## 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 Pharmacy Ownership Change  
 Nature of License  
2602 W. Charleston Blvd. Ste #13  
 Name and Address of Establishment for Which License Is Requested  
Kens Pharmacy  
 If applicable, Name Under Which It Is Now Operated

### 1. PERSONAL INFORMATION:

Kennedy Eileen Sinola  
 Last Name First Name Middle Name  
Eileen Dymovsky  
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)  
Sunday Grace Dr. Henderson NV 89052  
 Present Residence Address-Street or RFD City State/Zip  
2662 W. Horizon Ridge Pkwy Henderson NV 89052  
 Present Business Address City State/Zip  
Pharmacist - Floater 5/2017-present  
 Occupation Dates  
 Phone:  
 Residence  
 Business 702-616-9660  
Los Angeles, CA  
 Date of Birth Place of Birth (City, County, State)  
29 Female  
 Age Sex  
Brown Brown 218 5'8"  
 Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics knee scar - right knee

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No

If naturalized, certificate No N/A Date

Place N/A (If naturalized, document must be verified.)

### 2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial ek



A. **Current Marriage** 04/25/2015 Los Angeles, CA  
Date City, County and State  
 Spouse's full name (Maiden) Christopher J Kennedy 284-84-9459  
S.S. No.  
 Date of Birth \_\_\_\_\_ Place of Birth Cincinnati, OH  
 Resident address Sunday Grace Dr. Henderson NV 89052  
Street City State Zip  
 Telephone: Residence \_\_\_\_\_ Business N/A  
 Spouse's employer N/A Occupation Engineer  
 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
<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>Veronica Kennedy</u>	<u>05/28/2016</u>	<u>Lee's Summit, MO</u>	<u>Sunday Grace Dr. Henderson NV 89052</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 EX

**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			
<u>Oleg Dymovsky</u>	<u>---</u>	<u>Candlestick, Henderson, NV 89052</u>	<u>Travel Agent</u>
Mother			
<u>Isabel Dymovsky</u>	<u>---</u>	<u>Candlestick, Henderson, NV 89052</u>	<u>Travel Agent</u>
Father-in-Law			
<u>Jerry Kennedy</u>	<u>---</u>	<u>Ticonderoga Rd, Downer's Grove, IL 60516</u>	<u>Designer</u>
Mother-in-Law			
<u>Margaret Kennedy</u>	<u>---</u>	<u>Ticonderoga Rd, Downer's Grove, IL 60516</u>	<u>Teacher</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
Spouse			
<u>Andrea Dymovsky</u>	<u>---</u>	<u>Watkins Glen Ave. Henderson, NV 89052</u>	<u>Travel Agent</u>
<u>N/A</u>			
Spouse			
<u>Matthew Kennedy</u>	<u>---</u>	<u>2nd Ave #65 NY, NY 10003</u>	<u>Accountant</u>
<u>N/A</u>			
Spouse			
<u>Erin Kennedy</u>	<u>---</u>	<u>Ticonderoga Rd. Downer's Grove, IL 60516</u>	<u>Travel Guide</u>
<u>N/A</u>			
Spouse			

**4. EDUCATION:**

	Name of School	Location	Dates Attended	Graduate
Grammar School	<u>John Burroughs Middle School</u>	<u>Los Angeles, CA</u>	<u>- 2002</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	<u>Beverly Hills High School</u>	<u>Beverly Hills, CA</u>	<u>2002 - 2006</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College	<u>UC San Diego</u>	<u>San Diego, CA</u>	<u>2007 - 2011</u>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
University				
Other	<u>Midwestern University-Glendale</u>	<u>Glendale, AZ</u>	<u>2011 - 2014</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Pharm D.College or university where obtained Midwestern University - Glendale, AZApplicant's initial EC

**5 MILITARY INFORMATION:**A. Have you ever served in any armed forces? Yes ☐ No ☒Branch N/A Date of entry-active service N/ADate of separation N/A Type of discharge N/ARating 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 N/A State N/A Date registered N/A**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? \_\_\_\_\_ 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
<u>N/A</u>				

Applicant's initial DE



- 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
9/12/88 - 11/96	932 N Laurel Ave.	Los Angeles	CA
11/96 - 7/2007	2323 Hercules Dr.	Los Angeles	CA
7/07 - 5/11	9085 Judicial Dr.	San Diego	CA
5/11 - 5/14	5901 W. Behrend Dr.	Glendale	AZ
5/14 - 5/17	908 SW 36th St	Lees Summit	MO
5/17 - present	Sunday Frame Dr.	Henderson	NV



## 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
11/2005-6/2007	CVS Pharmacy	Moved
Title	Description of Duties	Name of Supervisor
Tech/ clerk	Technician (clerk)	Esther Semanova
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
9/11-3/14	Safeway Pharmacy	Moved
Title	Description of Duties	Name of Supervisor
Pharmacy intern	under Pharmacist supervision	Adrijana Ketic / Richard Smith
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
8/14-3/17	CVS Pharmacy	Moved / transfer
Title	Description of Duties	Name of Supervisor
Staff pharmacist	Pharmacist duties - retail	Gina Rochette / Brad Archer
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
5/17-present	CVS Pharmacy	currently on disability - surgery
Title	Description of Duties	Name of Supervisor
Fluor Pharmacist	retail pharmacist duties	Chris Scalabitti
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

EX

## 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>Michelle G. Arbit</u>	Home	<u>100 Universal City Plaza, Bldg 230</u>	<u>CA</u>	<u>91602</u>	<u>(323) 528-7900</u>	<u>29</u>
Employer <u>NBC Universal</u>	Business	<u>Universal City, CA 91608</u>	<u>CA</u>	<u>91608</u>	<u>(818) 232-1611</u>	
Name <u>Mushin Abtaneli</u>	Home	<u>2020 S. Central Ave,</u>	<u>CA</u>	<u>90035</u>	<u>(310) 423-4086</u>	<u>14</u>
Employer <u>McMormik Ambulance</u>	Business	<u>W. Cortez Pl.</u>	<u>CA</u>	<u>90210</u>	<u>(310) 837-0102</u>	
Name <u>Dinara Peret</u>	Home	<u>15170 W. Bell Rd. Ste 100</u>	<u>AZ</u>	<u>85332</u>	<u>(702) 339-7183</u>	<u>6</u>
Employer <u>Bates Pharmacy</u>	Business	<u>W. Packer Farm Trail</u>	<u>AZ</u>	<u>85334</u>	<u>(602) 398-3650</u>	
Name <u>Adrijana Ketic</u>	Home	<u>5777 E Mayo Blvd.</u>	<u>AZ</u>	<u>85033</u>	<u>(602) 628-3358</u>	<u>6</u>
Employer <u>Mayo Clinic</u>	Business	<u>W. Daniels St.</u>	<u>AZ</u>	<u>85254</u>	<u>(480) 342-1500</u>	
Name <u>Harrison Pharm</u>	Home	<u>101 Industrial Park Dr.</u>	<u>MA</u>	<u>02724</u>	<u>(417) 848-7735</u>	<u>7</u>
Employer <u>Walgreens</u>	Business	<u>Kelley St.</u>	<u>MA</u>	<u>02722</u>	<u>(417) 336-6901</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
<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

Kansas & Missouri - Pharm D. 2014 - present

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 EF

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:

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 ☒

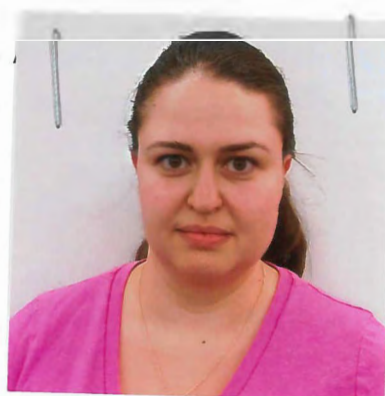
N/A

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 6/7/19

Applicant's initial EK



ss.

COUNTY OF CLARK

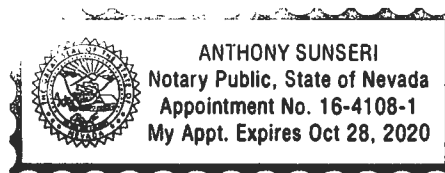
I, EILEEN SIMONE KENNEDY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge 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 27<sup>th</sup> day ofJUNE, 2018

Notary Public



(seal)

Applicant's initial ES

Applicant s initial \_\_\_\_\_ Page 10

# APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

 Date 6/7/13

## 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 Pharmacy Ownership Change  
 Nature of Pharmacy or Wholesaler  
2202 W. Charleston Blvd. Ste. #13  
 Name and Address of Business for Which Designated Representative Is Requested  
Kare's Pharmacy  
 If applicable, Name Under Which It Is Now Operated

### 1. PERSONAL INFORMATION:

Kennedy Eileen Simone  
 Last Name First Name Middle Name  
Eileen Dymovsky  
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)  
Sunday Grace Dr. Henderson NV 89052  
 Present Residence Address-Street or RFD City State/Zip  
2102 W. Horizon Ridge Pkwy Henderson NV 89052  
 Present Business Address City State/Zip  
Pharmacist - Fluor 5/1/07 - present  
 Present Position with the Pharmacy or Wholesaler Dates  
 Phone:  
 Residence  
 Business (702) 616-7600  
Los Angeles, CA  
 Date of Birth Place of Birth (City, County, State)  
29 Female  
 Age Sex  
Brown Brown 218 5'8"  
 Color of Eyes Color of Hair Complexion Weight Build Height

Scars, tattoos or distinguishing marks and/or characteristics Knee Scar - right knee

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No.

If naturalized, certificate No. N/A Date

Place N/A (If naturalized, document must be verified.)

### 2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial Ek

A. **Current Marriage** 04/25/2015 Los Angeles, CA  
 Date City, County and State  
 Spouse's full name (Maiden) Christopher J. Kennedy S.S. No. 284-84-9459  
 Date of Birth 11-1-1977 Place of Birth Cincinnati, OH  
 Resident address Sunday Grace Dr. Henderson NV 89052  
 Street City State Zip  
 Telephone: Residence 702-251-1111 Business N/A  
 Spouse's employer N/A Occupation Engineer  
 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
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N/A

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
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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>Veronica Kennedy</u>		<u>Lee's Summit, MO</u>	<u>Sunday Grace Dr. Henderson, NV 89052</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 CK



**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		<u>Candlestick</u>	
<u>Oleg Dymovsky</u>	<u>11-11-1960</u>	<u>Henderson, NV 89052</u>	<u>Travel Agent</u>
Mother		<u>Candlestick</u>	
<u>Isabel Dymovsky</u>	<u>1-1-1961</u>	<u>Henderson, NV 89052</u>	<u>Travel Agent</u>
Father-in-Law		<u>Ticonderoga Rd.</u>	
<u>Jerry Kennedy</u>	<u>1-1-1930</u>	<u>Downer's Grove, IL 60516</u>	<u>Designer</u>
Mother-in-Law		<u>Ticonderoga Rd</u>	
<u>Margaret Kennedy</u>	<u>1-1-1930</u>	<u>Downer's Grove, IL 60516</u>	<u>Teacher</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
Spouse		<u>Watkins Glen Ave</u>	
<u>Andrea Dymovsky</u>	<u>1-1-1960</u>	<u>Henderson, NV 89052</u>	<u>Travel Agent</u>
Spouse		<u>2nd Ave Fl. 5</u>	
<u>Matthew Kennedy</u>	<u>1-1-1960</u>	<u>NY, NY 10003</u>	<u>Accountant</u>
Spouse		<u>Ticonderoga Rd</u>	
<u>Erin Kennedy</u>	<u>1-1-1960</u>	<u>Downer's Grove, IL 60516</u>	<u>Tour Guide</u>
Spouse		<u>N/A</u>	
Spouse			

**4. EDUCATION:**

	Name of School	Location	Dates Attended	Graduate
Grammar School	<u>John Burroughs Middle School</u>	<u>Los Angeles, CA</u>	<u>98 - 2002</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	<u>Beverly Hills High School</u>	<u>Beverly Hills, CA</u>	<u>2002 - 2006</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	<u>UC San Diego</u>	<u>San Diego, CA</u>	<u>2007 - 2011</u>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Other	<u>Midwestern University - Glendale</u>	<u>Glendale, AZ</u>	<u>2011 - 2014</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Pharm D.College or university where obtained Midwestern University - Glendale, AZApplicant's initial JK



**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 N/A State N/A Date registered N/A

**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 or

- 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
--------------------------	-------------------	------	-----------------

9/12/98 - 11/96	932 N Laurel Ave	Los Angeles	CA
11/96 - 7/07	2328 Hercules Dr.	Los Angeles	CA
7/07 - 5/11	9085 Judicial Dr.	San Diego	CA
5/11 - 5/14	5901 W Behrend Dr.	Gilbert	AZ
5/14 - 5/17	908 SW 36th St	Lees Summit	MO
5/17 - present	... Sunday Grove Dr.	Henderson	NV

Applicant's initial

*OK*

**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
<del>8/11 - 6/2017</del>	<del>CVS Pharmacy</del>	<del>1000</del>
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
9/2011 - 3/2017	Safeway 20427 N 27th Ave, Phoenix, AZ 85027	1800
Title	Description of Duties	Name of Supervisor
Pharmacist intern	Under pharmacist supervision	Adrijana Felix
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
8/14 - 3/2017	CVS Pharmacy 3005 Commercial St, Harrisburg, MO 64501	5000
Title	Description of Duties	Name of Supervisor
Staff Pharmacist	Pharmacist-retail duties	Bradley Archer
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
05/2017 - present	CVS Pharmacy 2662 W Horizon Ridge Pkwy, Henderson, NV 89102	2000
Title	Description of Duties	Name of Supervisor
Pharmacist Florist	Retail pharmacist	Chris Scalzitti
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

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## 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>Michelle G. Arat</u>	Home	<u>Studio City, CA</u>	<u>91602</u>		<u>(323) 528-7900</u>	<u>29</u>
Employer <u>NBC Universal</u>	Business	<u>100 Universal City Plaza 31st Fl</u>	<u>Universal City, CA 91603</u>	<u>4th Floor</u>	<u>(818) 232-1611</u>	
Name <u>Nathan Natanali</u>	Home	<u>Los Angeles, CA</u>	<u>90035</u>		<u>(310) 433-4586</u>	<u>14</u>
Employer <u>McComick Ambulance</u>	Business	<u>Compton, CA</u>	<u>90220</u>	<u>W. El Cortez St.</u>	<u>(310) 827-0102</u>	
Name <u>Dwaine Perez</u>	Home	<u>Peoria, AZ</u>	<u>85383</u>		<u>(702) 339-2153</u>	<u>6</u>
Employer <u>Bell's Pharmacy</u>	Business	<u>1570 W. Bell Rd. Ste 100</u>	<u>Surprise, AZ</u>	<u>85374</u>	<u>(623) 329-3650</u>	
Name <u>Abrigona Katic</u>	Home	<u>Phoenix, AZ</u>	<u>85083</u>		<u>(623) 628-3308</u>	<u>6</u>
Employer <u>Mate Clinic</u>	Business	<u>5777 E. Mayo Blvd.</u>	<u>Phoenix, AZ</u>	<u>85251</u>	<u>(480) 342-1500</u>	
Name <u>Hargrave Pharm</u>	Home	<u>Quincy, MA</u>	<u>01921</u>		<u>(417) 843-7735</u>	<u>7</u>
Employer <u>Walgreens</u>	Business	<u>101 Industrial Park Dr</u>	<u>Haverhill, MA</u>	<u>01832</u>	<u>(417) 326-6901</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

Kansas & Missouri - Pharm D. 2014 - 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.

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 EL

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 ☒

N/A

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 ☒

N/A

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 ☒

N/A

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 ☒

N/A

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

See personal history  
Record

Date of photograph 6/7/13

Applicant's initial [initials]

STATE OF NEVADA

SS.

COUNTY OF CLARK

I, EILEEN SIMONE KENNEDY, 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.



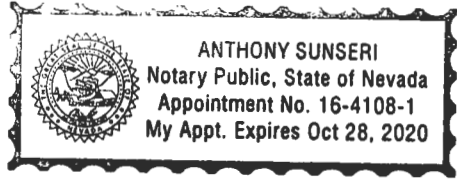
Original Signature of Applicant

Subscribed and Sworn to before me this 17<sup>th</sup> day of

JUNE, 2018.



Notary Public



(seal)

Applicant's initial ek

This image shows a full page of a handwriting practice worksheet. It consists of numerous horizontal dashed lines spaced evenly across the page, providing a guide for letter height and placement. The lines are light gray and extend from the left margin to the right edge of the page. There are no other markings, text, or illustrations on the page.



Date 6/7/18

## 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 Pharmacy Ownership Change  
2002 W Charleston Blvd Ste 13  
 Name and Address of Establishment for Which License Is Requested  
Ken's Pharmacy  
 If applicable, Name Under Which It Is Now Operated

## 1. PERSONAL INFORMATION:

Kennedy Christopher Jerome  
 Last Name First Name Middle Name  
Chris  
 Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)  
Sunday Grace Dr Henderson NV 89052  
 Present Residence Address-Street or RFD City State/Zip  
Sunday Grace Henderson NV 89052  
 Present Business Address City State/Zip  
Engineer/Stay at home Dad  
 Occupation Dates 5/2017 - Present  
 Phone: Residence \_\_\_\_\_ Business N/A  
32 Cincinnati, Hamilton County, OH  
 Date of Birth Place of Birth (City, County, State)  
32 Male  
 Age Sex  
Blue Brown White 245 Large 6'0"  
 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 N/A Date \_\_\_\_\_

Place N/A (If naturalized, document must be verified.)

## 2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial CJE



## MARITAL INFORMATION-Continued

A. **Current Marriage** 04/25/15 Pos Los Angeles, Ca  
 Date City, County and State  
 Spouse's full name (Maiden) Eileen Dymarsky S.S. No. \_\_\_\_\_  
 Date of Birth \_\_\_\_\_ Place of Birth Los Angeles, Ca  
 Resident address Sunday Grace Dr Henderson NV 89052  
 Street City State Zip  
 Telephone: Residence \_\_\_\_\_ Business N/A  
 Spouse's employer CVS Occupation Pharmacist  
 Address of employer 2662 W Horizon Ridge 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
------	--------	------	-------	-----	-----------

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
------	------------	-------------	-------------------

Veronica Kennedy Lee's Summit, MO Sunday Grace Dr 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 CK

**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

Jerry Kennedy	Cincinnati, OH	Ticonderoga, IL 60516	Designer
---------------	----------------	-----------------------	----------

Mother

Martie Kennedy	Cincinnati, OH	Ticonderoga, IL 60516	Teacher
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Father-in-Law

Oleg Dymovsky	Henderson, NV 89052	Candlestick	Travel Agent
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Mother-in-Law

Isabel Dymovsky	Henderson, NV 89052	Candlestick	Travel Agent
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**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
---------------	------------	---------	------------

Erin Kennedy		Ticonderoga, IL 60516	Tour guide
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Spouse

N/A

Matthew Kennedy		2nd Ave #LS, NY, NY 10003	Accountant
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Spouse

N/A

Andrea Dymovsky		Watkins Glen Ave, Henderson, NV 89052	Travel Agent
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Spouse

NA

Spouse

**4. EDUCATION:**

Name of School	Location	Dates Attended	Graduate	
Grammar School	St. Joseph	Downers Grove, IL	1992 - 2000	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School	Montini	Lombard, IL	2000 - 2004	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College University	Rose-Hulman	Terre Haute, IN	2004 - 2008	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other	Rockhurst	Kansas City, MO	2013 - 2015	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any Masters / MBACollege or university where obtained Rockhurst University

Applicant's initial

CSK

**5 MILITARY INFORMATION:**A. Have you ever served in any armed forces? Yes ☐ No ☒Branch N/A Date of entry-active service N/ADate of separation N/A Type of discharge N/ARating 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 DuPage State IL Date registered 3/11/2004**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? \_\_\_\_\_ 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
<u>N/A</u>				

Applicant's initial CJS



- 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
--------------------------	-------------------	------	-----------------

1989 - 7/2004	7309 Ticonderoga	Downers Grove	IL
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7/2004 - 5/2008	5500 Wabash Ave	Terre Haute	IN
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6/2008 - 6/2009	8701 Buckingham Ln	Kansas City	MO
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7/2009 - 7/2011	3036 SW Gentry Ct.	Lee's Summit	MO
-----------------	--------------------	--------------	----

7/2011 - 7/2013	2886 Afton Circle	Orlando	FL
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8/2013 - 5/2014	3036 SW Gentry Ln	Lee's Summit	MO
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5/2014 - 5/2017	908 SW 36th St	Lee's Summit	MO
-----------------	----------------	--------------	----

5/2017 - Present	Sunday Grace Dr	Henderson	NV
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Applicant's initial

CJK

**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
5/2008 - 5/2017	Honeywell FMET/14510 Botts Rd, KC Mo 64117	Moved to NV
Title	Description of Duties	Name of Supervisor
Engineer III	Project management and R&D	Michelle Wood
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
8/2005 - 5/2008	Homework Hotline/5500 Wabash Ave, Terre Haute IN 47803	Graduated / Moved to KC
Title	Description of Duties	Name of Supervisor
Tutor	Tutored Math and Science	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
5/2017 - Present	Unemployed / Father	N/A
Title	Description of Duties	Name of Supervisor
N/A	Raising daughter	N/A
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

CJK

## 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>Michelle Arbit</u>	Home	<u>Fair Ave #102</u>	<u>Studio City</u>	<u>Ca 91602</u>	<u>323-528-7100</u>	<u>5</u>
Employer <u>NBC Universal</u>	Business	<u>100 Universal City Plaza 4th Floor</u>	<u>Universal City</u>	<u>Ca 91608</u>	<u>818-232-1611</u>	
Name <u>Nashin Nataneli</u>	Home	<u>South Point View St.</u>	<u>Los Angeles</u>	<u>Ca 90035</u>	<u>310-433-4086</u>	<u>5</u>
Employer <u>McGonick Ambulance</u>	Business	<u>2020 S Central Ave</u>	<u>Compton</u>	<u>Ca 90220</u>	<u>310-837 0102</u>	
Name <u>Michael Bund</u>	Home	<u>SW Gentry Ct.</u>	<u>Lee's Summit</u>	<u>Mo 64082</u>	<u>847-401 3782</u>	<u>10</u>
Employer <u>Honeywell</u>	Business	<u>14510 Bollis Rd</u>	<u>SC</u>	<u>Mo 64147</u>	<u>816-488-2575</u>	
Name <u>Adrijana Ketic</u>	Home	<u>W Prickly Pear Tr.</u>	<u>Phoenix</u>	<u>AZ 85083</u>	<u>623-628-3308</u>	<u>5</u>
Employer <u>Mayo Clinic</u>	Business	<u>5777 E. Mayo Blvd</u>	<u>Phoenix</u>	<u>AZ 85254</u>	<u>480-342-1500</u>	
Name <u>Hang Pham</u>	Home	<u>W Daniels St.</u>	<u>Ozark</u>	<u>Mo 65724</u>	<u>417-848-7735</u>	<u>5</u>
Employer <u>Walgreens</u>	Business	<u>1st Industrial Park Dr</u>	<u>Hollister</u>	<u>Mo 65612</u>	<u>417-336-6901</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
<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

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

CJE



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:

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 ☒

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 CJA

STATE OF Nevada

SS.

COUNTY OF Clark

I, Chris Kennedy, 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.

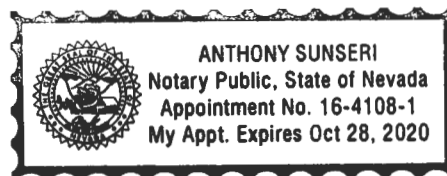
Chris Kennedy  
Original Signature of Applicant

Subscribed and Sworn to before me this 7<sup>th</sup> day of

JUNE, 2018

[Signature]

Notary Public



(seal)

Applicant's initial CK Page 9



This image shows a full page of white paper with horizontal blue or grey ruling lines. The lines are evenly spaced and run across the width of the page, providing a template for handwriting practice or general writing. There are no margins, text, or other markings on the page.

Applicant's initial CJK Page 10

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509 – (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.

<input checked="" type="checkbox"/> New Pharmacy or <input type="checkbox"/> Ownership Change (Provide current license number if making changes: PH____) Check <u>box</u> below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.	
<input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,10,11a&b <input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b	<input type="checkbox"/> Partnership - Pages 1,2,6,10,11a&b <input type="checkbox"/> Sole Owner – Pages 1,2,8,10,11a&b

**GENERAL INFORMATION to be completed by all types of ownership**

Pharmacy Name: VITALITY PHARMACY  
 Physical Address: 3175 ST. ROSE PKWY., SUITE 120  
 City: HENDERSON State: NV Zip Code: 89052  
 Telephone: PENDING <sup>CELL PERSONAL</sup> Fax: PENDING  
 Toll Free Number: N/A E-mail: PENDING <sup>PERSONAL</sup>  
 Website: PENDING  
 Managing Pharmacist: KHOE HA License Number: 18165

**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 ☒ EXPLANATION TO 'YES' ANSWER ON NEXT PAGE
- 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.

KH05 HA  
Original Signature of Person Authorized to Submit Application, no copies or stamps

KH05 HA  
Print Name of Authorized Person

05/14/2018  
Date

Board Use Only

Date Processed: \_\_\_\_\_

Amount: \$502.00

May 14, 2018

This is a signed statement of explanation for a "yes" answer to question #3 on page 2.

On 01/08/2018 the California Board of Pharmacy came to Kmart Pharmacy #4751 Tehachapi, CA where I am employed for an inspection and did a subsequent investigation involving records from 12/27/2014 to 12/27/2017.

On 04/17/2018 a citation was issued for 1 irregular and invalid prescription (RX# 4536165) filled on 05/03/2017. A copy of the citation is attached for your record. I am in the process of contesting this citation. In regards to this 1 prescription, as a pharmacist I feel I did my due diligent at the time that the prescription was filled. When the prescription was drop off, my staff and I performed the following check list before filling the prescription as is our protocol:

- 1) Verified patient identity at drop off
- 2) CURES the patient to verify medication is not too soon or being abuse
- 3) Doctor was out of area thus called and doctor office verified prescription was written for patient
- 4) Verified patient identity at pick up

 KHOI HA 05/14/2018

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# APPLICATION FOR NEVADA PHARMACY LICENSE

**OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**

State of Incorporation: NEVADA

Parent Company if any: KHOI HA PLLC

Mailing Address: 1368 RIVER SPEY AVE

City: HENDERSON State: NV Zip: 89012

Telephone: 714-326-4323 Fax: N/A

Contact Person: KHOI HA

**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 SHARES WERE ISSUED (KHOT HAS SOLE OWNER/MANAGER)

b) \_\_\_\_\_

Name	Business Address
------	------------------

c) \_\_\_\_\_

Name	Business Address
------	------------------

d) \_\_\_\_\_

Name	Business Address
------	------------------

- 2) Provide the number of shares issued by the corporation. 0

- 3) 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 9 am 6 pm Saturday N/A am      pm

Sunday N/A 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: KHOE HA PLLC

NV BUSINESS ID: NV 20171490636

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy  
FOR Corporations, Partnership or Sole Owners

I, KHOI HA

Responsible Person of KHOI HA PLLC DBA VITALITY 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

KHOI HA

Print Name of Authorized Person

05/14/2018

Date

### Managing Pharmacist

 Pharmacist Name: KHOI HA

 License #: 18165

 Pharmacy Name: VITALITY 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? <i>P. SIGN STATEMENT OF EXPLANATION IS ATTACHED TO "YES" ANSWER.</i>	<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>CA</u> Date: <u>04/17/2018</u> Case #: <u>CI 2017 79526</u>		
And/or Criminal Action: State: <u>NV</u> Date: <u>10/06/2015</u> Case #: <u>12CR014329</u>		
County: <u>CLARK COUNTY</u> Court: <u>HENDERSON MUNICIPAL COURT</u>		

**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.

KHOI HA  
 Signature

05/14/2018  
 Date



**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](http://www.pharmacy.ca.gov)

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**April 17, 2018****DATED MATERIAL ENCLOSED**

KHOI VINH HA  
1368 RIVER SPEY AVE  
HENDERSON, NV 89012

**RE: CI 2017 79526  
KHOI VINH HA  
RPH 56072**

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](http://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:**

- May 17, 2018: Unless the Citation is contested payment of fine(s) must be received by the Board.
- May 01, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- May 17, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

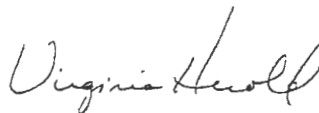
Page two  
KHOI VINH HA  
CI 2017 79526

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 Jennifer Sevilla, Associate Enforcement Analyst at (916) 574--7925.

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 **May 17, 2018**.
- 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 May 01, 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 May 17, 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, Associate Enforcement Analyst, at (916) 574-7924.

**BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**

## CITATION AND FINE

<b>Citation Number</b> CI 2017 79526	<b>Name, License No.</b> KHOI VINH HA, RPH 56072
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<b>JURISDICTION: Bus. &amp; Prof. Code § 4314; CCR, title 16, § 1775; Bus. &amp; Prof. Code § 4113 subd. (c)</b>		
<b>VIOLATION CODE SECTION</b>	<b>OFFENSE</b>	<b>AMOUNT OF FINE</b>
<b>CCR, Title 16, § 1761 subd. (a) &amp; (b)/Health &amp; Safety Code § 11164 subd. (a)</b>	<b>No pharmacist shall compound or dispense any prescription, which contains any significant error or omission.../A pharmacist shall not compound or dispense a prescription for a controlled substance where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose/Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance</b>	<b>\$200.00</b>

### CONDUCT:

Irregular and invalid prescriptions

California Code of Regulations Section 1761, states in pertinent subdivisions:

- (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
- (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

As related, California Health and Safety Code Section 11164 states in pertinent part, except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

- (a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1.

Khoi Vinh Ha (RPH 56072) while employed as Pharmacist in Charge of Kmart Pharmacy #4751 (PHY 38996), located at 710 West Tehachapi, Tehachapi, CA, failed to comply. Specifically, an inspection on 01/08/2018, and a subsequent investigation involving records from 12/27/2014 – 12/27/2017, found RPH Ha approved the following prescription to be dispensed by Kmart Pharmacy #4751:

Date	Number	Patient	Drug	Qty
05/03/17	4536165	LP	promethazine/codeine	240

The above prescription document did not have all features required for controlled substance prescription security forms and was missing at least the following:

1. A watermark printed on the backside of the prescription blank which reads: "California Security Prescription."
  - a. Read: "DocuGard"
2. An identifying number assigned to the approved security printer by the Department of Justice
3. A lot number printed on the form and each form within that batch numbered sequentially
4. Six quantity check off boxes printed so the prescriber may indicate the quantity by checking the applicable box where the following quantities appear:
  - 1–24
  - 25–49
  - 50–74
  - 75–100
  - 101–150
  - 151 and over
  - a. Read: "101-150 & over"
5. A statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  - a. Read: "Prescription is void if the number of drugs is not noted"

In addition to the invalid nature of the prescription forms, some of following irregularities also were present:

- Cash payment
- Out of the area prescriber information reported to CURES

RPH Ha and Kmart Pharmacy #4751 dispensed this irregular and invalid controlled substance prescription without verification and resolution of the irregularities with the prescriber. This was a violation of pharmacy law.

**CITATION ISSUED ON: April 17, 2018**

**TOTAL AMOUNT OF FINE(S): \$200.00**

**PAYMENT OF FINE(S) DUE BY: May 17, 2018**

# California State Board of Pharmacy

## REQUEST FOR OFFICE CONFERENCE

**Licensee: KHOI VINH HA**

**License No: RPH 56072**

**Citation Number : CI 2017 79526**

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: KHOI VINH HA

Signature: [Signature]

Dated: 06/01/2018

Address of Service: 716 W. 10TH AVE. SUITE 200

City: SACRAMENTO State: CA Zip: 95861

Telephone: (Business) (916) 522 3594 Residence: [Redacted]

**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

**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:

KHOI VINH HA  
RPH 56072

Respondent

Citation Case No : CI 2017 79526

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)



# APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

 Date 5/14/2018

## 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 COMMUNITY PHARMACY  
 Nature of Pharmacy or Wholesaler  
VITALITY PHARMACY 3175 ST. ROSE PKWY., SUITE 120 HENDERSON, NV 89052  
 Name and Address of Business for Which Designated Representative Is Requested  
N/A  
 If applicable, Name Under Which It Is Now Operated

### 1. PERSONAL INFORMATION:

Last Name HA First Name KHOI Middle Name VENH

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

N/A

Present Residence Address-Street or RFD 2012 - NOW City HENDERSON State/Zip NV, 89012  
RIVER SPEY AVE Dates

Present Business Address 2004 - NOW City TEHACHAPI State/Zip CA, 93561  
710 W. TEHACHAPI BLVD. Dates

Present Position with the Pharmacy or Wholesaler PHARMACIST IN CHARGE K MART PHARMACY 4751 Phone:  
 Residence 661-822-3594 Business

Date of Birth \_\_\_\_\_ Place of Birth (City, County, State) HO CHI MINH CITY, VIETNAM

Age 43 Social Security Number \_\_\_\_\_ Sex MALE

Color of Eyes BROWN Color of Hair BLACK Complexion YELLOW/ASIAN Weight 160 LBS Build MEDIUM 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 N/A

If naturalized, certificate No N/A Date \_\_\_\_\_

Place N/A (If naturalized, document must be verified.)

### 2. MARITAL INFORMATION:

Single ☐ Married ☒ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial KH

## MARITAL INFORMATION-Continued

A. **Current Marriage** 2006 - NOW LAS VEGAS, CLARK COUNTY, NEVADA  
 Date  
 Spouse's full name (Maiden) TUJET THI NGUYEN City, County and State  
 S.S. No. \_\_\_\_\_  
 Date of Birth \_\_\_\_\_ Place of Birth DENVER, CO  
 Resident address RIVER SPEY AVE HENDERSON NV 89012  
 Street City State Zip  
 Telephone: Residence CELL Business 702-754-1900  
 Spouse's employer SUNSET CLINIC Occupation PHYSICIAN ASSISTANT  
 Address of employer 8530 W. SUNSET RD. #110 LAS VEGAS NV 89113  
 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
MAIBELLA ALU HA		LAS VEGAS, NV	RIVER SPEY AVE HENDERSON, NV 89012
THAIER VINH HA		LAS VEGAS, NV	RIVER SPEY AVE 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 KH

**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 LONG HA		N. JACKSON AVE. #F24 SAN JOSE, CA 95116	RETIRED ASSEMBLY LINE WORKER
Mother CHI VU		S. 6TH AVE. #83 HACIENDA HEIGHTS, CA 91745	RETIRED HAIR STYLIST
Father-in-Law TRUOC NGUYEN		DEWEY ST. WHEAT RIDGE, CO 80212	DECEASED HAIR SPECIALIST COMBS
Mother-in-Law THUAN NGUYEN		DEWEY ST. WHEAT RIDGE, CO 80212	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
KIM HA (SISTER)		W. CHERRYWOOD LN ANAHEIM, CA 92804	HAIR STYLIST
Spouse RANDY WISHMYER		W. CHERRYWOOD LN ANAHEIM, CA 92804	STRENGTHEN AND CONDITIONING COACH
KHANG HA (BROTHER)		LAGUNA TERRACE DR HOUSTON, TX 77041	ACCOUNTANT
Spouse DIVORCE			
QUYNH BUI (SISTER)		HERMITAGE PL ALPHARETTA, GA 30005	FINANCIAL CONSULTANT
Spouse MAN BUI		HERMITAGE PL ALPHARETTA, GA 30005	GLOBAL MARKETING MANAGER IBM
Spouse			

**4. EDUCATION:**

Name of School	Location	Dates Attended	Graduate
Grammar School FLAGSTAFF MIDDLE SCHOOL	FLAGSTAFF, AZ	1987-1989	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
High School SINAGUA HIGH SCHOOL	FLAGSTAFF, AZ	1989-1992	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
School LOS ANGELES HIGH SCHOOL	FOUNTAIN VALLEY, CA	1992-1993	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
College CALIFORNIA STATE UNIVERSITY FULLERTON	FULLERTON, CA	1993-1999	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
University UNIVERSITY OF SOUTHERN CALIFORNIA PHARMACY	LOS ANGELES, CA	2000-2004	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other			Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Type of degree obtained, if any... DOCTOR OF PHARMACY

College or university where obtained... UNIVERSITY OF SOUTHERN CALIFORNIA

Applicant's initial... KH

**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
11/22/2012	37	DUI	HENDERSON, NV	10/06/2015 GUILTY RECKLESS DRIVING	HENDERSON POLICE DEPARTMENT

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 \_\_\_\_\_ KH

**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
05/2012 - NOW	REVER SPEY AVE	HENDERSON	NV, CLARK COUNTY
09/2004 - 05/2012	3491 BAGNOLI CT	LAS VEGAS	NV, CLARK COUNTY
05/2000 - 09/2004	? MAIN ST	AL HAMBRA	CA, LOS ANGELES COUNTY
05/1992 - 05/2000	4080 W. 1ST ST	SANTA ANA	CA, ORANGE COUNTY

Applicant's initial KA

**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 09/2004 - NOW	Name/Mailing Address of Employer/Business KMAR PHARMACY   710 W. TEHACHA BLVD TEHACHA, CA 93561	Number of Employed Hours APPROXIMATELY 26,880 HOURS
Title STAFF RPH PHARMACEUTICAL CHARGE	Description of Duties RPH DUTIES (FILLING, DISPENSING, COUNSELING, ETC) RUNNING DAY TO DAY OPERATIONS OF PHARMACY	Name of Supervisor DAVID HAN / ANDREW HENNER
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 KH

# 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>MEINH PHAN</u>	Home	<u>E. LOWRIDGE DR</u>	<u>CA</u>	<u>92867</u>	<u>714-200-5000</u>	<u>26 YEARS</u>
Employer <u>DAVID EVANS AND ASSOCIATES INC</u>	Business	<u>17782 17TH ST SUITE 200</u>	<u>CA</u>	<u>92780</u>	<u>714-665-4543</u>	
Name <u>REBECCA LEE RPH</u>	Home	<u>BICENTENNIAL WAY #913</u>	<u>CA</u>	<u>95403</u>	<u>626-512-3181</u>	<u>15 YEARS</u>
Employer <u>KAISER PERMANENTE</u>	Business	<u>461 BICENTENNIAL WAY</u>	<u>CA</u>	<u>95403</u>	<u>707-393-3722</u>	
Name <u>CRATIC WILLEY RPH</u>	Home	<u>RAWLINGS WAY</u>	<u>CA</u>	<u>92530</u>	<u>714-334-5606</u>	<u>14 YEARS</u>
Employer <u>FORMER KMART RPH</u>	Business	<u>RETIRED</u>				
Name <u>CHRISTIAN NGUYEN RPH</u>	Home	<u>PORTOLA ST</u>	<u>CA</u>	<u>92395</u>	<u>760-628-8728</u>	<u>8 YEARS</u>
Employer <u>ALLCARE PHARMACY</u>	Business	<u>12498 HESPERIA RD #102</u>	<u>CA</u>	<u>92395</u>	<u>760-241-0508</u>	
Name <u>CHAM DANG TRAN RPH</u>	Home	<u>PINEY SUMMIT AVE</u>	<u>NV</u>	<u>89141</u>	<u>714-654-2243</u>	<u>6 YEARS</u>
Employer <u>FORMER KMART RPH</u>	Business	<u>CURRENTLY HOME TAKING CARE NEW BABY</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

RPH LICENSE IN CALIFORNIA 2004 - NOW

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

KH

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 ☐

A SIGNED STATEMENT OF EXPLANATION OF ANSWER "YES" IS ATTACHED:

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 6/4/2018

Applicant's initial KH



Juliana Zschoche  
 South Wolfe Street  
 Apartment  
 Baltimore, Maryland 21231

June 18<sup>th</sup>, 2018

Nevada Board of Pharmacy  
 431 W. Plumb Lane  
 Reno, Nevada 89509

To Whom it May Concern,

I am writing to request placement on the Nevada Board of Pharmacy Meeting agenda in July. This request is regarding approval to work at a site other than a licensed pharmacy in the state of Nevada. I am a currently licensed pharmacist in another state who has completed the application process for licensure in the state of Nevada and will be sitting for my MJPE on July 13th. I am working with CrowdRx, Inc. – who is providing emergency medical services for Burning Man in August in Nevada. As this is not a licensed pharmacy, according to state law I must obtain approval to engage in any pharmacy practice at a site other than a licensed pharmacy. I have reviewed the Nevada Administrative Code that lists the necessary information regarding this request. I will be prepared with this requested information in writing for the Board Meeting.

Thank you for your assistance with this request. Please do not hesitate to let me know if any information is needed prior to the meeting and any next steps.

Respectfully submitted,  
 Juliana



Juliana Zschoche, PharmD, BCPS  
 Clinical Pharmacy Specialist – Emergency Medicine  
 600 North Wolfe Street  
 Carnegie Bldg Room 180  
 Baltimore, MD 21287  
 Office: (410) 955-7123

[jzschoc1@jhmi.edu](mailto:jzschoc1@jhmi.edu)

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane • Reno, NV 89509

## APPLICATION BY RECIPROCATATION AS A PHARMACIST

If you are requesting licensure by reciprocation (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: Juliana Middle: Helene Last: Zschoche

Mailing Address: South Wolfe Street Apt

City: Baltimore State: Maryland Zip Code: 21231

Telephone: \_\_\_\_\_ E-mail Address: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Place of Birth: Rochester, NY, USA

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: Maryland Date of Issuance: 7/17/2014

**College of Pharmacy Information**

Graduation Date: 05/11/2014  
(mm/dd/yy)

Degree Received: ☒ PharmD ☐ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: Ohio Northern University - Raabe College of Pharmacy

Location of School: 525 S. Main St. Ada, OH 45810

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: 6/4/18 Amount: \$330.00 Entity #: 101140  
Email: 6/4 MPJE: 6/4

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>NONE</u>	_____	Yes <input 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: \_\_\_\_\_

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: N/A

	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.

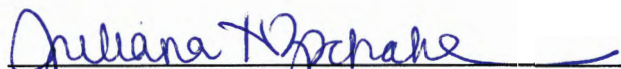
4. Are you the subject of a court order for the support of a child?.....Yes ☐ No ☒  
**4a. If you marked Yes. to the question 4.** are you in compliance with the court order?.....Yes ☐ No ☐

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

5/21/2018

Date

**Shirley Hunting**

---

**From:** Lisa Harris Pharm.D. MBA < , - :>  
**Sent:** Monday, June 04, 2018 6:57 PM  
**To:** Shirley Hunting  
**Subject:** Lisa Harris Baker

Hello,

I have moved back to Nevada from Missouri fulltime and I'm ready to retake my PARE exam. I'd like to set up a date and time. I will be contacting the NABP tomorrow, but I know they will need to have approval from your office first. I can be reached at 702 342 3334 to answer any questions you may have.

Thank you,

Lisa Harris Baker  
NV R.PH #14725

**FILED****AUG 10 2016****NEVADA STATE BOARD  
OF PHARMACY****BEFORE THE NEVADA STATE BOARD OF PHARMACY**

<b>NEVADA STATE BOARD OF PHARMACY,</b>	)	
	)	<b>CASE NO. 16-014-RPH-S</b>
<b>Petitioner,</b>	)	
<b>v.</b>	)	<b>FINDINGS OF FACT,</b>
	)	<b>CONCLUSIONS OF LAW, AND</b>
<b>LISA HARRIS BAKER, R.PH.</b>	)	<b>ORDER</b>
<b>Certificate of Registration No. 14725,</b>	)	
	)	
<b>Respondent.</b>	/	

The Nevada State Board of Pharmacy (Board) heard this matter at its regularly scheduled meeting on July 20, 2016, in Las Vegas, Nevada. S. Paul Edwards, Esq., presented the case on behalf of the Board Staff. Respondent Lisa Harris Baker, R.Ph. Certificate of Registration No. 14725 ("Ms. Baker"), appeared and represented herself at the hearing. Based on the evidence presented, including the testimony of Ms. Baker and others, and the documentary evidence admitted into the record, the Board finds and concludes as follows:

**FINDINGS OF FACT**

1. On May 15, 2014, Board Staff sent Ms. Baker a letter informing her that she had not completed the required thirty (30) continuing education units (CEUs) she needed for the November 1, 2011 to October 31, 2013 renewal period.

2. Board Staff sent that letter based on the results of a random audit conducted by Board Staff, which determined that Ms. Baker completed only twelve (12) of the required thirty (30) CEUs she was required to complete in order to renew her pharmacist license.

3. In the May 2014 letter, Board Staff directed Ms. Baker to complete, among other things, a total of one-hundred and eight (108) CEUs for the biennium ending October 31, 2015, in lieu of formal discipline. That one-hundred and eight (108) CEUs consisted of:

a. Eighteen (18) CEUs Ms. Baker failed to complete for the renewal period of November 1, 2011, to October 31, 2013; and

b. Ninety (90) CEUs for the renewal period of November 1, 2013 through October 31, 2015.

4. The letter informed Ms. Baker that her CEUs would again be audited for the renewal period of November 1, 2013 through October 31, 2015, to verify her compliance with Board Staff's instructions.

5. In November 2015, after Ms. Baker should have completed the one-hundred and eight (108) CEUs, she contacted a Board Staff by phone and stated that she did not complete the required CEUs for the November 1, 2013 to October 31, 2015 renewal period.

6. Despite her failure to complete the required CEUs, Ms. Baker signed her pharmacist license renewal application in December 2015, certifying that she had completed all required CE hours due for the November 1, 2013 to October 31, 2015 renewal period.

7. As indicated by the May 2014 letter, Board Staff conducted an audit of Ms. Baker's CEUs for the biennium ending October 31, 2015.

8. Board Staff sent her its first notice to provide her CEU certificates by email on January 22, 2016, using an email provided to Board Staff by Ms. Baker. The deadline for her to respond was February 10, 2016.

9. Board Staff sent Ms. Baker a second notice to provide her CEU certificates on February 12, 2016, with a deadline of March 8, 2016.

10. Ms. Baker did not timely provide her CEU certificates as required.

11. Board Staff's CEU audit found that Ms. Baker completed none of the required one-hundred and eight (108) CEUs for the biennial period November 1, 2013 to October 31, 2015.

12. Board Staff sent Ms. Baker the Notice of Intended Action and Accusation in this matter on March 22, 2016, by certified mail, to the address last provided to Board Staff by Ms. Baker.

13. Board Staff had Ms. Baker personally served with the Notice of Intended Action and Accusation in this matter on April 11, 2016.

14. Ms. Baker did not file an answer or notice of defense in response to the Notice of Intended Action and Accusation.

15. On July 18, 2016, two days before her hearing, Ms. Baker sent to Board Staff by email three CPE Monitor Activity Transcripts purporting to show that she had met her CEU requirements.

a. The first CPE Monitor Activity Transcript for the date range 11/01/2013 to 10/31/2015, showed that Ms. Baker completed at total of 57.75 CEUs during that period.

b. The second CPE Monitor Activity Transcript for the date range 10/14/2014 to 10/31/2015, showed that Ms. Baker completed at total of 27.5 CEUs during that period. However, that time period is reflected in the first CPE Monitor Activity Transcript includes 10/14/2014 to 10/31/2015, and each of the 27.5 CEUs on that transcript were also reflected on the first CPE Monitor Activity Transcript for the date range.

c. The third CPE Monitor Activity Transcript Ms. Baker provided reflected her CEUs for date range of 11/01/2015 to 10/31/2016, and shows that she completed at total of 84.5 CEUs during that period.

16. Ms. Baker presented each of those CPE Monitor Activity Transcripts as evidence at the hearing.

17. Based on the CPE Monitor Activity Transcripts Ms. Baker provided, the evidence is that Ms. Baker completed only 57.75 of the 108 CEUs she was required to complete for the renewal period ending October 31, 2015.

18. The evidence is that Ms. Baker failed to complete 50.25 of the one hundred and eight (108) CEUs she was required to complete by October 31, 2015.

19. The foregoing findings are supported by the exhibits offered by the Petitioner and/or the Respondent during the hearing, which the Board admitted into the record, and by the testimonial evidence presented by both parties during the hearing.



### CONCLUSIONS OF LAW

20. The Board has jurisdiction over this matter and this respondent because Ms. Baker is a pharmacist licensed by the Board.

21. By failing to respond to the Board Staff's request for documents relating to her CEUs, Lisa Harris Baker violated NAC 639.330 and NAC 639.945(m), as alleged in the Second Cause of Action, which violations are ground for action pursuant to NRS 639.210(4), (12) and (17), as NRS 639.255.

22. By signing her renewal application and certifying that she had completed the required CEUs for the biennial period of November 1, 2013 to October 31, 2015, when she did not complete 50.25 of the CEUs required by the Board, Lisa Harris Baker violated NRS 639.281, as alleged in the Third Cause of Action, which violation is grounds for action pursuant to NRS 639.210(4), (9), (10) and (12), and NRS 255.

23. Board Staff withdraw its first cause of action.

#### **BASED UPON THE FOREGOING, THE BOARD HEREBY ORDERS:**

24. Respondent Lisa Harris Baker, R.Ph., Certificate of Registration No. 14725, shall:

a. Pay a fine of One Thousand Dollars (\$1000.00) associated with the violations set forth above. Ms. Baker shall pay the forgoing fine with a *cashier's check, certified check or money order* made payable to "Nevada State Treasurer," to be received by the Board's Reno office within ninety (90) days of the effective date of this Order;

b. Pay administrative fees of Four Hundred and Ninety-Five Dollars (\$495.00) to partially off-set the Board's costs of investigating and prosecuting this matter. Ms. Baker shall pay the forgoing fine with a *cashier's check, certified check or money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office within ninety (90) days of the effective date of this Order.;

25. Additionally, Ms. Baker's pharmacist license, Certificate of Registration No. 14725, is hereby suspended effective the date of this Order. The suspension is stayed, effective immediately, for a period of up to twelve (12) months during which time Ms. Baker must take and pass the National Association of Boards of Pharmacy (NABP)'s Pharmacist Assessment for

Remediation Evaluation (PARE) exam, and comply with all terms and conditions of this Order and any other outstanding orders by the Board.

26. At the end of the twelve-month stay period, the stay will automatically lift and Ms. Baker's pharmacist license will remain suspended unless she has (a) passed the PARE Exam, and (b) complied with all other terms of this Order and all other outstanding orders by the Board.

27. Board Staff is authorized to review this case and, at its sole discretion, lift the suspension on Ms. Baker's license prior to the end of the twelve-month stay period without requiring Ms. Baker to reappear before the Board after she has passed the PARE exam and complied with the terms of this Order and any other outstanding orders by the Board.

28. For the renewal period of November 1, 2015 to October 31, 2017, Ms. Baker shall complete the thirty (30) hours of CEU that the Board ordinarily requires for renewal of a pharmacist license. Ms. Baker may not use any of the 84.5 CEUs she completed since November 1, 2015, as reported on her CPE Monitor Activity Transcripts for the time period from 11/01/2015 to 10/31/2016, to satisfy the 30-hour requirement.

29. Ms. Baker's CEU credits will be audited after the next renewal period to verify that she completed the total of thirty (30) hours of CEU required by this Order.

30. Any failure by Ms. Baker to comply with any term in this Order shall result in the immediate lifting of the stay and may also result in further discipline, up to and including revocation of the her license.

**IT IS SO ORDERED.**

Signed and effective this 10<sup>th</sup> day of August, 2016.




---

Leo Basch, President  
Nevada State Board of Pharmacy

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane ~ Reno, NV 89509

## PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION

**Registration Fee: \$40.00 - (non-refundable money order only, no cash)**

Complete Name (no abbreviations):

First: Maurice Middle: Robert Last: LewisHome Address: Scenic Desert Ct. Apt #: \_\_\_\_\_City: Las Vegas State: NV Zip Code: 89131

Telephone: \_\_\_\_\_ Social Security Number: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Place of Birth: Chandler Arizona Sex: ☒ M or ☐ FE-mail Address: Maurice.Lewis@Northwestcareercollege.edu

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: NORTHWEST CAREER COLLEGE Store #: \_\_\_\_\_Address: 7398 SMOKE RANCH ROADCity: LAS VEGAS State: NV Zip Code: 89120Signature of Managing Pharmacist: [Signature] Lic #: PT07935 Date: 6/21/18

(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 type="checkbox"/> | <input checked="" 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 &amp; provide an explanation &amp; documentation:

Board Administrative Action:	State	Date:	Case #:
		/ /	
Criminal Action:	State	Date:	Case #:
		/ /	
		County	Court

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



Larry L. Pinson, Pharm.D.  
Executive Secretary  
Nevada State Board of Pharmacy  
431 W. Plumb Lane  
Reno, NV 89509

June 5, 2018

*RE: LEWIS, MAURICE – NOTIFICATION OF POSITIVE DRUG SCREENING*

Dear Dr. Pinson,

This letter serves as the institution's official notification to the Nevada State Board of Pharmacy that Mr. Maurice Lewis, a Pharmacy Technician in Training at NCC, has been placed on a mandatory leave of absence from his program of study, effective 06/04/2018.

Mr. Lewis was placed on a leave of absence upon completion of his most recent term after NCC received notification last month of a drug screening test result that was positive for THC. While Mr. Lewis has not violated any NCC code of conduct policies related to his behavior on campus, he is being placed on leave of absence in accordance with our Admissions Policies related to the Pharmacy Technician program.

Mr. Lewis has expressed interest in continuing his education and has been notified that he will need to appear in front of the Board to appeal his case and complete any action plan(s) set forth by the Board related to his state licensure before he can resume his studies at NCC. He has confirmed that this is his intention, so we would like to assist him with getting scheduled to appear in front of the Board.

Please feel free to call me at (702) 254-7577 or email me at [Thomas.kenny@northwestcareercollege.edu](mailto:Thomas.kenny@northwestcareercollege.edu) with any questions!

Respectfully,

Dr. Thomas Kenny  
Director of Regulatory Affairs

7398 Smoke Ranch Rd  
Las Vegas, Nevada 89128

phone: 702-254-7577  
[northwestcareercollege.edu](http://northwestcareercollege.edu)

June 18, 2018

Dave Wuest  
Deputy Executive Secretary  
Nevada State Board of Pharmacy  
431 W. Plumb Lane  
Reno, NV 89509

**Re: CVS Health Request in regards to NAC 639.250**

Dear Deputy Executive Secretary Wuest,

I am writing to you in my capacity as Sr Director of Pharmacy Regulatory Affairs for CVS Health. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points to care to patients in the state of Nevada through our integrated offerings across the spectrum of pharmacy care. We would like to thank the Board for their vigilance in continuously improving the laws and regulations that guide pharmacists, intern pharmacists and pharmaceutical technicians serving Nevada patients.

NRS 639.1371(1) allows the Board to expand ratio by regulation which is currently addressed in NAC 639.250. CVS Health is requesting the Board to review and consider an expansion to pharmacy technician supervision restrictions set forth in NAC 639.250. As today's pharmacy practice environment evolves, we have seen state boards of pharmacy relax or eliminate restrictive ratios, in particular based on practice settings that are non-dispensing. Understanding that NRS 639.012 (Pharmacy definition) does not contemplate a non-dispensing pharmacy model, this type of pharmacy "front end" model where activities such as but not limited to prescription data entry, drug utilization and data entry verification occur separate from dispensing is a prominent model used in pharmacy practice today. This type of pharmacy model provides an environment in which less distractions are present, allowing pharmacists and technicians to have a sole focus on the activity in front them which leads to higher accuracy. Also, this allows a pharmacist in a dispensing pharmacy additional time for counseling and enhanced patient care. Based upon this reasoning, we request the Board consider an increased supervisory allowance, similar to Texas expansion in 2014 and most recently in Florida this year, which allows a pharmacist to supervise eight pharmaceutical technicians in the non-dispensing area of a pharmacy or any non-dispensing pharmacy.

We propose the amended language below for consideration:

**NAC 639.250 Restrictions on supervision.** (NRS 639.070, 639.0727, 639.1371) Except as otherwise provided in NAC 639.258:

1. Except as otherwise provided in this section, in a hospital, a pharmacist who is dispensing prescriptions may not supervise more than a total of three pharmaceutical technicians at one time. A pharmacist who is supervising distributive functions may not supervise more than a total of two pharmaceutical technicians and one pharmaceutical technician in training while the trainee is performing technician functions in on-the-job training.
2. Except as otherwise provided in this section, in any pharmacy, other than a hospital pharmacy, a pharmacist may not supervise more than a total of three pharmaceutical technicians or one pharmaceutical technician and two pharmaceutical technicians in training at one time.
3. In any telepharmacy, remote site or satellite consultation site, a pharmacist may not supervise more than a total of three pharmaceutical technicians at one time.

4. In any pharmacy that does not dispense controlled substances or dangerous drugs as defined in NRS 639.0065, a pharmacist may not supervise more than a total of eight pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time.

5. In any pharmacy that has a physically separate area from which controlled substances or dangerous drugs are not dispensed as defined in NRS 639.0065, a pharmacist may not supervise more than a total of either pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time. A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the dispensing and non-dispensing area.

46. A pharmacist may supervise more pharmaceutical technicians and pharmaceutical technicians in training at one time than are otherwise allowed pursuant to subsections 1 and 2 if:

(a) Not more than three of the pharmaceutical technicians or pharmaceutical technicians in training are performing the duties of a pharmaceutical technician as set forth in NAC 639.245; and

(b) The record kept by the pharmacy pursuant to NAC 639.245 identifies the pharmaceutical technicians and pharmaceutical technicians in training who are performing the duties of a pharmaceutical technician as set forth in NAC 639.245.

[Bd. of Pharmacy, § 639.215, eff. 6-26-80] — (NAC A 12-3-84; 2-18-88; 3-27-90; 11-15-93; 12-13-96; R016-99, 11-3-99; R037-07, 1-30-2008; R098-13, 3-28-2014)

We appreciate your time and consideration in regards to this request. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,



Lauren Paul, PharmD.  
Sr Director, Pharmacy Regulatory Affairs  
CVS Health

# NEVADA STATE BOARD OF PHARMACY



## POLICY MANUAL 2018

## INTRODUCTION

Board members and employees have a duty to carry out and enforce the provisions of Nevada law to protect the health, safety and welfare of the public. *See* NRS 622.080, NRS 639.070(1)(a), NRS 639.213 and NRS 639.2171(1).

### **General Purpose and Scope**

These policies and procedures apply to all Board members and employees. They are not intended to be exhaustive and do not override the specific provisions of law as applied to a particular set of facts. To the extent possible, these policies and procedures are intended to supplement statutes, regulations and executive orders governing the Board, together with the State Administrative Manual and other statewide policies and procedures that apply to all State Executive Branch agencies. If there is a conflict between such other provisions and the provisions of this manual, the other provisions control. In some instances, certain statewide policies and procedures are incorporated by reference in this manual. The Executive Secretary may implement additional policies and procedures not inconsistent with this manual and applicable law.

### **Employee Input and Improvements**

Throughout the Board's history, its employees have been the best source for innovation and improvement of the Board's operations. All employees are encouraged to comment to the Executive Secretary or the General Counsel upon these policies and procedures at any time. These policies and procedures should accurately reflect the actual operations of the Board and lead to greater efficiency in our service to the public.

### **Review and Changes to the Policies and Procedures**

The Board may require changes to these policies and procedures whenever the Board deems necessary. The Executive Secretary and the General Counsel shall review these policies and procedures at least once biennially and make any recommendations for changes to the Board.

### **No Third-Party Rights**

This manual is intended to guide the internal operations of the Board and its staff and is not intended to create any rights, duties, or obligations regarding any person who is a not Board member or employee.



## EMPLOYMENT POLICIES

Board employment policies and practices will conform to the requirements of NRS Chapter 281 and Chapter 613.

### **Employment At Will**

Each employee of the Board is employed at will, meaning that the employee may be terminated for any reason or no given reason and with or without any previous disciplinary action or notice. The Executive Secretary serves at the will of the Board. All other employees serve at the will of the Executive Secretary. The Executive Secretary may enlist the assistance of one or more Board members or the entire Board to review applications, interview candidates, or ratify hiring or termination decisions, but the Executive Secretary may also make any employment decisions without the assistance of the Board, as the Executive Secretary deems in his or her discretion to be appropriate or necessary.

### **Work Hours**

An employee is considered full-time if he or she is expected to regularly work 40 or more hours per week. An employee is considered part-time if he or she is expected to regularly work less than 40 hours but more than 24 hours per week. An employee is considered occasional if he or she is expected to regularly work less than 24 hours per week. Occasional employees receive no benefits unless otherwise provided in these policies and procedures. Unless otherwise allowed by the Executive Secretary, every full-time employee is expected to work 40 hours per week.

### **Compensatory Time**

If an employee works 15 or more minutes beyond his or her regular work day or on a weekend or holiday, he or she may record that time as compensatory time. Compensatory time is kept and used in quarter-hour increments. Each employee is responsible to record his or her own compensatory time. The Executive Secretary shall review each employee's total of compensatory time at the end of the calendar year.

An employee may use his or her compensatory time flexibly as long as the use of the compensatory time does not affect pending assignments. An employee needs prior approval from the Executive Secretary or the General Counsel to use compensatory time. Las Vegas employees must also notify the Las Vegas Office Manager of any leave requested before taking any such leave.

An employee may carry forward from one calendar year to the next a maximum amount of compensatory time equal to three times the maximum amount of annual leave he or she is allowed to carry forward from one calendar year to the next. All compensatory time in excess of the allowable maximum will be forfeited on January 1 of each year.

Upon termination of employment, an employee is entitled to be paid for unused compensatory time at his or her regular hourly rate up to the allowable maximum amount, which shall correspond to the maximum amount for annual leave set forth in the table below. Unlike sick leave and annual leave, compensatory time may not be donated to other employees.

## **Annual Leave**

Annual leave for full-time employees shall accrue and may be accumulated based upon the length of time that the employee has worked for the Board according to the following schedule:

<u>Time Employed</u>	<u>Hrs./Pay Period</u>	<u>Max. Accumulation</u>
5 years or less	3.33 hrs./pay period	160 hours
5 to 10 years	5.00 hrs./pay period	160 hours
10 to 20 years	6.65 hrs./pay period	240 hours
More than 20 years	6.65 hrs./pay period	320 hours

A part-time employee shall accrue and may accumulate annual leave at a rate 75% of that rate that would be allowed to a full-time employee with the same number of years of employment.

An employee should notify the Executive Secretary or the General Counsel and schedule his or her use of annual leave upon the Board's master calendar as soon in advance of the use of the leave as possible (and in the usual case no later than three weeks before the leave) so that the Executive Director and the General Counsel can schedule coverage. Las Vegas employees must also notify the Las Vegas Office Manager of any leave requested before taking any such leave. Reasonable leave requests will be granted unless, in the discretion of the Executive Secretary or the General Counsel, such leave would compromise the efficiency or work of the Board. Employees are encouraged not to seek leave during dates of Board meetings or from September 1 through November 15 of each year. The Executive Secretary may grant leave without prior notice to an employee for unforeseen or unanticipated circumstances of personal misfortune (such as a death of a family member or friend).

At the end of each calendar year, an employee will forfeit any annual leave he or she has accumulated that exceeds the maximum accumulation for that particular employee. An employee will be paid for his accumulated annual leave upon any termination of his or her employment with the Board at his or her most recent hourly rate up to a maximum of the number of annual hours he or she could accumulate.

Annual leave must be taken in half-hour increments. An employee must use compensatory time in excess of 20 hours for any absence from the office before he or she may use annual leave. Employees are encouraged to use their leave throughout the year rather than using it all in the last quarter of the calendar year.

An employee may donate accumulated annual leave to another employee. The terms of the donation, including a determination of whether and how the leave will be repaid, must be made in writing between the two employees and must be approved in writing by the Executive Secretary. A copy of the written agreement must be provided to the Administrative Assistant so that the terms of the agreement can be accommodated by the payroll service. The donor employee will be without recourse if the donee employee terminates his or her employment before he or she has repaid the donated leave.

## Sick Leave

Full-time employees accrue sick leave at the rate of 5.0 hours per pay period. Part-time employees accrue sick leave at the rate of 3.75 hours per pay period. There is no limit to the number of hours of sick leave that may be accrued by an employee. An employee whose employment is terminated by reason of retirement or death may receive payment for his or her accrued sick leave at his or her most recent hourly pay based upon the number of years of employment by the Board according to the following schedule:

<u>Time Employed</u>	<u>Maximum Paid</u>
Less than 10 years	None
10 to 15 years	\$3,750
15 to 20 years	\$6,000
20 to 25 years	\$9,000
More than 25 years	\$12,000

Whenever possible, an employee should notify the Executive Secretary or the General Counsel (and the Las Vegas Office Manager if the employee is a Las Vegas employee) when he or she intends to use sick leave. Sick leave is only to be used if:

- The employee is unable to perform the duties of his or her position because he or she is sick, injured, or physically incapacitated due to a *bona fide* medical condition.
- The employee is quarantined.
- The employee is receiving medical, psychological, optometric, or dental service or examination.
- A member of the employee's family is sick, injured, physically incapacitated, quarantined, or receiving treatment or examination for a *bona fide* medical condition and the employee is needed to minister, transport, or otherwise assist the family member.

An employee may be asked to provide evidence of the reason given for the use of sick leave by the Executive Secretary or the General Counsel. Misuse of sick leave is a cause for discipline up to and including termination.

## Extraordinary Leave

An employee may seek from the Executive Secretary or the General Counsel extraordinary leave under such conditions and for such time as the employee deems needed when:

- The employee is unable to perform his or her duties because of his or her own serious, *bona fide* illness or accident which is life threatening or which will require convalescence exceeding ten working days.
- The employee is unable to perform his or her duties because of the serious, *bona fide* illness or accident which is life threatening or which will require convalescence exceeding ten working days for a member of the employee's family or other person who will rely upon the employee's presence.
- The death of a member of the employee's family or close friend that may require the absence of the employee for more than three working days.
- Any other unforeseen or unfortunate personal circumstance that will require the absence of the employee for more than three working days.

The Executive Secretary or the General Counsel will attempt, as much as possible, to accommodate the employee's request for extraordinary leave. Las Vegas employees must also notify the Las Vegas Office Manager of any leave requested before taking any such leave. An employee will use his or her accrued sick leave (when appropriate), compensatory time, and annual leave for extraordinary leave. If the extraordinary leave will continue beyond all such accrued leave, other employees may donate their accrued leave of any type to assist the employee on extraordinary leave. Throughout the period of extraordinary leave, the employee on extraordinary leave shall call the Executive Secretary or the General Counsel to notify him or her of any significant change of circumstances regarding the leave and when the employee might be able to return to work.

If the extraordinary leave will continue beyond all the employee's accrued leave and the other employees' donations of leave are inadequate to cover the employee's extraordinary leave with pay, the employee and the Executive Secretary shall discuss whether the employee will be allowed to go on leave without pay or whether other arrangements, including termination of the employee's employment, are appropriate.

## Miscellaneous Special Leave

**Administrative Leave** – Administrative leave is leave with pay that is not deducted from the employee's annual or compensatory leave amounts. Administrative leave will be granted an employee under the following circumstances:

- **Blood Donation** – An employee may take leave with pay for the time necessary to donate blood or blood products (such as platelets) as long as the Executive Secretary or the General Counsel has approved the leave in advance.

- Jury or Witness Duty – An employee will be granted administrative leave for the actual time he or she is required to serve as a juror or as a witness in a court or administrative proceeding other than a hearing or meeting with the Board. Any jury or witness fees must be paid to the Board.

Military Service Leave – An employee who is a member of the National Guard or a Reserve unit of the military will be granted leave for training under the same conditions as would apply to any other request for annual or compensatory leave except that such leave can only be denied by the Executive Secretary if the employee's absence would substantially impair the necessary work of the Board.

## **Holidays**

The Board will observe legal holidays as specified in NRS 236.015, for which all employees will be paid based upon their current salary. If a legal holiday falls on a day within the workweek that is not a regular workday for an employee, that employee shall claim 25% of their regular hours per workweek as compensatory time.

## **Annual Salary Reviews**

Every year before the Board's regularly scheduled meeting in May or June, the Executive Secretary shall review the work of each employee to make a recommendation to the Board regarding potential increases to that employee's salary. The Executive Secretary may recommend a merit increase per employee and may recommend different percentages for each employee depending upon the Executive Secretary's evaluation of the employee's work in the preceding year. At its meeting in May or June, the Board may increase each employee's salary by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U) for the West Region for the preceding year plus a merit increase based upon the Executive Secretary's recommendation and the Board's own discretion. Salary increases shall be effective July 1 of each year.

## **Outside Employment**

Before an employee may engage in any employment other than his or her employment with the Board, the employee shall discuss such outside employment with the Executive Secretary or the General Counsel. The Executive Secretary or General Counsel may approve the outside employment as long as it does not constitute a conflict of interest with the operations of the Board, does not create the appearance of impropriety, and does not interfere with the employee's ability to perform his or her functions for the Board.

## **Travel Expenses**

Board members and employees in travel status shall receive reimbursement in accordance with NRS 281.160 and Chapter 0200 of the State Administrative Manual.

## **Use of Board Equipment and Time**

Each employee shall, during his or her hours of duty as an employee and subject to such other laws or regulations as pertain thereto, devote his or her full time, attention and efforts to the business of the Board. Employees may make incidental use of their time and Board property for personal use under the following conditions:

- The use of the property does not interfere with the performance of the employee's duties.
- The cost or value related to the use is nominal.
- The use does not create the appearance of impropriety.

An employee should direct any question regarding whether a particular use of Board property complies with this policy to the Executive Secretary or the General Counsel before the employee makes the personal use of the Board property.

## **Americans with Disabilities Act**

The Board will comply with the Americans with Disabilities Act by following the Employment Provisions Guide for State of Nevada Executive Branch Agencies set forth in Appendix A.

## **Public Employees' Retirement Program**

The Board participates in the Public Employees' Retirement Program (PERS) in accordance with NRS Chapter 286 and will follow the PERS Policies and Procedures for the Retirement System available at <https://www.nvpers.org/>

## **Public Employees' Benefits Program**

The Board participates in the Public Employees' Benefits Program (PEBP) in accordance with NRS Chapter 287 and will follow the PEBP Policies and Procedures for Employee Health Insurance available at <https://pebp.state.nv.us/>

## **Public Employees' Deferred Compensation Program**

The Board participates in the Public Employees' Deferred Compensation Program (NDC) in accordance with NRS 287.250-.370 and will follow the NDC Policies and Procedures for the Program available at <http://defcomp.nv.gov/>

## **Workers' Compensation Insurance**

The Board purchases workers' compensation insurance coverage for employees through a private insurer.

## SEXUAL HARASSMENT AND DISCRIMINATION

All Board members and employees are subject to the State of Nevada Executive Branch Sexual Harassment and Discrimination Policy set forth in Appendix B. Each Board member and employee shall sign the acknowledgment therein for retention in the individual's personnel file that he or she has read and understands the Sexual Harassment and Discrimination Policy.

## INFORMATION TECHNOLOGY AND SECURITY

All Board members and employees are subject to the State of Nevada Executive Branch Information Security Program Policy set forth in Appendix C. Each Board member and employee shall sign the Acceptable Use Agreement governing the use of Board information technology (IT) resources set forth in Appendix D for retention in the individual's personnel file.

## ETHICS IN GOVERNMENT

All Board members and employees are subject to the Nevada Ethics in Government Law, NRS Chapter 281A. Each Board employee shall sign the acknowledgment set forth in Appendix E for retention in the individual's personnel file that he or she has read and understands the Nevada Ethics In Government Manual. Each Board employee shall sign the Policies & Procedures for Screening of Staff to Avoid Conflicts of Interest set forth in Appendix F for retention in the individual's personnel file.

## PUBLIC RECORDS

The Board Coordinator is the designated records official for the Board responsible for compliance with the Nevada Public Records Act, NRS Chapter 239, together with NAC Chapter 239, Chapter 0400 and Chapter 2000 of the State Administrative Manual, and State records retention schedules. Board members and employees shall not use their personal electronic devices and personal accounts in the transaction of public business since this generates a public record. The Board shall follow the records retention schedules set forth at

<http://nsla.libguides.com/state-records-services/retention-schedules>

and the Nevada Public Records Manual available at

[http://nsla.libguides.com/ld.php?content\\_id=34967931](http://nsla.libguides.com/ld.php?content_id=34967931).

## DUTIES OF THE EXECUTIVE SECRETARY

### TEMPORARY LICENSES

The Executive Secretary may only consider a request for a temporary license under NAC 639.200 if the person making the request is a pharmacist and has:

- Filed a fully completed an appropriate application,
- Paid all required fees,
- Nothing in his work or life history that would disqualify him or her or would require an appearance before the Board pursuant to NRS 639.210, and
- Demonstrated a compelling reason for the request.

The Executive Secretary may only consider a request for a temporary license under NAC 639.200 if the requesting party is a pharmacy and has:

- Filed a fully completed and appropriate application,
- Paid all required fees,
- Nothing in its operational history that would disqualify it or would require an appearance before the Board pursuant to NRS 639.210,
- Licenses already with the Board for one or more similar pharmacies, and
- Demonstrated a compelling reason for the request.

If the Executive Secretary grants a temporary license, he shall inform the person making the request of the time after which the license will expire, which time is presumptively 90 days. The Executive Secretary shall report all temporary licenses granted to the Board at each of the Board's meetings.

### Responsibility for Employees

The Executive Secretary is responsible for the hiring, discipline, and termination of all employees of the Board. The Executive Secretary has the discretion to assign work among the employees as he or she deems necessary and proper for the efficient and effective function of the Board.

Board members who have questions or concerns regarding the operation of the Board offices or the work of any particular employee should address such questions or concerns to the Executive Secretary. Employees who have questions or concerns regarding their employment or the interpretation of any of these Policies and Procedures should talk with the Executive Secretary regarding their concerns.



## Press Relations and Public Speaking

Questions from reporters or the public should be addressed to the Executive Secretary unless another person in the office has been designated by the Executive Secretary to receive such inquiries. Employees should not speak to reporters about anything unless specifically designated to do so by the Executive Secretary. Board members may speak to the press about Board matters, but they are encouraged either to direct the press to the Executive Secretary or to inform the Executive Secretary of the press contact immediately after the press contact. Board members may not speak on behalf of the entire Board unless authorized by the Board to do so. Board members may not discuss with the press anything related to a pending disciplinary matter until the Board has finally ruled in the matter and any judicial review of the matter is concluded.

The Executive Secretary is encouraged to speak to the public regarding issues of interest to the public and the Board related to the practice of pharmacy and the work of the Board. The Executive Secretary may assign public speaking duties to other employees as he or she deems appropriate. The Executive Secretary may seek permission or direction from the Board regarding a given appearance, or from the President if time does not allow for the issue to be raised with the entire Board.

## Oversight of Board Finances and Investing of Board Funds

The Executive Secretary has the authority and responsibility to prudently manage the Board's finances. The Executive Secretary may sign contracts on behalf of the Board, may sign negotiable instruments on behalf of the Board, may commit Board funds to investments or other accounts, and may take whatever other action he or she deems necessary to maximize the Board's funds. The Executive Secretary must present a financial report at each meeting of the Board.

The Executive Secretary shall invest the Board's funds as follows:

1. **Cash in Board Checking Accounts:** It is the responsibility of the Executive Secretary to maintain cash balances at levels which enable the Board to meet obligations as they become due. The Executive Secretary may establish a zero-balance checking account where excess cash is invested in a short-term Treasury fund that provides for one-day liquidity; or procure overnight repurchase agreements in order to ensure that funds are not at risk. The Board of Pharmacy will ensure the following:
  - The Board members will annually affirm the decision to exceed the FDIC limit of \$250,000 when investing in funds approved by statute.
  - The limit of \$250,000 is only exceeded in institutions with total assets exceeding \$10 billion and with a Thompson BankWatch or equivalent issuer rating of B/C or better.
  - Institutions are scrutinized annually to ensure that the high ratings are maintained.

2. **Acceptable investments for funds not required for satisfying current obligations.** The Executive Secretary shall determine the investments based on its cash flow needs and safety and liquidity of investment. The Executive Secretary may invest Board funds that are not needed for current obligations only in the following:

- Savings accounts protected by U.S. Government guarantees, interest bearing demand accounts, time or certificates of deposits in banks and savings and loan institutions physically located within Nevada. The Board of Pharmacy will ensure the following:
  - The Board of Pharmacy members will annually affirm the decision to exceed the FDIC limit of \$250,000.
  - The limit of \$250,000 is only exceeded in institutions with total assets exceeding \$10 billion and with a Thompson BankWatch or equivalent issuer rating of B/C or better.
  - Institutions are scrutinized annually to ensure that the high ratings are maintained.
- U.S. Treasury bills, notes and bonds. Securities issued by U.S. Government agencies such as: Federal Farm Credits, Federal National Mortgage Association and Federal Home Loan Association. These securities may not have maturities greater than 10 years. Average maturities may not exceed five years. Board will not invest in securities of more than 24 months.

3. **There shall be no investment of Board funds in:**

- State, local, or corporate notes and bonds.
- Equities (common and preferred stocks or long-term investments).
- Short-term Treasury Mutual Funds.
- Money Market Mutual Funds.

## **Operating Reserves**

The Executive Secretary shall ensure compliance with the Board's reserve policy set forth in Appendix G.

## **Contract Approval**

The Executive Secretary shall ensure compliance with the requirements of NRS Chapter 333, NAC Chapter 333, and Chapter 0300 of the State Administrative Manual for all contracts.

## **Financial Reporting**

The Executive Secretary shall ensure compliance with the financial reporting requirements of NRS 218G.400.

## DUTIES OF THE DEPUTY EXECUTIVE SECRETARY

The Deputy Executive Secretary shall be a licensed pharmacist in this State and shall perform those duties assigned by the Executive Secretary, which may include the authority to act on behalf of the Executive Secretary when the Executive Secretary is absent from the Board offices or otherwise unavailable, including, without limitation, the authority to sign accusations on behalf of the Executive Secretary pursuant to NRS 639.241(2). The Deputy Executive Secretary may have signature authority on the Board's bank, investment, and credit accounts.

## DUTIES OF THE LAS VEGAS OFFICE MANAGER

The Las Vegas Office Manager shall have the following responsibilities, duties, and obligations for the Board:

- Day-to-day operations and activities of the Las Vegas office
- Disseminating information to the Executive Secretary or the General Counsel regarding situations, news articles, and any other information pertinent to or that would affect the Board
- Assuring that the Las Vegas office operates similarly to the Reno office
- Overseeing the day-to-day activities of the Las Vegas staff in order to coordinate with the Reno office regarding investigation and inspection assignments
- Carrying out the policies, procedures, and directives of the Executive Secretary and the General Counsel
- Controlling the use of the Board's credit card to assure it is used only for allowable purchases, including consulting with the Reno office regarding such use of the Board's credit card
- Assuring that the Las Vegas staff have the necessary support and assistance to carry out its functions
- Assuring that the Las Vegas staff cares for its assigned equipment and cars, including surplus or replacing equipment when needed
- Reporting to the Executive Secretary and General Counsel regarding the performance of Las Vegas staff

## DUTIES OF THE GENERAL COUNSEL

### **Legal Duties**

The General Counsel shall have the following legal responsibilities and obligations for the Board, subject to the requirements and restrictions of the Nevada Rules of Professional Conduct:

- Taking any action on behalf of the Board deemed necessary to protect the State's legal interests until such time as the Board may adequately consider the matter
- Providing day-to-day legal advice to Board members and employees on matters over which the Board has supervision, control, jurisdiction or advisory power
- Drafting and reviewing legal papers and correspondence
- Preparing and prosecuting disciplinary actions
- Representing the Board in all legal proceedings
- Representing the Board before legislative committees
- Drafting regulations and bill drafts
- Advising the Board at its meetings except when the General Counsel is prosecuting disciplinary cases, in which case the Board is advised by a representative of the Attorney General's Office
- Responding to simple inquiries from the public, licensees, or applicants for licensure on Nevada's pharmacy laws, which shall not constitute legal advice

### **General Counsel Authority to Act**

The General Counsel is hereby authorized and directed to take any action on behalf of the Board deemed necessary to protect the State's legal interests until such time as the Board may adequately consider the matter. This may include filing a response to a petition for judicial review of a final decision of the Board in a contested case. This may also include filing a protective notice of appeal from an adverse ruling or judgment whenever the Board, for any reason, is unable to take action on an appeal during the prescribed statutory period for taking an appeal. Under such circumstances, the Board will thereafter act, in the normal course of business, to ratify, or direct dismissal, of the appeal.

### **Administrative Duties**

The General Counsel also has all the responsibilities, duties, and authority of the Executive Secretary when the Executive Secretary or Deputy Executive Secretary are both absent from the Board offices or otherwise unavailable. The General Counsel may have signature authority on the Board's bank, investment, and credit accounts. The General Counsel will also perform such duties as are assigned from time-to-time by the Executive Secretary.

## BOARD VEHICLES

Investigators and Inspectors will be provided vehicles for their use whenever they are on Board business. Other Board staff and Board members are authorized to use Board vehicles for Board functions. The use of Board vehicles must comply with Chapter 1300 of the State Administrative Manual and the following:

- **Use a Board vehicle when on Board business.** If an employee will be conducting Board business on a given day or portion of a day within 15 minutes of his or her home, the employee may use his or her personal vehicle for his or her own convenience for that day or portion of a day, but such use will not be reimbursed for mileage. If an employee must use his or her personal vehicle because a Board vehicle is unavailable, the employee will be reimbursed at the standard mileage reimbursement rate authorized by the Governor's Finance Office Budget Division.
- **Leave Board vehicles at the Board office when no longer on Board business.** Occasionally an Investigator or Inspector may be asked by a Board member, the Executive Secretary, or the General Counsel to leave a Board car somewhere else, such as at a hotel or airport, in which case the Inspector or Investigator should do so.
- **Pursuant to NRS 204.080 private use of a Board vehicle is prohibited.**
- **Maintain Board vehicles.** Each Inspector or Investigator is responsible to make sure that his or her Board vehicle receives regular maintenance including oil changes (every 3,500 miles), tire rotations, tune-ups, and washings as needed, with prior authorization from the Executive Secretary. The Board will not reimburse inappropriate or unapproved expenses such as running out of fuel, running down the battery, charges for lost keys, parking citations, or traffic tickets or other moving violations.
- **Report traffic tickets.** Any employee or Board member who drives a Board-provided car must report to the Executive Secretary immediately any traffic ticket. Violation of this policy by receiving excessive traffic tickets, by receiving traffic tickets for driving behavior that endangers the employee or the public, or by failing to report a traffic ticket to the Executive Secretary immediately may result in discipline, including termination of employment.
- **Operating a Board vehicle under the influence of alcohol or drugs is prohibited.** Violation of this policy could result in discipline, including termination, regardless of whether the employee was arrested or charged with such conduct.
- **Damage to the car that did not result from an accident must be reported to the Executive Secretary or the General Counsel immediately.**

## Accident Procedure

Any Board member or employee who has an accident involving a Board vehicle must follow the provisions of Chapter 2900 of the State Administrative Manual and the following procedure:

- **Remain on the scene and immediately notify the appropriate law enforcement agency, give the exact location and advise them if there are any injuries.**
- **Notify the Executive Secretary or the General Counsel immediately.** The employee must notify the Executive Secretary or the General Counsel of the extent of injuries of all parties involved and the extent of the property damage to the extent this information is available.
- **Obtain the name, address, and car license numbers of other parties and the names and addresses of witnesses, and document the accident with photos or video to the extent feasible.**
- **Complete law enforcement and risk management accident reports. DO NOT SIGN OR MAKE A STATEMENT AS TO RESPONSIBILITY.**
- **The State Accident Report (Form No. RSK-001) MUST be submitted within two working days to the Executive Secretary.** The Executive Secretary must submit the form immediately upon receipt to the Department of Administration Risk Management Division.

## FINANCIAL ADMINISTRATION

### Internal Accounting and Administrative Control

The Executive Secretary shall implement a system of internal accounting and administrative control for the Board subject to the following limitations:

- Incoming mail shall be logged by Board staff other than the Director of Finance or the Licensing Specialist.
- The Licensing Specialist shall review all checks and money orders for payment of licensing fees and make all deposits.
- The Board shall not accept cash payments.
- Only the Executive Secretary, Deputy Executive Secretary and General Counsel may have signature authority on the Board's bank, investment, and credit accounts.

### Grants Management

The Board shall comply with the applicable Grants Management Common Rule for any federal grant funds, including, without limitation, 2 CFR Part 200.

## LEGAL AND ADMINISTRATIVE ACTIONS

### **Defense and Indemnification**

Generally, the State will defend and indemnify Board members and employees for actions taken in good faith within the scope of their statutory duties. The Board pays premiums into the State Tort Claims Fund. However, Board members and employees must comply with the requirements of NRS Chapter 41 and Chapter 2900 of the State Administrative Manual for defense and indemnification.

### **Service of Process**

Board members and employees shall immediately notify the General Counsel and the Office of the Nevada Attorney General whenever served with a complaint in federal or state court, or a petition for judicial review, or if otherwise presented with legal documents, since service must be effected in strict compliance with FRCP 4(j)(2), NRS 41.031(2) or NRS 233B.130(2), which includes service upon the Office of the Nevada Attorney General.

### **Documentation of Attorney's Fees and Costs**

The Board may recover reasonable attorney's fees and costs that are incurred as part of its investigative, administrative and disciplinary proceedings pursuant to NRS 622.400. In any matter that results in disciplinary action, whether by stipulated settlement or by Board order following a hearing, the Board may order reimbursement for expenses necessarily incurred in protecting the public. This may include, without limitation, time and travel costs incurred by Investigators in the investigation of the matter, the General Counsel in the prosecution of the matter, the Board Coordinator in providing legal support, Board members in hearing the matter, witnesses and expert witness fees, and the Office of the Nevada Attorney General in serving as Board counsel.

The Board may also recover reasonable attorney's fees and costs that are incurred as a prevailing party in judicial actions related to the Board's enforcement authority pursuant to NRS 622.410.

The Board must document that attorney's fees and costs are both reasonable and actual; therefore, Investigators, the General Counsel and the Board Coordinator will document their time on the investigation and prosecution of any disciplinary matter, or on any litigation related to the Board's enforcement authority, using a timekeeping system approved by the General Counsel.

## COMPLAINT INVESTIGATION PROCEDURES

The following procedures for the investigation of complaints should be followed by Investigators in the usual course. Deviation from the procedures may occur from time to time as situations and circumstances require, but such deviations should be approved in advance by the Executive Secretary whenever practicable.

1. **The Executive Director and General Counsel will conduct an initial review of all complaints submitted.** The review will include an initial screening consistent with the Policies & Procedures for Screening of Staff to Avoid Conflicts of Interest set forth in Appendix F. The review will also include a determination of whether the complaint is against licensee(s), whether the matter is within the Board's jurisdiction or the jurisdiction of another board, and whether the complaint states a claim. If the complaint is within the Board's jurisdiction and warrants investigation, the matter will be referred to the Board Coordinator. If the complaint appears within the jurisdiction of another board, it will be referred to the appropriate board. If the complaint does not warrant an investigation and/or fails to state a claim, the General Counsel will respond in writing as necessary.
2. **Board Coordinator logs in complaints, assigns them a number, and routes them to the appropriate Investigator.** The Board Coordinator should process the complaint within one working day of receipt.
3. **The Investigator contacts the complainant within two working days after receiving the complaint.** Unless the Investigator feels that early contact with the complainant would impair the investigation, the Investigator should make initial contact with the complainant as soon as possible.
4. **The complaint is investigated in a timely manner.** The Board staff has broad legal authority to access and inspect premises and records. Investigators should request that the Executive Secretary issue subpoenas for the production of witnesses, documents or papers to the extent necessary. As questions or tactical decisions arise, Investigators should consult the Executive Secretary or General Counsel.
5. **The Investigator submits a report to the Board Coordinator.** Investigators should prepare a detailed narrative report on the standard form. The report should attach copies or references to the evidence collected in the investigation, including written or recorded statements of witnesses. The factual assertions that form the basis for the findings and conclusions in the report and any allegations of violations of law should not be based solely on uncorroborated hearsay but must be supported by direct evidence. The report should also document the time expended by the Investigator on the case.
6. **The Investigative Committee will review the report and determine how to proceed.** The Investigative Committee will be comprised of the Executive Secretary, the General Counsel, the Board Coordinator, and, if required, the Investigator(s) involved in the investigation.



## INSPECTION PROCEDURES

The Board staff has broad legal authority to access and inspect premises and records. The following inspection procedures should be followed by Inspectors in the usual course. Deviation from the procedures may occur from time to time as situations and circumstances require, but such deviations should be approved in advance by the Executive Secretary whenever practicable. Following should be the usual steps in the inspection process:

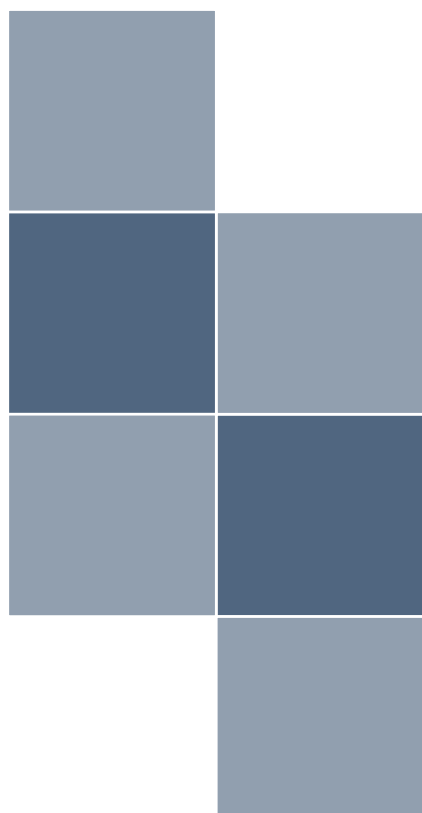
1. **The Administrative Assistant notifies the pharmacies and facilities to be inspected in the first week of the month preceding the month in which the inspection will occur.** The notification will consist of a form letter, a pre-inspection form, and a workplace assessment tool with instructions that the pharmacy would need to have the forms completed and all materials available for a random inspection one month later. (For example, the materials would be provided in the first week of January for facilities that would be inspected in February.)
2. **The Administrative Assistant notifies the Inspector of the pharmacies and facilities to be inspected one week before the inspections will occur.** On a monthly basis, the Administrative Assistant will schedule pharmacies and facilities to be inspected based upon locale and will notify the Inspectors of their upcoming inspections one week before the actual inspections are to occur. The Administrative Assistant shall also notify the General Counsel and the Las Vegas Office Manager of the weekly assignments so that questions of rescheduling or efficiency can be addressed to them.
3. **The Inspector conducts the assigned inspections unannounced.** The Inspector will visit the assigned inspections in such order as he or she deems efficient, as long as the weekly assignments are completed. The managing pharmacist is not required to be present at an inspection, nor are appointments to be made. Inspectors should minimize disruption of the pharmacy's operations by doing inspections as unobtrusively as possible. Inspectors should request the production of any records necessary to an inspection and must note all deficiencies to be addressed and corrected. Inspectors should immediately notify the General Counsel if the issuance of an administrative warrant is necessary.
4. **The Inspector sends the completed inspection forms to the Administrative Assistant.** The Administrative Assistant will log in the date of completion of all inspection forms.
5. **The Administrative Assistant responds appropriately to all notes on the inspection forms.** If the Inspector has noted deficiencies, the Administrative Assistant will prepare a letter for the Executive Secretary's signature to the pharmacy or facility informing the pharmacy or facility of the time within which the deficiency must be addressed and corrected. The Administrative Assistant will also log and schedule the follow-up visit (when appropriate) by putting the follow-up visit on the appropriate schedule for the Inspector.

6. **The Administrative Assistant will follow-up on deficiencies.** Where a letter has been sent regarding deficiencies and the deficiencies have not been timely addressed and corrected, the Administrative Assistant will notify the Board Coordinator of the failure to remedy the deficiencies so that the Board Coordinator can open a complaint matter against the pharmacy or facility.
7. **The Administrative Assistant will prepare reports.** The Administrative Assistant will enter the workplace assessment tool data into the Board's computer system within five business days of receipt of the reports from the Inspector. The Administrative Assistant will prepare and provide to the General Counsel at least quarterly a status report of the inspections completed by each Investigator.

## ELECTION OF BOARD OFFICERS

NRS 639.040(1) requires the Board to elect a President and a Treasurer from among its members. The election of Board officers will be conducted under the following procedure:

1. The Board will hold an election for the offices of President and Treasurer at the regularly-scheduled meeting in June of even-numbered years.
2. The term of office will commence at the next Board meeting for a period of two years.
3. The outcome of the election will be determined by majority vote.
4. There will be no term limits.
5. In the event of the termination of an officer's tenure on the Board, an election will be held at the next regularly-scheduled Board meeting to fill the vacancy.



# THE AMERICANS WITH DISABILITIES ACT (ADA) & THE ADA AMENDMENTS ACT (ADAAA) Employment Provisions Guide for State of Nevada Executive Branch Agencies

**January 2018**

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## INTRODUCTION

This guide discusses the application of the employment provisions of the Americans with Disabilities Act (ADA) of 1990. The ADA is a federal antidiscrimination statute designed to remove barriers, which prevent individuals with disabilities who are qualified from enjoying the same employment opportunities, services and privileges available to persons without disabilities. The ADA Amendments Act (ADAAA), effective January 1, 2009, was adopted by Congress with the intention of restoring the original intent of the ADA by providing a clear and comprehensive national mandate for the elimination of discrimination.<sup>1</sup> The ADAAA overturns several United States Supreme Court decisions that had limited coverage under the ADA.

Like the Civil Rights Act of 1964 that prohibits discrimination on the basis of race, color, religion, national origin, and sex, the ADA seeks to ensure access to employment opportunities based on merit. It does not guarantee equal results, establish quotas, or require preferences favoring individuals with disabilities over those without disabilities. However, while the Civil Rights Act of 1964 prohibits any consideration of personal characteristics such as race or national origin, the ADA takes a different approach. When an individual's disability creates a barrier to employment opportunities, services or privileges, the ADA requires an employer to consider whether reasonable accommodation could remove the barrier.

While the ADA focuses on eradicating barriers, it does not relieve an individual with a disability from the obligation to perform the essential functions of a position. To the contrary, the ADA is intended to enable an individual with a disability who is qualified to access the privileges and services offered and to compete in the workplace based on the same performance standards and requirements that agencies expect of individuals who are not disabled. However, where an individual's functional limitation(s) impedes job performance, an employer must take steps to reasonably accommodate, and thus help overcome the particular impediment(s), unless to do so would impose an undue hardship.

The process of identifying whether, and to what extent, a reasonable accommodation is required should be flexible, made on a case-by-case basis and requires participation by both the employer and individual. No specific form of accommodation is guaranteed to all individuals with a particular disability; however, the accommodation process must be consistent and non-discriminatory. An accommodation must be tailored to match the needs of the individual with a disability and the needs of the individual's position.

State government is a covered entity for the purposes of the ADA and must comply with the non-discrimination provisions of the ADA.

This guide is not a substitute for legal advice and is subject to change without notice. If you need specific information regarding the ADA, consult your human resources staff, your agency's

attorney, federal and State enforcement and technical assistance agencies or the Division of Human Resource Management (see [Resources & References](#)).



## WHAT IS A DISABILITY?

It is important to remember that the definition of disability, as defined by the ADA, is legal and not medical. If an individual is deemed “disabled” under a different law (e.g., Social Security Act) it does not mean that the individual automatically meets the definition of disability under the ADA/ADAAA.

Also an individual may be covered by more than one of the definitions of disability.

### PHYSICAL OR MENTAL IMPAIRMENT WHICH SUBSTANTIALLY LIMITS ONE OR MORE MAJOR LIFE ACTIVITIES

#### PHYSICAL OR MENTAL IMPAIRMENT

The ADAAA specifically states that the definition of disability should be interpreted broadly and that determining whether “an individual's impairment is a disability under the ADA should not demand extensive analysis”.<sup>1</sup>

A physical impairment is defined by the Equal Employment Opportunity Commission (EEOC) as any physiological disorder, or condition, cosmetic disfigurement, or anatomical loss affecting one or more body systems such as neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, immune, circulatory, hemic and lymphatic, skin, and endocrine. A mental impairment is defined by the EEOC as any mental or psychological disorder, such as an intellectual disability, organic brain syndrome, emotional or mental illness, and specific learning disabilities.<sup>2</sup>

The definition of the term “impairment” does not include physical characteristics such as eye color, hair color, left handedness, or height, weight or muscle tone that are within “normal” range and are not the result of a physiological disorder. Similarly, the definition does not include common personality traits such as poor judgment or a quick temper where they are not symptoms of a mental or psychological disorder. Environmental, cultural, or economic disadvantages such as poverty, lack of education or a prison record

What is a disability as defined by the ADA (ADAAA)?

What is a disability as defined by the ADA (ADAAA)?

- A physical or mental impairment which substantially limits one or more major life activities;
- A record of an impairment; or
- Being regarded as having an impairment.

are not impairments. Advanced age, in and of itself, is also not an impairment.

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## MAJOR LIFE ACTIVITIES

What is a major life activity? A major life activity is a basic activity that most people in the general population can perform with little or no difficulty.

Major life activities include, but are not limited to:

- Caring for oneself
- Performing manual tasks
- Seeing
- Hearing
- Eating
- Sleeping
- Walking
- Standing
- Sitting
- Reaching
- Lifting
- Bending
- Speaking
- Breathing
- Learning
- Reading
- Concentrating
- Thinking
- Communicating
- Interacting with others

- Working
- Operation of a major bodily function

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## MAJOR BODILY FUNCTIONS

Major bodily functions are included as major life activities and may include, but are not limited to:

- Functions of the immune system
- Special sense organs and skin
- Normal cell growth
- Digestive
- Genitourinary
- Bowel
- Bladder
- Neurological
- Brain
- Respiratory
- Circulatory
- Cardiovascular
- Endocrine
- Hemic
- Lymphatic
- Musculoskeletal
- Reproductive

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## SUBSTANTIALLY LIMITS

A common sense assessment based on comparing an individual's ability to perform a specific major life activity with most people in the general population is used to determine whether an impairment "substantially limits". The ADAAA indicated that a limitation need not

“significantly” or “severely” restrict a major life activity to meet the standard of “substantially limits”.<sup>1</sup>

The EEOC regulations provide rules to use when determining whether an impairment is substantially limiting.

1. The term “substantially limits” should be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of the ADA.
2. An impairment is a disability if it substantially limits the ability of the individual to perform a major life activity as compared to most people in the general population.
3. Determination of whether an impairment substantially limits a major life activity should not demand extensive analysis.
4. The determination of whether an impairment substantially limits a major life activity requires an individualized assessment.
5. The comparison of a major life activity to the performance of the same major life activity by most people in the general population will not require scientific, medical or statistical analysis.
6. The determination of whether an impairment substantially limits a major life activity shall be made without regard to ameliorative (improving) effects of [mitigating measures](#).
7. An impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active.
8. An impairment that substantially limits one major life activity need not substantially limit other major life activities in order to be considered a substantially limiting impairment.
9. The effects of an impairment lasting or expected to last fewer than six months can be substantially limiting.<sup>2</sup>

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## MITIGATING MEASURES

The positive effects of mitigating or compensating measures cannot be considered when determining whether an individual meets the definition of disability. However, the negative effects of mitigating factors may be considered.

Mitigating measures, may include, but are not limited to:

- Medications
- Medical supplies

- Equipment or appliances
- Low-vision devices (which do not include ordinary eyeglasses or contact lens)
- Prosthetics including limbs and devices
- Hearing aids and cochlear implants or other implantable hearing devices
- Mobility devices
- Oxygen therapy equipment and supplies
- Use of assistive technology
- Reasonable accommodations or auxiliary aids or services
- Learned behavioral or adaptive neurological modifications
- Surgical intervention, except where it has permanently eliminated the impairment

The one mitigating factor that may be considered in determining whether an individual is disabled is the use of "ordinary eyeglasses or contact lenses" that are intended to fully correct the individual's visual acuity or refractive error.<sup>1</sup>

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#### PREDICTABLE ASSESSMENTS

The EEOC regulations give examples of impairments that will, in virtually all cases, result in a determination of substantial limitation of a major life activity.<sup>2</sup> For this reason, the individualized assessment of the limitations on the individual should be simple and straightforward. The examples are:

- Deafness
- Blindness
- Intellectual disability
- Partially or completely missing limbs
- Mobility impairments requiring the use of a wheelchair
- Autism
- Cancer
- Cerebral palsy
- Diabetes

- Epilepsy
- HIV/AIDS
- Multiple sclerosis (MS)
- Muscular dystrophy
- Major depression
- Bipolar disorder
- Post-traumatic stress disorder (PTSD)
- Obsessive compulsive disorder
- Schizophrenia

#### RECORD OF AN IMPAIRMENT

An individual would have a record of a disability if the individual had a history of, or was misclassified previously as having, an impairment that substantially limits one or more major life activity.

For example, a cancer survivor would be an individual with a record of an impairment. Or an individual, who was incorrectly diagnosed with bipolar disorder due to a reaction to medication, also has a record of an impairment even though the individual did not actually have the disorder.

#### “REGARDED AS” HAVING AN IMPAIRMENT

An individual is “regarded as” having a disability if:

1. Subjected to an employment action prohibited under the ADA; and
2. The action was taken because of an actual or perceived impairment regardless of whether the impairment is, or is perceived to be, substantially limiting a major life activity.

Regarding an individual as disabled could include taking a prohibited action based on symptoms of an impairment or the use of mitigating measures.

An employee who is only “regarded as” having a disability is not entitled to accommodation.

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## TRANSITORY AND MINOR

An individual is not “regarded as” having an impairment, if the impairment is both transitory and minor. A transitory impairment is an impairment with an actual or expected duration of 6 months or less.

## ALCOHOL

Alcoholism can, in some circumstances, meet the standard of a covered disability. However, an employer does not have to allow either consumption of alcohol on duty or an employee being under the influence while working.

## CONTROLLED SUBSTANCES

Individuals who currently use controlled substances illegally are not individuals with disabilities protected under the Act. This includes individuals who use prescription drugs illegally as well as those who use illegal controlled substances. However, individuals who have been rehabilitated and do not currently use controlled substances illegally may be protected under the ADA.

## EXCLUSIONS

Pregnancy in of itself is not a disability as defined by the ADA.

The following conditions are also excluded from the definition of disability under the ADA:

- Pedophilia
- Exhibitionism
- Voyeurism
- Other sexual behavior disorders
- Compulsive gambling
- Kleptomania
- Pyromania
- Psychoactive substance use disorders resulting from current illegal use of controlled substances

## IMPACT ON EMPLOYMENT PRACTICES

The ADA/ADAAA prohibits discrimination based on disability in regards to:

- Recruitment, advertising, job application;
- Hiring, promotion, demotion, transfer, layoff, termination, return from layoff, rehire;
- Discipline;
- Compensation;
- Job assignments, job classifications, organizational structures, position descriptions, seniority;
- Leave;
- Benefits;
- Training;
- Sponsored activities; or
- Any other term, condition or privilege of employment.

## DISCRIMINATION

Discrimination under the ADA includes limiting, segregating, classifying, harassing, retaliating, denying or otherwise making an employment decision based on an individual's disability. Discrimination is also prohibited under an agency's contracts with any other entity (i.e. benefits, training).

The ADAAA does not protect an individual who is denied an employment opportunity or a reasonable accommodation because he or she does not have a disability.

## ASSOCIATION PROVISION

Discrimination can also be based on a relationship with someone with a disability. The word relationship, as used in this context, is not limited to family relationships; it can include association with an individual with a disability. The EEOC states that the intent of the provision is "to prevent employers from taking adverse actions based on unfounded stereotypes and assumptions about individuals who associate with people who have disabilities."<sup>5</sup> Refusing to hire an individual with a spouse with a disability based on the assumption that he or she would have to frequently be absent from work to take care of his or her spouse, would be an example of discrimination based on association with an individual with a disability. Accommodation does not have to be provided



to an individual without a disability due to that individual's association with someone with a disability.

## ESSENTIAL FUNCTION

Essential functions are so necessary to the position that an individual cannot do the job without being able to perform them.

## MARGINAL FUNCTIONS

Marginal functions can be described as peripheral, minimal, extra, borderline, incidental and/or nonessential. Marginal functions can be reassigned to another individual without compromising the core of the position's duties.

## ESSENTIAL FUNCTIONS DEVELOPMENT

It is important to establish or re-evaluate the essential functions of a position before taking an employment action such as recruiting, hiring or promoting. Also, the essential functions of a position should be reviewed and revised as needed when the work performance standards are updated.

To establish the essential functions of a position, the position must be clearly defined and its component tasks and requirements analyzed to determine the physical and mental demands these tasks place on the employee and the environmental conditions in which the position is performed.

The factors to be considered in determining whether a function is essential are, as outlined in federal regulation are:

- Whether the position exists to perform the function;
- The number of other employees available among whom the performance of that function can be distributed;
- The degree of expertise or skill required to perform the function; and
- Whether an employee is currently performing or has performed the function;

## What is an essential function?

Essential functions are so necessary to the position that an individual cannot do the job without being able to perform them.

- The consequences of not requiring the incumbent to perform the function;
- The amount of time spent performing the function.

When identifying essential functions, it is important not to confuse method with function. For example, it would not be correct to say that an employee has to “drive to meetings” when the actual task is to “attend meetings”. Do not make assumptions about what the position does, such as relying on job titles or traditional roles.

Keep in mind that functions that are performed infrequently or little time is spent on can also be considered essential. The deciding factor may be the consequence of not performing the function. For example, a firefighter may only occasionally have to carry a person from a burning building but it is still an essential function.

The agency’s judgment is a factor in determining which functions are essential.

The [Essential Functions Position Analysis form \(ADA-1\)](#) was developed to assist in identifying which functions are essential. Class specification, work performance standards, [Position Questionnaire \(NPD-19\)](#), the employee that currently is in the position and the employee's supervisor are excellent resources in determining what functions are actually performed and the factors that determine whether they are essential or marginal.

The [Physical and Cognitive Characteristics Inventory form \(ADA-2\)](#) may also be used in developing the essential functions for a position.

The essential functions of a position are documented on the [Position Functions form \(ADA-3\)](#).

## MEDICAL INQUIRIES

The rules on medical inquiries/examinations apply to all employees, not just those with a disability.

The EEOC has stated that medical examinations include, but are not limited to:

- "vision tests conducted and analyzed by an ophthalmologist or optometrist;
- blood, urine, and breath analyses to check for alcohol use;
- blood, urine, saliva, and hair analyses to detect disease or genetic markers (e.g., for conditions such as sickle cell trait, breast cancer, Huntington's disease);
- blood pressure screening and cholesterol testing;
- nerve conduction tests (i.e., tests that screen for possible nerve damage and susceptibility to injury, such as carpal tunnel syndrome);
- range-of-motion tests that measure muscle strength and motor function;

- pulmonary function tests (i.e., tests that measure the capacity of the lungs to hold air and to move air in and out);
- psychological tests that are designed to identify a mental disorder or impairment; and,
- diagnostic procedures such as x-rays, computerized axial tomography (CAT) scans, and magnetic resonance imaging (MRI)."<sup>3</sup>

Tests for illegal use of drugs, physical agility, the ability to read and evaluate objects, psychological tests that measure personality traits such as honesty, preferences and habits and polygraph examinations are generally not considered medical examinations under the ADA and not subject to the ADA restrictions on such examinations.<sup>3</sup>

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#### PRE-OFFER

An employer may not inquire as to whether an individual has a disability or conduct a medical inquiry/examination prior to a conditional offer of employment. Nor can an employer inquire at the pre-offer stage about an applicant's workers' compensation history. Agencies may ask questions that relate to the applicant's ability to perform job-related functions. However, these questions should not be phrased in terms of disability. If there is a reasonable belief that a candidate will not be able to perform a job function because of a known disability, a candidate may be asked to describe or to demonstrate how, with or without reasonable accommodation, the candidate would perform a job-related function(s) during an interview. However, a candidate may not be asked for information regarding the possible disability nor should the request for a description or demonstration of how the candidate would perform a job function(s) be made more than once.

A test that is not a medical examination would not be subject to the prohibition against pre-employment medical examinations if given to all similarly situated applicants or employees, regardless of disability. However, if such a test screens out or tends to screen out an individual with a disability or a class of such individuals because of disabling condition(s), the State or agency must be prepared to show that the test is job-related and consistent with business necessity and also that the test or the essential function cannot be performed with a reasonable accommodation.

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#### POST-OFFER

An employer may condition a job offer on the satisfactory result of a pre-employment and post-offer medical examination or inquiry if this is required of all candidates in the same position or class; however, the examination or inquiry must comply with [GINA](#).

If an individual is not hired because a pre-employment and post-offer medical examination or inquiry reveals a disability, the reason(s) for not hiring must be job-related and consistent with business necessity. The employer also must show that no [reasonable accommodation](#) was

available that would enable this individual to perform the essential job functions or that the accommodation that would allow the individual to perform the essential job functions would impose an [undue hardship](#).

A pre-employment, post-offer medical examination may also disqualify an individual who would pose a [direct threat](#) to health or safety. Such a disqualification is job-related and consistent with business necessity. However, again the employer also must show that no reasonable accommodation was available that would lower the threat to an acceptable level.

A pre-employment and post-offer medical examination may not disqualify an individual with an impairment who is currently able to perform the essential job functions because of speculation that the impairment may cause a risk of future disability.

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## AFTER EMPLOYMENT

Medical questions or evaluations after employment must be job related and consistent with business necessity. Generally an evaluation meets that standard when the agency “has a reasonable belief, based on objective evidence, that: (1) an employee’s ability to perform essential job functions will be impaired by a medical condition; or (2) an employee will pose a direct threat due to a medical condition.”<sup>3</sup>

Agencies may also additionally conduct post employment medical examinations for the following reasons:

- The examinations are required by federal law or regulation; or
- When the examination is voluntary (neither requiring participation nor penalizing for not participating<sup>3</sup>) and a part of an employee health program.

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## BACKGROUND AND REFERENCE CHECKS

The rules regarding what medical information may be requested pre-offer, post-offer and after employment also apply to background and reference checks. In general, the EEOC takes the perspective that a job offer is real only if all relevant non-medical information (e.g., background and reference checks) which reasonably could be obtained are analyzed prior to giving the offer. However, the EEOC has recognized that there are times when an employer cannot reasonably obtain and evaluate all non-medical information at the pre-offer stage.<sup>13</sup>

## RECRUITMENT

In general, the ADA does not require employers to take affirmative action in employing people with disabilities (i.e., agencies are not required by the ADA to recruit, hire and promote individuals with disabilities as part of a mandate to make their work force more diverse). Rather, the ADA

requires agencies to modify their hiring processes and employment practices so that discrimination does not occur when a person with a disability applies or is hired.

However, the ADA does not invalidate Section 503 of the Rehabilitation Act, which requires federal contractors and subcontractors with contracts and subcontracts of \$10,000 or more per year to take affirmative action in hiring and promoting individuals with disabilities.

It is generally recommended to base a job posting/notice/advertisement on the essential functions.

[Accommodation](#) may be requested in the application and interview processes.

## INTERVIEWING

The prohibition on pre-offer medical inquiries also applies to questions asked during interviews. Locations for interviews should be [accessible](#) and an applicant is entitled to [accommodation](#) for the interview.

NAC 284.441 requires the appointing authority to provide a description of the essential functions of the position to each applicant who is being considered for a position. The information must be provided in a timely manner to allow an applicant with a disability to determine his or her need for reasonable accommodation.

## SELECTION PROCESS

It is the employer's responsibility to select the most qualified candidate for a position. The ADA makes it unlawful to discriminate against an individual with a disability who is qualified on the basis of a disability. Agencies must determine whether or not an individual with a disability is qualified at the time of the hiring decision, based on the person's present capabilities. Agencies should not make decisions based on speculation about what may happen in the future or concerns about increased insurance premiums or workers' compensation costs.

The appointing authority shall consider the essential functions of the position that have been identified when determining which applicant will be offered employment. If the disability of an applicant prevents or impedes the performance of one or more of the marginal functions of the position, the agency should not consider those functions when determining which applicant will be offered employment.

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## QUALIFICATION STANDARDS AND TESTS

It is unlawful for an employer to use qualification standards, employment tests or other selection criteria that screen out or tend to screen out an individual with disability or a class of individuals with a disability(s) on the basis of disability, unless the standard, test or other selection criteria, as used by the State or agency, is shown to be job-related for the position in question and is consistent

with business necessity. This provision is applicable to all types of selection criteria, including safety requirements, vision or hearing requirements, walking requirements, lifting requirements, and employment tests. Legitimate production standards will generally not be subject to a challenge under this provision.

Accommodations may be needed to assure that tests or examinations measure the actual ability of an individual to perform the essential functions, rather than reflecting limitations caused by a disability. Tests should be given to people who have sensory, speaking, or manual impairments in formats that do not require the use of their impaired skills; unless that is the job-related skill the test is designed to measure.

For example, an applicant for a position may have dyslexia, a learning disability, which causes difficulty in reading. The applicant may be given an oral rather than a written test, unless reading is an essential function of the position. Or the individual might be allowed more time to take a test, unless the test is designed to measure speed required for an essential function.

An employer has an obligation to inform applicants in advance that a test will be given, so that an individual who needs an accommodation can make such a request.

## TRAINING

Individuals with disabilities must be provided equal access to training.

[Reasonable accommodation](#) should be provided, when needed, to individuals with disabilities to give them equal opportunity to benefit from training to perform their positions effectively and to advance in employment. An employer is responsible to provide reasonable accommodation whether the training occurs at the worksite or elsewhere.

## EVALUATIONS, PERFORMANCE MANAGEMENT & DISCIPLINE

An employer can hold an employee with a disability to the same conduct standard (as long as it is job-related and consistent with business necessity) applied to employees without disabilities. For example, the ADA does not prevent an agency from maintaining a workplace free of violence or threats of violence, or from disciplining an employee who steals or destroys property. Thus, an employer may discipline an employee with a disability for engaging in such misconduct if it would impose the same discipline on an employee without a disability.

However, other conduct standards that are not be job-related for the position in question and consistent with business necessity an agency cannot discipline for or hold the individual accountable for. For example, an employee with a known psychiatric disability works in a warehouse loading boxes onto pallets for shipment. He has no customer contact and does not come into regular contact with other employees. Over the course of several weeks, he has come to work appearing increasingly disheveled. His clothes are ill-fitting and often have tears in them.

He also has become increasingly anti-social. Coworkers have complained that when they try to engage him in casual conversation, he walks away or gives a curt reply. When he has to talk to a coworker, he is abrupt and rude. However, his work has not suffered. The agency's policy states that employees should have a neat appearance at all times. The policy also states that employees should be courteous to each other. When told that he is being disciplined for his appearance and treatment of coworkers, the employee explains that his appearance and demeanor have deteriorated because of his disability, which was exacerbated during this time period. The dress code and coworker courtesy rules are not job-related for the position in question and consistent with business necessity because this employee has no customer contact and does not come into regular contact with other employees. Therefore, rigid application of these rules to this employee would violate the ADA.<sup>6</sup>

An employer can also hold an employee with a disability to the same production standards for performance of essential functions, with or without accommodation, as other similarly situated employees without disabilities. An agency can hold employees with disabilities to the same performance standards as other employees regarding marginal job functions, unless the disability affects the ability to perform these marginal functions. If the ability to perform marginal functions is affected by the disability, the agency must provide some type of reasonable accommodation, unless to do so would be an undue hardship.

An agency should not evaluate on a lower standard or discipline less severely employees with disabilities. However, an agency may not discipline or terminate an employee with a disability if the agency has refused to provide a requested reasonable accommodation that did not constitute an undue hardship, and the reason for unsatisfactory performance was the lack of accommodation.

#### **REQUIRING "FULL RECOVERY" BEFORE RETURN TO WORK**

An agency may not refuse to allow an individual with a disability to return to work on the basis that the employee is not fully recovered, unless he or she:

#### **Caution:**

The federal 9<sup>th</sup> Circuit Court of Appeals (which Nevada is a part of) has concluded that conduct resulting from a disability "is considered to be part of the disability, rather than a separate basis for termination." (*Dark v. Curry Co.* 451 F.3d 1078, 9<sup>th</sup> Cir. 2006) Additionally, the 9<sup>th</sup> Circuit has stated that a "decision motivated even in part by the disability is tainted and entitles a jury to find that an employer violated antidiscrimination laws." (*Gambini v. Total Renal Care, Inc.*, 486 F.3d 1087, 9<sup>th</sup> Cir. 2007) It is suggested that agencies consult their agency's attorney before proceeding with discipline for misconduct that is directly related to an individual's disability.



- Cannot perform the essential functions of the position with or without reasonable accommodation; or
- Would pose a direct threat.

### ADDRESSING GRIEVANCE(S)

The suggested procedure for handling ADA issues is through communication between the employee, supervisor and human resource staff.

An agency may have an ADA grievance policy in place; in which case, the procedures outlined may be used to resolve issues which have not been handled through communication between the parties.

Additionally, [NAC 284.696](#) states that an employee alleging unlawful discrimination may:

- Report the alleged discrimination to:
  - The section of the Division of Human Resource Management that investigates discrimination (800-767-7381);
  - The Attorney General;
  - The employee's appointing authority;
  - An equal employment opportunity officer;
  - A human resource representative of the agency in which the employee is employed; or
  - The office charged with enforcing affirmative action within the appropriate university, state college or community college which is part of the Nevada System of Higher Education.
- Use the grievance procedure; or
- File a complaint with:
  - The Nevada Equal Rights Commission or
  - The United State Equal Employment Opportunity Commission.

### POSTER

The ADA requires that agencies post a notice describing the provisions of the ADA, a poster is available from the EEOC. See the [Poster Adviser](#) on the Division of Human Resource Management's website for a link to the current version online. The notice must be made accessible to applicants and employees.



## ACCOMMODATION PROCESS

The accommodation requirement is best understood as a means by which barriers to the equal employment opportunity of an individual with a disability are removed or alleviated.

These barriers may be, but are not restricted to:

- Physical or structural obstacles that inhibit or prevent the access of an individual with a disability to job sites, facilities or equipment
- Rigid work schedules that permit no flexibility as to when work is performed or when breaks may be taken
- Inflexible job procedures that unduly limit the methods of communication that are used in the position or the way in which particular tasks are accomplished

An agency is obligated to make an accommodation only to the known limitations of an individual with a disability who is otherwise qualified. In general, it is the responsibility of the applicant or employee with a disability to inform the employer that an accommodation is needed to:

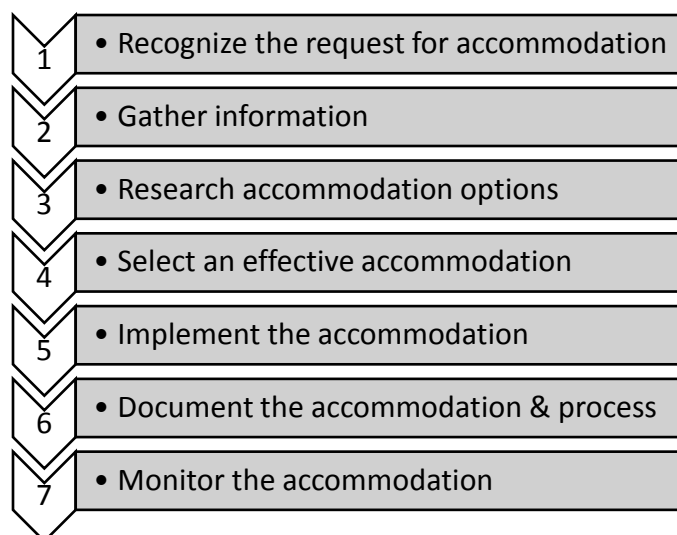
- participate in the application process;
- perform the essential job functions; and/or
- receive equal benefits and privileges of employment.

The ADA provides that an agency cannot require an individual with a disability who is qualified to accept an accommodation that is neither requested nor needed by the individual. However, if a necessary reasonable accommodation is refused, the individual potentially could be considered not qualified for the position if unable to perform the functions of the position.

An agency is not required to provide an accommodation if unaware of the need or disability. However, if an individual's need for accommodation is a) obvious and b) the individual's disability prevents the individual from requesting an accommodation; the agency must begin the accommodation process.

If an agency can grant requested assistance without further consideration, it is suggested

### INTERACTIVE PROCESS



that the assistance be provided without labeling it as an "accommodation". If requested assistance cannot be granted without further consideration, then the agency would need to proceed with the interactive process.

What is the interactive process? It can be described as a process to clarify what the individual needs and to identify a reasonable accommodation. Responsibility to move the interactive process forward rests on both the agency and individual. It is suggested to restrict communication to fact finding and problem resolution only and not to discuss performance problems as part of the interactive process.

Also keep in mind that certain steps in the interactive process may be taken at the same time or skipped (if the agency or individual already has addressed the issue).

### RECOGNIZE THE REQUEST FOR ACCOMMODATION

What is a request for accommodation? Communication of a need for an "adjustment or change... for a reason related to a medical condition".<sup>4</sup>

An individual may use "plain English" to request accommodation. An applicant or employee does not have to specifically request a "reasonable accommodation" or mention the "ADA". A request for accommodation may be as simple as, "I need <accommodation> because of my <medical condition>".

However, just because an individual requests an accommodation, it is not a guarantee that the individual will be provided an accommodation or the specific accommodation requested. An individual with a disability should request a reasonable accommodation when he or she knows that there is a workplace barrier that is preventing him or her, due to a disability, from effectively competing for a position, performing the functions of a position, or gaining equal access to a benefit of employment. When an individual decides to request accommodation, the individual or his or her representative (e.g., family member, friend, health professional) must let the employer know that he or she needs an adjustment or change at work for a reason related to a medical

What if you are not sure if an individual is requesting an accommodation?  
Ask the individual to clarify what is being requested and why.  
Ask the individual to clarify what is being requested and why.

condition. Requests for reasonable accommodation do not need to be in writing. Individuals may request accommodation in conversation or may use any other method of communication.

## GATHER INFORMATION

### REVIEW ESSENTIAL FUNCTIONS

Review the [Position Functions \(ADA-3\)](#) to verify that they are correct and current. Do they accurately reflect the individual's position?

### COMMUNICATE WITH INDIVIDUAL REGARDING IMPAIRMENT

Unless the individual's impairment is obvious, the agency may need to communicate with the individual regarding what his or her limitation(s) are and how long they will last. This communication may involve providing the individual with the position's essential functions and a list of questions for his or her health care provider.

### HEALTH CARE PROVIDER

A health care provider can provide the facts necessary to establish whether an individual meets the definition of disability, whether an accommodation is necessary and may recommend an accommodation.

Agencies should provide health care providers who conduct an examination with information about the individual's job, specifically the essential functions. The [Medical Inquiry in Response to an Accommodation Request form \(NPD-86\)](#) has been developed as a template; however, the questions asked of the health care provider must be chosen and adapted based on the individual's specific circumstances. Also, information that has already been provided may not be requested again.

### SECOND OPINION

The ADA does not prevent an employer from requiring an individual to go to an appropriate health professional of the employer's choice if the individual provides insufficient information from his treating

#### Keep in mind:

#### Keep in mind:

An employer may not ask for documentation when:

- Both the disability and the need for reasonable accommodation are obvious; or
- The individual has already provided the employer with sufficient information to substantiate that he or she has an ADA disability and needs reasonable accommodation.

An agency may not request complete medical records or health information unrelated to the disability.

health care professional to substantiate that he or she has an ADA disability and needs a reasonable accommodation. However, if an individual provides insufficient documentation in response to the agency's initial request, the agency should explain why the documentation is insufficient and allow the individual an opportunity to provide the missing information in a timely manner. Documentation is insufficient if it does not establish the existence (or not) of an ADA disability and explain the need for reasonable accommodation.

If an agency requires an employee to go to a health professional of the employer's choice, the agency must pay all costs associated with the visit(s). State administrative regulations provide a procedure for obtaining a second and third medical opinion, see [NAC 284.566](#).

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#### DOES THE INDIVIDUAL HAVE A COVERED DISABILITY?

It is the agency's responsibility to determine whether an individual meets the definition of disability under the ADA. The ADAAA states that this should not require extensive analysis.

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#### IS THE INDIVIDUAL QUALIFIED?

This analysis is a two step inquiry. 1. Does the individual have the skills, experience, education and other job-related requirements (e.g., certification, licensure) of the position? 2. Can the individual perform the essential functions of the position with or without accommodation?

Future, potential difficulties may not be considered in deciding if an individual is qualified.

If an agency adjusts a position and its essential functions based upon business necessity, an individual may no longer be qualified. Also, if an individual poses a direct threat in that position, then the individual is not qualified.

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#### DOES THE INDIVIDUAL POSE A DIRECT THREAT?

A direct threat is a significant risk ("a high, and not just a slightly increased, risk"<sup>6</sup>) of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation. The risk must be specific, current (not speculative) and based on objective facts.

In determining whether an individual with a disability poses a direct threat, the factors to consider include:

- the duration of the risk;
- the nature and severity of the potential harm;
- the likelihood that the potential harm will occur; and

- the imminence of the potential harm.

### DOES THE INDIVIDUAL NEED AN ACCOMMODATION?

Is the requested accommodation because of or related to the disability? An agency has a responsibility to provide accommodation for limitation(s) relating to a disability. It is not the agency's responsibility to provide accommodation to an individual with a disability if that accommodation will not compensate for the impairment affecting the employee's employment.

## RESEARCH ACCOMMODATION OPTIONS

### COMMUNICATION WITH INDIVIDUAL

In consultation with the individual to be accommodated, potential accommodations should be identified and assessed as to the effectiveness each would have in enabling the individual to perform the essential functions of the position. If this consultation with the individual does not reveal a potential reasonable accommodation, several other sources of information are available.

### RESOURCES

There are various resources for researching potential accommodations, see [Resources & References](#).

## SELECT AN EFFECTIVE ACCOMMODATION

Once potential accommodations have been identified, the agency should assess the effectiveness of each potential accommodation in assisting the individual in need of the accommodation to:

- participate in the application process;
- perform the essential job functions; and/or
- receive equal benefits and privileges of employment.

If more than one accommodation will effectively enable the individual to perform the essential functions or if the individual would prefer to provide the accommodation, the preference of the individual should be given primary consideration. However, it should be noted that the agency is encouraged, but not obligated, to select the preference of the individual. The agency providing the accommodation has the ultimate discretion to choose between effective reasonable accommodations, and may choose a less expensive, easier to provide or less disruptive of agency operations reasonable accommodation. Accommodations should be considered on a case-by-case basis.

When selecting a reasonable accommodation the following factors should be considered:

- the individual's impairment(s);
- the position's essential functions;
- impact on workflow;
- applicable productivity standards; and
- interaction with co-worker(s).

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### IS THE ACCOMMODATION AN UNDUE HARDSHIP?

#### “29 CFR §1630.2 Definitions...

(p) *Undue hardship*—(1) *In general.* *Undue hardship* means, with respect to the provision of an accommodation, significant difficulty or expense incurred by a covered entity, when considered in light of the factors set forth in paragraph (p)(2) of this section.

(2) *Factors to be considered.* In determining whether an accommodation would impose an undue hardship on a covered entity, factors to be considered include:

(i) The nature and net cost of the accommodation needed under this part, taking into consideration the availability of tax credits and deductions, and/or outside funding;

(ii) The overall financial resources of the facility or facilities involved in the provision of the reasonable accommodation, the number of persons employed at such facility, and the effect on expenses and resources;

(iii) The overall financial resources of the covered entity, the overall size of the business of the covered entity with respect to the number of its employees, and the number, type and location of its facilities;

(iv) The type of operation or operations of the covered entity, including the composition, structure and functions of the workforce of such entity, and the geographic separateness and administrative or fiscal relationship of the facility or facilities in question to the covered entity; and

(v) The impact of the accommodation upon the operation of the facility, including the impact on the ability of other employees to perform their duties and the impact on the facility's ability to conduct business.”

The general principle is that an accommodation does not have to be offered if it is an undue hardship for the State of Nevada. Although the full resources of the State of Nevada, not just the

unit the employee is in, would be considered when making this decision, agency management and the Department of Administration's Budget Division may need to be consulted.

A potential negative effect on the morale of other employees is not an undue hardship.

#### IMPLEMENT THE ACCOMMODATION

When offering a reasonable accommodation, it is suggested to explain the reason that particular accommodation is being offered (especially if it is not the accommodation that the individual requested). The Agency Response form (NPD-87) documents the decision in writing.

Proceed with implementing the accepted reasonable accommodation as soon as possible.

#### DOCUMENT THE ACCOMMODATION & PROCESS

If the interactive process breaks down, liability under the ADA will rest on whoever (employer or individual) did not meet their obligations in the process. Documentation will assist an agency in establishing that it fulfilled its obligations in the process.

It is recommended to write a summary of any meetings, submit a copy to attendees asking for revisions/corrections, finalize and then redistribute to all attendees. Summaries of any analysis and records of any research, printouts or notes from conversations should also be kept as documentation. And most importantly, there should be documentation outlining the final decision regarding any accommodation or decision against providing accommodation and the individual's response to an offer of reasonable accommodation. See [Confidentiality](#) for the guidelines on storage of documents containing medical information.

#### MONITOR THE ACCOMMODATION

An agency should follow up with an individual regarding the effectiveness of a reasonable accommodation. The follow up should be scheduled, performed and documented. The length of time between follow ups will depend on the type of accommodation provided. Follow ups should include communication with the individual.

If the follow up indicates that the reasonable accommodation is not allowing the individual to participate in the application process, perform the essential job functions or receive equal access to benefits and privileges of employment, the agency should re-enter the interactive process with the individual.

## TYPES OF ACCOMMODATION

### ACCESSIBILITY

Employment activities must take place in an integrated setting. Employees with disabilities may not be segregated into particular facilities or parts of facilities. This means that architectural barriers might have to be removed or altered to provide structural accessibility to the workplace. However, an employer is not required to make structural modifications that are unreasonable and would impose an undue hardship.

In existing structures, structural modifications are necessary to the extent that they will allow an employee with a disability to perform the essential functions of the job including access to work stations and normal support facilities such as bathrooms, water fountains, and lunchrooms.

The State Public Works Division may be able to provide limited consultation regarding accessibility issues, see the [Resources](#) page for contact information.

### POSITION RESTRUCTURING

Position restructuring as a reasonable accommodation may involve reallocating or redistributing the marginal functions of a position. An agency is not required to reallocate essential functions of a job as a reasonable accommodation. Essential functions, by definition, are those that a qualified individual must perform, with or without accommodation.

For example, firefighters are required to pass an annual physical agility test, which would include a lifting requirement, upon employment and annually thereafter as an essential function of the position. If an individual became disabled and could no longer meet the lifting requirement, it would not be reasonable to remove this test as it is essential to the job.

Although an agency is not required to reallocate essential job functions, it may be a reasonable accommodation to change when or how the essential functions are performed. For example:

- Reassigning duties among co-workers. For example, if an administrative assistant had a vision impairment that prevented him or her from typing in small spaces on forms, whenever such forms needed to be prepared, the marginal function might be assigned to another administrative assistant without a visual impairment. In exchange, the administrative assistant with a disability could assume one of the other administrative assistant's marginal functions, such as filing.
- Eliminate non-essential tasks. For example, if a duty(s) of the position is not necessary, it could be eliminated entirely. A mail clerk, rather than traveling to the post office in the early morning, might be allowed to wait for regular mail delivery.



- Reassign visits to accessible sites. For example, a repair person who uses a wheelchair could service the accessible sites, while the other sites could be assigned to someone without a mobility impairment.
- Allow work in other than the traditional office setting. For example, a telephone surveyor could make calls on a designated line from home instead of having to come regularly to an inaccessible office to make the calls.
- Assign uninterrupted work times for particular tasks. For example, an individual with a learning disability may have problems when his or her attention is interrupted. Scheduling uninterrupted work time might allow greater concentration and heighten the performance of such an individual.

## LEAVE

Flexible leave policies should be considered as a reasonable accommodation when an individual with a disability requires time off from work because of his or her disability. An agency is not required to provide additional paid leave as an accommodation, but should consider allowing use of accrued leave or leave without pay, where this will not cause an undue hardship. Such employees may meet the eligibility requirements of the Family and Medical Leave Act and the rights and benefits under this law need to be considered, see the [FMLA Overview](#).

How much leave is reasonable? The length of the leave granted will depend on the employee's disability and position. Most courts and the EEOC have indicated that indefinite leave is not reasonable. Also, providing leave for unpredictable attendance is generally not considered reasonable under the ADA.

## MODIFICATION OF WORK SCHEDULE

Many people with disabilities are fully qualified to perform jobs with the accommodation of a modified work schedule (e.g., a schedule other than a standard 8:00 a.m. to 5:00 p.m. workday or a standard Monday to Friday workweek). Depending on the nature of the work assignment and operational requirements, modifications to work schedules and hours may be a reasonable accommodation as long as it does not result in an undue hardship. Modified work schedules may include flexibility in work hours, the workweek, or part-time work. For example:

- An employee who is unable to drive at night (e.g., an employee with poor night vision) could be assigned day-shift work.
- An employee may need additional rest periods (e.g., employees diagnosed with multiple sclerosis, cancer, diabetes, respiratory conditions, mental illness).

- An employee with mobility or other impairments may find it difficult to use public transportation during peak hours, or may depend upon special para-transit schedules.
- An employee who needs kidney dialysis treatment may be unable to work two days per week because treatment is only available during work hours on weekdays.

## AUXILIARY AIDS

Some examples of auxiliary aids are interpreters, note takers, computer-aided transcription services, written materials, exchange of written notes, telephone handset amplifiers, assistive listening systems, telephones compatible with hearing aids, closed caption decoders, open and closed captioning, text telephones (TTYs), videotext displays, video interpreting services (VIS), accessible electronic and information technology, readers, taped texts, audio recordings, Braille materials and displays, screen reader software, magnification software, optical readers, secondary auditory programs (SAP) and large print materials.

### INTERPRETERS

“Effective October 1, 2008, regulations for the fields of Interpreting for the Deaf and CART (Computer Aided Realtime Translation) were developed. These regulations require providers of Interpreting/CART to be registered with the State of Nevada in order to legally perform CART or Interpreting in the State of Nevada.”<sup>10</sup> The Department of Health and Human Services, Aging and Disability Services Division maintains a [list of registered CART/Interpreters](#) on their website.

### MODIFICATION OR PURCHASE OF EQUIPMENT OR DEVICES

Purchase of equipment or modifications for existing equipment may be an effective accommodation for an employee to overcome existing barriers in performing the functions of a position. These devices range from very simple solutions, such as an elastic band that can enable a person with cerebral palsy to hold a pencil and write, to electronic equipment that can be operated with eye or head movements by people who cannot use their hands. Other types of equipment and devices that may be appropriate include, but are not limited to:

- Telephone headsets and adaptive light switches;
- Speakerphones;
- A supportive desk chair;
- A raised desk;
- Modified equipment controls for hand or foot operation;
- Keyboard hand rest and a finger guide mounted on equipment;

- Armrest attachments; or
- Buzzers to replace warning lights.

An agency is only obligated to provide equipment that is needed to perform a job; generally, there is no obligation to provide equipment that the individual uses regularly in daily life (e.g., hearing aid, wheelchair).

However, an agency may be obligated to provide items of this nature if special adaptations are required to perform a job. For example, an employee with a mobility impairment may own and use a manual wheelchair. If the employee's job requires movement between buildings that are widely separated and the employee's mobility impairment prevents operation of a wheelchair manually for that distance, or if heavy, deep-pile carpeting prevents operation of a manual wheelchair, then it may be a reasonable accommodation to provide an employee with a motorized wheelchair.

## MODIFICATION OF WORK ENVIRONMENT

### MODIFICATION OF POLICIES AND/OR PROCEDURES

Modifications or adjustments in the ways that tests and training are administered or revisions to other employment policies and practices may be reasonable accommodations to provide equal employment opportunities for individuals with disabilities.

Modifications to policies and procedures may include:

- Modifying a policy prohibiting animals in the workplace, so that a person with a disability may be accompanied by a service animal (dog or miniature horse<sup>12</sup>)
- Modifying an emergency evacuation procedure to provide effective evacuation for individuals with difficulty in mobility in case of emergency
- Providing accessible parking for an individual with a qualified sticker, license plate or placard

When the accommodation provided for an individual with a disability is the modification of a policy, the agency may still continue to apply the policy to all other employees.

## TELECOMMUTING

The EEOC has stated that telecommuting is a potential reasonable accommodation if it is effective and does not constitute an undue hardship.<sup>9</sup> However, some questions to be considered when deciding whether telecommuting is a reasonable accommodation are:

- Is teamwork an essential function of the position?
- Does the position require the individual to be physically present?
- Does the individual need physical access to documents and information?
  - Are any of the documents or information confidential?
- Does the position have clearly defined and measurable work activities?
- Does the position need close supervision?
- Does the position require special equipment?

## REASSIGNMENT

Before considering reassignment of an employee to a vacant position, accommodations that will allow the employee to remain in his or her position should be considered. Reassignment is only required for current employees, not prospective employees. The State is not required to consider a different position for a job applicant who is not able to perform the essential functions of a position, with or without reasonable accommodation. Reassignment to a vacant position cannot be denied based on the fact that the individual is not a permanent employee. However, if the employee never adequately performed the essential functions with or without reasonable accommodation, reassignment is not necessary as the individual was never qualified.

Reassignment may not be used to limit, segregate, or otherwise discriminate against an employee with a disability. An agency may not reassign people with disabilities only to certain undesirable positions, or only to certain offices or facilities.

## Appendix to Title 29, Part 1630—Interpretive Guidance on Title I of the Americans with Disabilities Act

“The appropriate reasonable accommodation is best determined through a flexible, interactive process that involves both the employer and the individual with a disability...

When an individual with a disability has requested a reasonable accommodation to assist in the performance of a job, the employer, using a problem solving approach, should:

(1) Analyze the particular job involved and determine its purpose and essential functions;

(2) Consult with the individual with a disability to ascertain the precise job-related limitations imposed by the individual's disability and how those limitations could be overcome with a reasonable accommodation;

(3) In consultation with the individual to be accommodated, identify potential accommodations and assess the effectiveness each would have in enabling the individual to perform the essential functions of the position; and

(4) Consider the preference of the individual to be accommodated and select and implement the accommodation that is most appropriate for both the employee and the employer...”

Reassignment shall be made to a position equivalent to the one presently held in terms of pay, privileges, benefits, geographical location and responsibilities, if the individual is qualified for the new position and if such a position is vacant or will be vacant within a reasonable amount of time unless it is demonstrated that such an appointment would cause an undue hardship to the appointing authority. A "reasonable amount of time" should be determined on a case-by-case basis.

An employee must be "qualified" for the new position. An employee is "qualified" for a position if the employee:

1. Satisfies the requisite skill, experience, education, and other job-related requirements of the position; and
2. Can perform the essential functions of the new position, with or without reasonable accommodation.

The employee does not need to be the best-qualified individual for the position in order to obtain it as a reassignment. An employee being reassigned does not have to compete for a position if it is equivalent or a lower grade than the employee's current position.

The State of Nevada shall offer to reassign an individual to an equivalent position in a different geographical location if there are no equivalent positions vacant or soon to be vacant in the same geographical location.

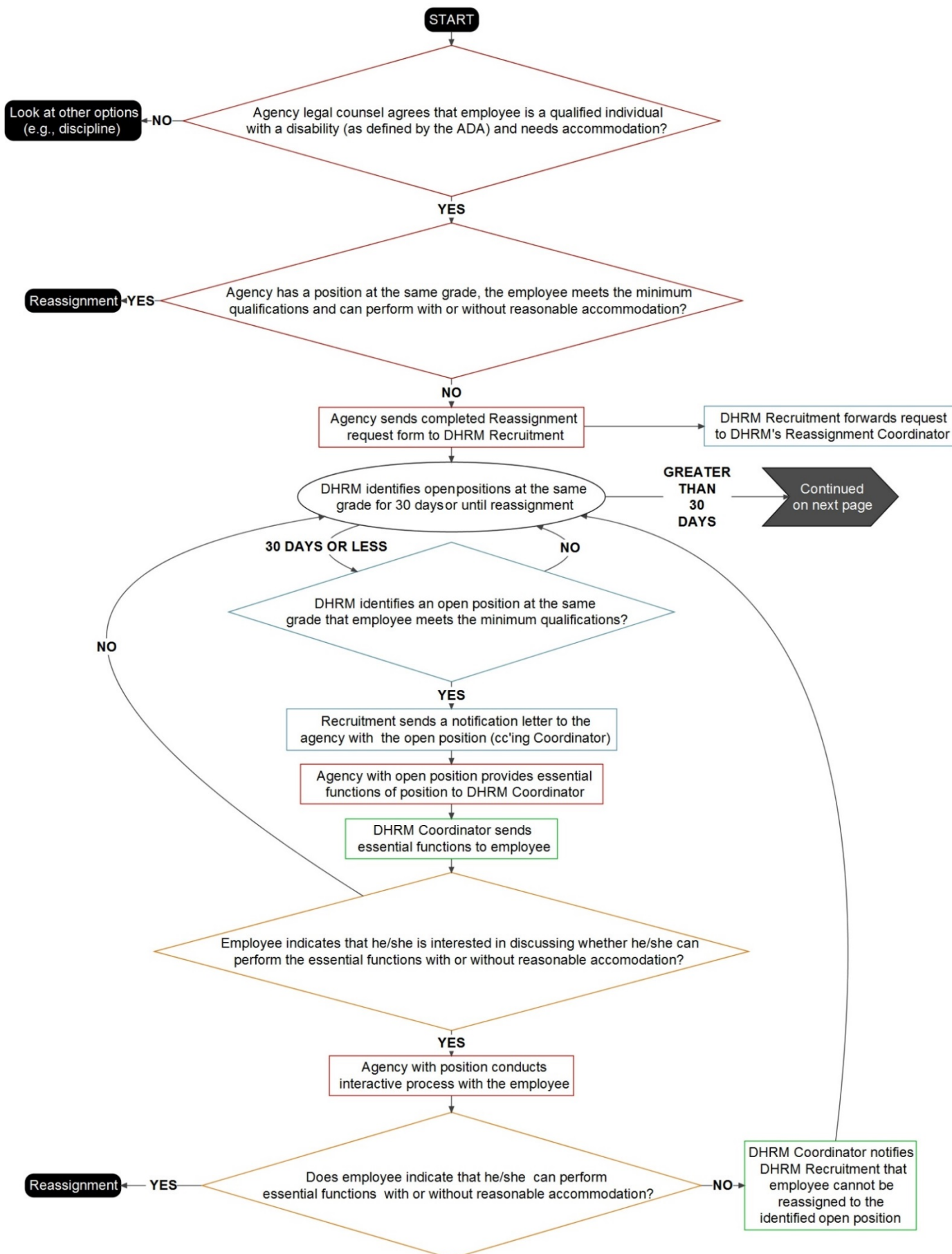
The State of Nevada shall offer to reassign an individual to a lower graded position (unless it is demonstrated that such an appointment would cause an undue hardship to the appointing authority) if there are no reasonable accommodations that would enable the employee to remain in the current position and there are no equivalent positions vacant or soon to be vacant for which the employee is qualified (with or without an reasonable accommodation). In such a situation, the State does not have to maintain the individual's salary at the level of the higher graded position. Refer to the rules governing compensation in the [Rules for State Personnel Administration](#) for how to calculate pay in the case of a voluntary demotion.

If there is more than one vacancy for which the employee is qualified, the State must place the individual in the position that comes closest to the employee's current position in terms of pay, status, privileges and responsibilities. If it is unclear which position comes closest, the employee should be consulted about his or her preference before determining the position to which the employee will be reassigned. Reassignment does not include giving an employee a promotion; thus, an employee must compete for any vacant position that would constitute a promotion.

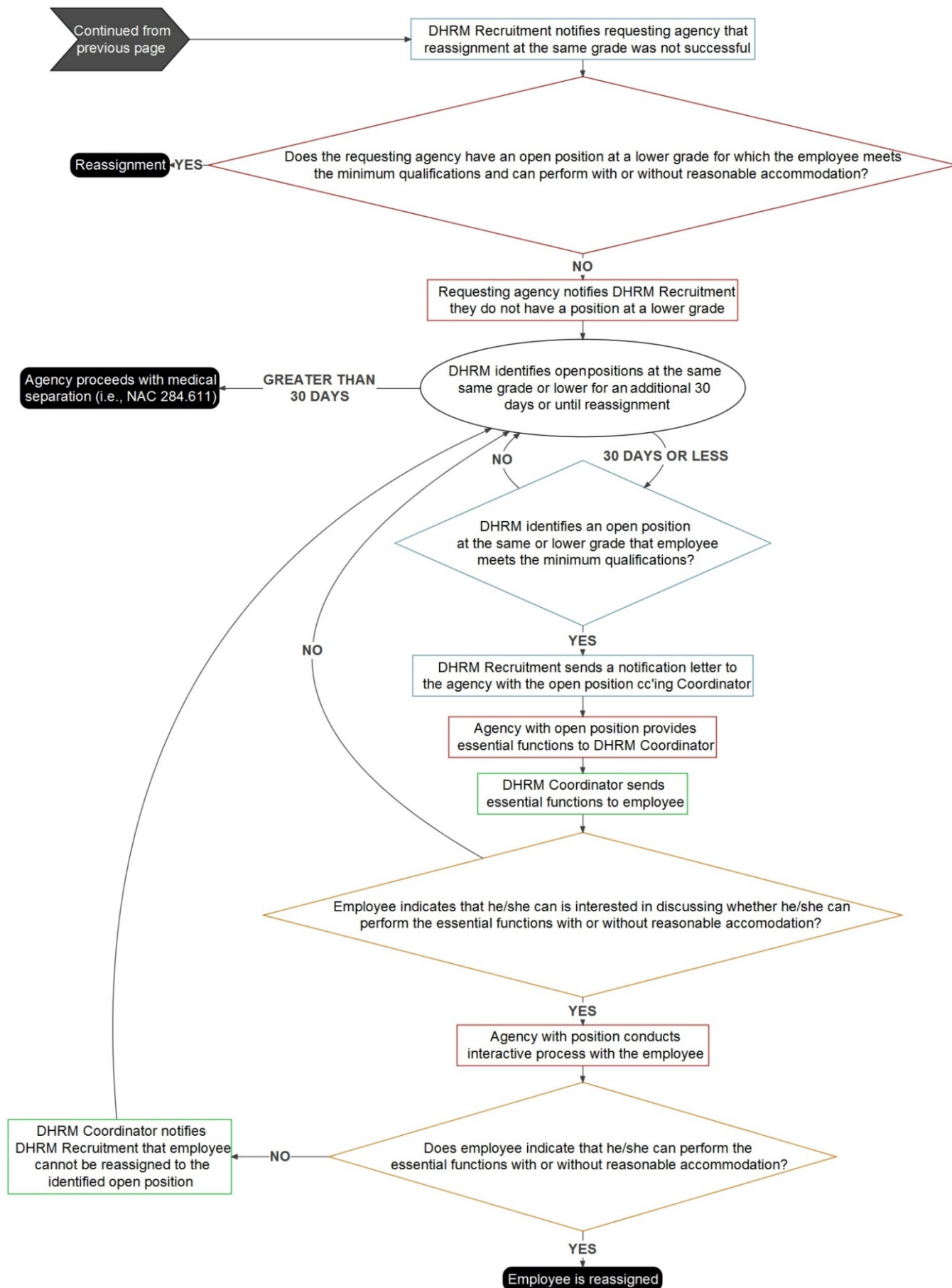
The State of Nevada is not required to create a new job or to bump another employee from a job in order to provide reassignment as a reasonable accommodation.

[\(Sections 2 – 4 of LCB File No. R097-16, 11-2-2016\)](#)

# REASSIGNMENT PROCESS







## FUNDING

The cost of accommodation does vary; however, the majority of accommodations can be provided at little or no cost.

Once the appropriate accommodation is identified, in consultation with the individual in need of the accommodation, an employer should work with their assigned Budget Analyst to determine appropriate State funding sources.

In addition, the U.S. Department of Veterans Affairs may provide financial assistance to disabled veterans for equipment needed to help perform jobs. Some organizations that serve people with particular types of disabilities also provide financial assistance for needed accommodations. Other types of assistance may be available in the community such as transportation services.

Also, the applicant or employee may be willing to share in the cost of the accommodation, which is an undue hardship on the State, or may already own the equipment or assistive device necessary to perform the essential functions of the job.



## CONFIDENTIALITY

All information obtained from medical examinations and inquiries must be collected and maintained on separate forms, in separate secure medical files and must be treated as confidential medical records per [NAC 284.726](#).

All medical-related information must be kept confidential, with the following exceptions:

- Supervisors and managers may be informed about necessary restrictions on the work or duties of an employee and necessary accommodations;
- First aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment;
- Government officials investigating compliance with the ADA must be given relevant information upon request;
- Relevant information may be provided to state workers' compensation offices, "second injury" funds and workers' compensation insurance carriers in accordance with state workers' compensation laws; or
- Relevant information may be provided to insurance companies where the company requires a medical examination to provide health or life insurance for employees.

## DEALING WITH RESPONSES FROM CO-WORKERS

Other employees may at times perceive an individual as being given preferential treatment. However, others (including co-workers) may not be told that the individual is receiving a reasonable accommodation because this would usually amount to a disclosure that the individual has a disability.

As long as there is no coercion by the employer, an individual with a disability may voluntarily choose to disclose to coworkers his or her disability and/or the fact that he or she is receiving a reasonable accommodation.

**What can a supervisor or human resources say when co-workers ask about another employee's accommodation?**

"The State's policy is to assist individuals who encounter difficulty in the workplace. However, many workplace issues encountered by individuals are personal and, in those circumstances, it is the State's policy to respect an individual's privacy. Your privacy would also be respected if you found it necessary to ask for some kind of workplace change for personal reasons."<sup>4</sup>

## OTHER LAWS & PROVISIONS

### FAMILY AND MEDICAL LEAVE ACT (FMLA)

The FMLA and the ADA both potentially grant an employee leave in certain circumstances. Under the ADA, unpaid (though applicable paid may be used) leave may be an accommodation and may be provided to an individual with a disability who is otherwise qualified when it is reasonable and unless (or until) it imposes an undue hardship on the operation of the employer's business. Under the FMLA, an "eligible" employee may take leave for a qualifying event, as outlined in the [FMLA Overview](#).

At the end of FMLA leave, an agency must return the employee to the same or an equivalent job. An employee with an ADA disability who is granted leave as a reasonable accommodation is entitled to return to his or her same position unless the agency demonstrates that holding open the position would impose an undue hardship or an employee is no longer qualified to return to his or her original position. If both laws apply, the agency must provide the employee with the greater benefit and restore the employee to his or her same position absent undue hardship.

Not all employees protected by the ADA are entitled to leave under the FMLA. Employees protected by the ADA must be independently determined to be eligible for FMLA coverage. An FMLA "serious health condition" is not necessarily an ADA "disability" and an ADA "disability" is not necessarily an FMLA "serious health condition". In addition, the fact that an individual has a record of a "serious health condition" does not necessarily mean that he or she has a record of an ADA disability.

When an employee requests leave under the FMLA for a "serious health condition", an agency will not violate the ADA by asking for the information specified in a FMLA certification form. An agency is entitled to know why an employee, who otherwise should be at work, is requesting leave as allowed under the FMLA. If the inquiries are strictly limited in this fashion, they would be "job-related and consistent with business necessity" under the ADA.

The FMLA limitation on the number of workweeks of leave taken does not mean that the ADA also limits employees to a specific number of workweeks of leave per year. An individual with a disability who is otherwise qualified may be entitled to more than 12 weeks of unpaid leave as an accommodation if the additional leave is reasonable and will not impose an undue hardship on the operation of the agency's business.

### GENETIC INFORMATION NONDISCRIMINATION ACT (GINA)

GINA defines genetic information as including, "information about an individual's genetic tests and the genetic tests of an individual's family members, as well as information about any disease,

disorder, or condition of an individual's family members (i.e. an individual's family medical history).”<sup>7</sup>

GINA prohibits requesting or receiving genetic information. Genetic information may be provided by a health care provider in response to medical inquiries as part of the ADA's interactive process. If an employee and/or his or her health care provider is warned not to provide genetic information, receipt of genetic information is not a violation of GINA. The EEOC's Regulations Under the Genetic Information Nondiscrimination Act of 2008 provides the following sample language to be included with requests for medical information:

“The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. ‘Genetic information’ as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services.”<sup>7</sup>

The EEOC has stated that genetic information may be kept with other medical information in compliance with the ADA's rules on medical records confidentiality.

#### HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA)

Title IV of the Act defines rules for protection of patient information. Health care providers, health organizations, and government health plans that use, store, maintain, or transmit patient health care information are required to comply with the privacy regulations of HIPAA. It sets limits on the use and release of health records and establishes safeguards to protect the privacy of health information. In general, a health care provider or plan may not use or disclose an individual's healthcare information without the patients permission except for treatment, payment or healthcare operations. Typically, most agencies, in regards to their employees, are not covered by HIPAA regulations. The requirements of the HIPAA Privacy Rule can apply when an employee's medical information is requested from a HIPAA-covered health care provider. Regardless of whether HIPAA applies in the situation, medical information must be kept confidential and separate from other personnel records.

## WORKERS' COMPENSATION

The purpose of workers' compensation is to provide a system for securing prompt and fair settlement of employees' claims against employers for occupational injury and illness. Whereas, the purpose of the ADA is to remove barriers which prevent qualified individuals with disabilities from enjoying the same employment opportunities that are available to persons without disabilities.

Whether an injured worker is protected by the ADA will depend on whether or not the individual meets the ADA definition of an individual with a disability who is qualified.

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### EARLY RETURN-TO-WORK PROGRAM

The State of Nevada has established an Early Return-to-Work Program to enhance recovery, help minimize workers' compensation costs and provide a service to employees who are injured or contract an occupational disease in the course and scope of their employment with the State. Employees will be placed in temporary modified duty positions, when feasible, during the course of recovery from an injury or occupational disease that precludes them from performing their normal job tasks. In the event of a permanent disability that prevents an employee from performing the essential functions of his or her regular position and for which reasonable accommodation cannot be made, every effort will be made to place the employee in an alternative vacant position that he or she is qualified to perform and that matches his or her physical limitations. See the [Early Return-to-Work Program, A Guide for Managers, Supervisors and Personnel Representatives](#) for additional information. The Risk Management Division serves as a technical resource for the Early Return-to-Work Program. Call (775) 684-3187 for information or assistance.

## VOCATIONAL REHABILITATION

Vocational rehabilitation is a State and federally funded program to help eligible individuals with disabilities obtain or retain a job. As appropriate to the vocational rehabilitation needs of each client and consistent with the individual's informed choice, vocational rehabilitation provides assessment and evaluation, counseling and guidance, training, interpretation, and other goods and services to allow an individual with a disability who is qualified to become employed or retain employment. The Rehabilitation Division of the Department of Employment, Training and Rehabilitation may be able to provide agencies with consultation in the accommodation process. See [Resources](#) for the Rehabilitation Division's contact information.

## SEPARATION FOR PHYSICAL, MENTAL OR EMOTIONAL DISORDER (NAC 284.611)

[NAC 284.611](#) allows for the separation of an employee for physical, mental or emotional disorder; however, the regulation outlines specific steps that must be taken before proceeding with this action. One of the steps is "determine whether reasonable accommodation can be made to enable the employee to perform the essential functions of his job".

## 700-HOUR STATUTE

The 700-Hour statute requires agencies to make temporary limited appointment of 700 hours' duration of individuals with disabilities. Individuals must be certified by the Rehabilitation Division of the Department of Employment, Training and Rehabilitation (see [Resources](#) for contact information in both northern and southern Nevada), possess the training and skills necessary for the position, and be able to perform the essential functions of the position with or without reasonable accommodation.

Once employed, the 700 hours of work experience are used to measure the individual's merit and fitness for the job. At the end of the appointment, if the individual's performance is satisfactory, he or she may continue in the position as a regular employee with the 700 hours counting toward the time required to earn permanent status.

A probationary or permanent employee who occupies a permanent full-time position is not eligible for the provisions of this section unless his or her disability jeopardizes his or her continued employment in his or her present position and placement on the list does not merely circumvent the provisions of the Rules for State Personnel Administration governing promotion or transfer, see [NRS 284.327](#) and [NAC 284.364](#).

## NEVADA PREGNANT WORKERS' FAIRNESS ACT

Upon request, an employee must be provided reasonable accommodations relating to her pregnancy, childbirth, or a related medical condition unless the accommodation would impose an undue hardship.

## RESOURCES & REFERENCES

### RESOURCES

Resource	Website/email address	Phone number(s)
AbleData	<a href="http://www.abledata.com">http://www.abledata.com</a>	
AccessibleTech.org	<a href="http://www.accessibletech.org">http://www.accessibletech.org</a>	
ADA Home Page	<a href="http://www.ada.gov">http://www.ada.gov</a>	
Bureau of Vocational Rehabilitation, Nevada Department of Employment, Training & Rehabilitation	<a href="http://www.detr.state.nv.us/Rehab%20pages/voc%20rehab.htm">http://www.detr.state.nv.us/Rehab%20pages/voc%20rehab.htm</a>	S. NV: (702) 486-5230  N. NV: (775) 684-4040  S. NV TTY: (702) 486-1018  N. NV TTY: (775) 684-8400
Division of Human Resource Management	<a href="http://hr.nv.gov">http://hr.nv.gov</a>	(775) 684-0111
Disability and Business Technical Assistance Centers (DBTAC): Pacific ADA Center	<a href="http://www.adapacific.org">http://www.adapacific.org</a>	

Resource	Website/email address	Phone number(s)
The Job Accommodation Network	<a href="http://www.askJAN.org">http://www.askJAN.org</a>	Voice  (800) 526-7234  TTY  (877) 781-9403
National Center for the Dissemination of Disability Research	<a href="http://www.ncddr.org">http://www.ncddr.org</a>	
The National Organization on Disability	<a href="http://www.nod.org">http://www.nod.org</a>	
Nevada PEP	<a href="http://www.nvpep.org">http://www.nvpep.org</a>	
Public Works Division	<a href="http://spwb.state.nv.us/">http://spwb.state.nv.us/</a>	(775) 684-4141
Registry of Interpreters for the Deaf	<a href="http://www.rid.org/">http://www.rid.org/</a>	(301) 608-0050
RESNA Technical Assistance Project	<a href="http://www.resna.org/">http://www.resna.org/</a>	Voice (703) 524-6686  TTY (703) 524-6639
Risk Management Division, Department of Administration (workers' compensation)	<a href="http://risk.state.nv.us">http://risk.state.nv.us</a>	(775) 687-3187

U.S. Equal Employment Opportunity Commission	<a href="http://www.eeoc.gov/">http://www.eeoc.gov/</a>	Voice (800) 669- 3362  TTY (800) 800- 3302
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## REFERENCES

- <sup>1</sup> ADA Amendments Act of 2008, Public Law 110-325, September 25, 2008
- <sup>2</sup> U.S. Equal Employment Opportunity Commission, Regulations to Implement the Equal Employment Provisions of the Americans with Disabilities Act, as Amended, Final Rule, Federal Register, Vol.76, No. 58
- <sup>3</sup> U.S. Equal Employment Opportunity Commission, Enforcement Guidance: Disability-Related Inquiries and Medical Examinations of Employees under the Americans with Disabilities Act (ADA), Number 915.002, 7/27/00
- <sup>4</sup> U.S. Equal Employment Opportunity Commission, Enforcement Guidance: Reasonable Accommodation and Undue Hardship under the Americans with Disabilities Act, Number 915.002, 10/17/02
- <sup>5</sup> U.S. Equal Employment Opportunity Commission, Questions and Answers about the Association Provision of the Americans with Disabilities Act, [http://www.eeoc.gov/facts/association\\_ada.html](http://www.eeoc.gov/facts/association_ada.html)
- <sup>6</sup> U.S. Equal Employment Opportunity Commission, Enforcement Guidance on the Americans with Disabilities Act and Psychiatric Disabilities, Number 915.002, 3/25/97
- <sup>7</sup> U.S. Equal Employment Opportunity Commission, Regulations Under the Genetic Information Nondiscrimination Act of 2008, Final rule, Federal Register, Vol. 75, No. 216
- <sup>8</sup> U.S. Equal Employment Opportunity Commission, Enforcement Guidance: Workers' Compensation and the ADA, Number 915.002
- <sup>9</sup> U.S. Equal Employment Opportunity Commission, Work At Home/Telework as a Reasonable Accommodation, <http://www.eeoc.gov/facts/telework.html> (last modified October 27, 2005)
- <sup>10</sup> Department of Health and Human Services, Division of Aging and Disability, Office of Disability Services website, [http://dhhs.nv.gov/Qry\\_CartInt\\_Registered.asp](http://dhhs.nv.gov/Qry_CartInt_Registered.asp) (accessed 7/6/11)
- <sup>11</sup> The Americans with Disabilities Act of 1990 and Injured Workers. (1997, 2001) [Brochure] Cornell University, Bruce Growick (<http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1027&context=edicollect>, accessed 7/26/11)
- <sup>12</sup> Department of Justice, Civil Rights Division, Nondiscrimination on the Basis of Disability in State and Local Government Services, Final Rule, Federal Register, Vol. 75, No.178
- <sup>13</sup> ADA Update on Medical Examinations and Disability-Related Inquiries, National Employment Law Institute, David K. Fram Esq., April 2013

# State of Nevada Executive Branch

## SEXUAL HARASSMENT AND DISCRIMINATION POLICY

Sexual harassment and discrimination based on race, color, national origin, religion, sex, age, disability, pregnancy, sexual orientation, genetic information, gender identity or expression, domestic relations<sup>1</sup> or compensation or wages<sup>2</sup> in any term, condition or privilege of employment are violations of State and/or federal law.

### I. PURPOSE

The purpose of this Policy statement regarding sexual harassment and discrimination is to clearly express the position of the State of Nevada that all employees have the right to work in an environment free from all forms of discrimination and conduct which can be considered harassing, coercive or disruptive.

Sexual harassment and discrimination are forms of misconduct that undermine the integrity of the employment relationship. No employee, either male or female, should be subjected to unsolicited and unwelcomed sexual overtures or conduct, either verbal, written (including digital media, i.e., email, text or digital photos or graphics) or physical. No employee should experience discrimination in hiring, promotion, discharge, pay, fringe benefits, job training, classification, referral, and other aspects of employment. Sexual harassment and discrimination are personally offensive, debilitate morale, and, therefore, interfere with work effectiveness. An employee who engages in discriminatory behavior, or behavior that constitutes sexual harassment, may be subject to disciplinary action up to and including dismissal.

### II. COVERAGE

This Policy is intended to be applicable to all State employees, officers, appointees such as board members, and volunteers in the executive branch of government. All elected officers are encouraged to adopt this Policy within their agencies.

<sup>1</sup> AB 229 (2017); AB 227 (2017).

<sup>2</sup> NRS 613.330.

### III. RESPONSIBILITY

- A. Sexual harassment and discrimination, whether committed by a supervisor, coworker, or member of the public is specifically prohibited as unlawful and against State policy. Appointing authorities are responsible for taking immediate and corrective action in response to complaints, regardless of whether the specific acts complained of were sanctioned or specifically forbidden and regardless of the manner in which the appointing authority becomes aware of the conduct.
- B. Appointing authorities must ensure that each employee is provided with a copy of this Policy informing them that sexual harassment and discrimination are prohibited conduct and will not be tolerated or condoned. All employees will acknowledge receipt and understanding of the Policy through a signed statement.
- C. All new employees, officers, appointees, board members and volunteers in the executive branch shall attend sexual harassment prevention training within six months of their appointment. Thereafter, employees are required to complete sexual harassment prevention refresher training once every two years.
- D. Managers and supervisors are also required to attend additional training related to equal employment opportunity within 12 months of supervisory appointment and every three years thereafter.
- E. Appointing authorities shall advise all employees of their responsibility to report incidents of sexual harassment and discrimination.
- F. Appointing authorities shall designate employees within each agency to act as coordinators for the reporting of complaints of sexual harassment or discrimination and will notify employees and the Sexual Harassment/Discrimination Investigation Unit of the coordinator's name and contact information.
- G. Supervisors shall have a complete understanding of this Policy. Supervisors who willfully disregard incidents of sexual harassment or discrimination by subordinates may be subject to discipline. Supervisors are responsible for ensuring their employees have received training as outlined in this Policy.

- H. It is the responsibility of appointing authorities to make sure their agencies are in full compliance with this Policy and associated legal guidelines.

#### **IV. STATE EMPLOYEES' RIGHTS AND RESPONSIBILITIES**

- A. Employees are entitled to work in a workplace free of sexual harassment and discrimination.
- B. Employees are responsible for ensuring they do not sexually harass or discriminate against any other employee, client, applicant for employment, or other individual(s).
- C. Employees are responsible for cooperating in the investigation of any complaint of alleged sexual harassment or discrimination. Employees are additionally responsible for cooperating with the efforts of their agency, division, board or commission to prevent and eliminate sexual harassment and discrimination and for maintaining a working environment free from such unlawful conduct. Pursuant to NAC 284.650, failure to participate in any investigation of alleged discrimination, including without limitation, an investigation of sexual harassment is cause for disciplinary action.

#### **V. LEGAL DEFINITIONS AND GUIDELINES**

- A. NAC 284.771 specifies that sexual harassment violates the policy of this State and is a form of unlawful discrimination based on sex under State and federal law. An employee shall not engage in sexual harassment against another employee, an applicant for employment, or any other person in the workplace.

Sexual harassment is a very serious disciplinary infraction. An appointing authority may impose harsh disciplinary sanctions on persons who commit sexual harassment, even on first-time offenders.

- B. As used in Section 703 of Title VII of the Civil Rights Act of 1964, "sexual harassment" means unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when:
  - 1. Submission to such conduct is made either explicitly or implicitly a term or condition of a person's employment; or

2. Submission to or the rejection of such conduct by a person is used as the basis for employment decisions affecting that person; or
  3. Such conduct has the purpose or effect of unreasonably interfering with a person's work performance or creating an intimidating, hostile or offensive work environment. 29 C.F.R. § 1604.11.
- C. Equal opportunity with regard to the terms, conditions and privileges of employment is mandated under Title VII of the Civil Rights Acts of 1964, the Americans with Disabilities Act of 2008, the Age Discrimination in Employment Act of 1967, the Equal Pay Act of 1963, Genetic Information Nondiscrimination Act of 2008, NRS 631.330, NRS 281.370, and numerous sections of Chapter 284 of the NRS which address the State's Personnel System.
- D. The State of Nevada is an equal opportunity employer and does not discriminate against job applicants or employees based on race, color, religion, sex, national origin, disability, age, pregnancy, sexual orientation, genetic information, gender identity or expression, domestic relations, or compensation or wages.
- E. Federal law prohibits retaliation against employees who bring sexual harassment or discrimination charges or assist in investigating such charges. Any employee making sexual harassment or discrimination complaints or assisting in the investigation of such a complaint will not be adversely affected in terms or conditions of employment, nor discriminated against, disciplined or discharged because of the complaint.

## **VI. PROCEDURE**

- A. Employee
1. Employees who believe they have been subjected to or witnessed sexual harassment or discrimination are encouraged to advise the person believed to have engaged in sexual harassment or discrimination that the conduct is unwelcome, undesirable or offensive. If the employee elects not to confront the alleged harasser or if the conduct persists after an objection, the employee shall report the incident to their supervisor or next level authority, or the employee may elect to report the incident as set forth below. Employees will be asked to complete a complaint form.

2. Employees may report incidents of sexual harassment or discrimination (a) to the coordinator within their agency designated to receive such complaints, or (b) by filing a complaint in NEATS on the Home Page, under Personal Tasks, "File a Sexual Harassment or Discrimination Complaint," or (c) by completing an NPD-30 Sexual Harassment or Discrimination Complaint Form located on the Division of Human Resource Management website, or (d) by calling the Division of Human Resource Management's Harassment/Discrimination Hotline at (800) 767-7381. Employees are always entitled to consult an attorney or labor representative or to report the incident to the Nevada Equal Rights Commission or the Equal Employment Opportunity Commission.
3. Employees should give the completed complaint form and any supporting documentation to the coordinator designated within their agency to receive such complaints or to the assigned investigator(s).

#### B. Appointing Authorities

1. After receiving notification of an employee's complaint, the appointing authority shall promptly notify the agency's assigned personnel, Deputy Attorney General or staff counsel assigned to represent the agency pursuant to State Administrative Manual § 1702 (legal counsel) and the Division of Human Resource Management's Sexual Harassment/Discrimination Investigation Unit. The agency coordinator will complete the complaint intake report and obtain a completed copy of the complaint form from the employee filing the complaint. The coordinator will forward a copy of the completed intake report to the agency's legal counsel and the Sexual Harassment/Discrimination Investigation Unit, along with any supporting documentation. The agency coordinator may also submit the complaint via NEATS.
2. The investigator will begin the investigation as soon as witnesses are available.
3. Investigations will be conducted as discreetly and with as little disruption to the workplace as possible. All information gathered in an investigation will be kept confidential, and

the confidential nature of the investigative process will be conveyed to the complainant, the accused and each witness.

4. The investigator will prepare a written report of findings, which will be submitted to the appointing authority, the agency's legal counsel, and the agency's chief personnel officer. The ultimate decision for remedial action is the responsibility of the appointing authority; however, the investigative staff may suggest mediation services, if appropriate.
5. After the investigation has been completed, the appointing authority will review the findings and recommendations and determine the appropriate resolution of the case. If warranted, the agency, after consultation with their legal counsel, may take disciplinary action up to and including termination. The agency shall retain a written record of the findings of the investigation and the resolution of the complaint as confidential records.
6. At the conclusion of the Division of Human Resource Management's Sexual Harassment/Discrimination Investigation Unit's investigation, the Division of Human Resource Management will notify the complainant in writing that the investigation was completed and forwarded to their agency for review. The agency, in consultation with their assigned legal counsel, shall notify both the complainant and the accused in writing at the conclusion of their administrative review. A copy of the Notification letter that is sent to the complainant and/or accused must be sent to the Sexual Harassment/Discrimination Investigation Unit for its files. Additionally, the agency shall take whatever corrective action it deems appropriate following consultation with its legal counsel. Corrective action that involves discipline of the accused is confidential pursuant to NAC 284.718 and must not be disclosed except as authorized pursuant to NAC 284.726.

#### C. Complaint Submitted Through the Hotline

1. When an employee transmits a complaint of sexual harassment or discrimination through the State hotline, the Sexual Harassment/Discrimination Investigation Unit will complete the initial intake report and/or submit the complaint in NEATS.

2. The agency coordinator will be notified of the complaint via NEATS.
3. The investigation will then proceed as described for complaints submitted to appointing authorities (*see* Item VI-B).





**STATE OF NEVADA  
EXECUTIVE BRANCH  
SEXUAL HARASSMENT & DISCRIMINATION  
POLICY**

**SEXUAL HARASSMENT AND DISCRIMINATION  
POLICY ACKNOWLEDGEMENT**

EMPLOYEE NAME: \_\_\_\_\_

EMPLOYEE ID #: \_\_\_\_\_

DEPT/DIV/AGENCY/ORG #: \_\_\_\_\_

☐

I have read and understand the *Sexual Harassment and Discrimination Policy* dated 4/18/18.

EMPLOYEE SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_

SUPERVISOR SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_

# STATE OF NEVADA



## INFORMATION SECURITY PROGRAM POLICY 100 REV C

Original Publication Date: **October 28, 2008 Interim Approval**

Revision Date: March 30, 2017 Approval

Established and Approved by the:  
**Nevada State Information Security Committee**

Approved by the:  
**State Chief Information Officer**

Sponsored by the:  
**Enterprise IT Services  
Office of Information Security**

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## Preface

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*Enterprise IT Services (EITS) has the statutory responsibility for establishing regulations and providing guidance to state entities within the Executive Branch of Nevada State Government for the protection of state information technology (IT) systems, and the data that those systems process, store, and transmit electronically. To support those responsibilities, EITS established the Office of Information Security (OIS) to develop appropriate security regulations and guidance, along with staff as subject matter experts to guide and assist state entities in establishing entity specific security policies, standards, processes and plans. NRS 242.101.*

*To ensure the security concerns and needs of state entities are included in the development of the State Information Security Program, a State Information Security Committee was established. This committee consists of representatives from state entities with information technology backgrounds who have a vested interest in the development of the security policies, standards and guidance.*

*As the State Information Security Program and the State Information Security Policy evolves, this document will be subject to review and update, which will occur biennially or when changes occur that signal the need to revise the State Information Security Policy. These changes may include the following:*

- *Changes in roles and responsibilities;*
- *Release of new executive, legislative, technical or State guidance;*
- *Identification of changes in governing policies;*
- *Changes in vulnerabilities, risks or threats; and/or*
- *Legislative Audit findings that stem from security audit.*

*The International Standard ISO/IEC 27002:2005 (E) Code of Practice for Information Security Management and the National Institute of Standards and Technology, NIST Publication 800 series were used as guidance in the development of this policy. All reference documents provide the best industry practices and the requirements of the federal government, which require state compliance due to receiving federal funds for information systems or from accessing, processing, storing or transmitting federal data.[ The requirements of NIST 800-53 and 800-100 will be the de facto state standard in situations where neither the state nor the agency has established a policy or standard on a specific security control ]*

*This policy has been developed and approved by the State Information Security Committee and has received final approval by the State Chief Information Officer. Revisions to this document are subject to the review and approval of the State Information Security Committee, with final approval of the State Chief Information Officer. When revisions are approved, a new version of the State Information Security Policy will be issued, and all affected state entities will be informed of the changes.*

*Additionally, compliance with this policy is mandatory. It is the State Chief Information Officer's direction that all state entities within the Executive Branch of Nevada State Government, with the exception of the Nevada System of Higher Education and the Nevada Criminal Justice Information Computer System, comply with the direction of this policy.*

*In cases where a state entity cannot comply with any section of the State Information Security Policy, justifications for the noncompliance must be documented using the Exception Request process provided in Appendix A of this document. The Exception Request must be submitted to EITS, Office of Information Security, Chief Information Security Officer (CISO) for approval. Resulting risks from a deviation to policy must be documented in the appropriate Information Security Plan.*

## Document Change History

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<b>Version Number</b>	<b>Release Date</b>	<b>Summary of Changes</b>	<b>Chapter Number/ Paragraph Number</b>	<b>Changes Made By</b>
<i>A</i>	<i>10/28/2008</i>	<i>Initial Document Release</i>		
<i>B</i>	<i>07/12/2011</i>	<i>Revised background checks.</i>	<i>3.4.2</i>	<i>S. Ingersoll</i>
<i>C</i>	<i>03/30/2017</i>	<i>Review and Update – Rename 4.100000</i>	<i>Multiple</i>	<i>EITS/OIS</i>

<b>TITLE</b>	<b>SIGNATURE</b>	<b>DATE</b>
<i>State IT Security Committee Chair</i>		
<i>State Chief Information Security Officer</i>		
<i>State Chief Information Officer</i>		

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## **CHAPTER 1                      INTRODUCTION**

### **1.0    Purpose**

The purpose of this policy is to define a set of minimum security requirements to protect state data and information technology (IT) systems that all state entities within the Executive Branch of Nevada State Government must meet. Any state entity, based on the business needs and/or specific legal requirements, may exceed the security requirements put forth in this policy, but must, at a minimum, achieve the security levels required by this policy.

The primary objective of Nevada Information Security Program Policy is to:

- effectively manage the risk of security exposure or compromise within state entity IT systems;
- communicate the responsibilities for the protection of state entity information;
- establish a secure processing base and a stable processing environment within state entities and throughout the state;
- reduce to the extent possible the opportunity for errors to be entered into an IT system supporting a state entity business processes;
- preserve management's options in the event of state data, information or technology being misused, lost or unauthorized access; and
- promote and increase the awareness of information security in all state entities and with all state employees.

### **1.1    Scope and Applicability**

This State Information Security Program Policy provides a baseline of security policies for the State of Nevada. This policy establishes mandatory policies to ensure confidentiality, integrity, availability, reliability, and non-repudiation within the State's infrastructure and its operations.

This policy applies to all state entities within the Executive Branch of Nevada State Government, excluding the Nevada System of Higher Education and the Nevada Criminal Justice Information Computer System, that operate, manage or use IT capabilities in support of the business needs of the entity. This policy is applicable to state employees, contractors and all other authorized users, including outsourced third parties, which have access to or manage state information. Where conflicts exist between this policy, a state entity policy or a federal policy, the more restrictive policy will take precedence.

This policy encompasses all systems for which the state has administrative responsibility, including systems managed or hosted by third parties on behalf of a state entity. It addresses all information, regardless of the form or format, which is created or used in support of business activities of state entities.

### **1.2    Authority**

The following state and federal statutes require states to protect their information resources and data by establishing information security programs and imposing special requirements for protecting personal information. The State Information Security Program Policy is the first step to ensuring compliance with these requirements.

Nevada Revised Statute (NRS) 242.101

The Clinger-Cohen Act of 1996

OMB Circular A-130, Management of Federal Information Resources and associated NIST Publications:

NIST 800-53 – Recommended Security Controls for Federal Information Systems and Organizations

NIST 800-100 – Information Security Handbook – Guide for Managers

Federal Information Security Management Act of 2002



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## CHAPTER 2 OVERVIEW

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This chapter provides an overview of this State Information Security Program Policy. It highlights the State's information security policy requirements, security responsibilities and summarizes subsequent sections of this document.

Enterprise IT Services (EITS) is responsible for establishing a State-wide information security program to assure that each information system and associated facility provides a level of security that is commensurate with the risk and magnitude of the harm that could result from loss, misuse, disclosure, or modification of the information contained in the system. Each system's level of security must protect the confidentiality, integrity and availability of the information and comply with all security and privacy-related laws and regulations.

The EITS Office of Information Security (OIS) must develop and administer the State Information Security Program that meets statutory, regulatory and State requirements, as well as the needs of the public. State entity Information Security Programs must comply with the State Information Security Program Policy and must meet the minimum standards set forth by this policy.

### 2.1 Document Organization

Security controls are delineated in three primary categories of administration, operational and technical, which is the organizational structure of this document. Best practices from the International Standard, ISO/IEC 27002:2005 (E), Code of Practice for Information Security Management and the National Institute of Standards and Technology, NIST Special Publication 800-100, Information Security Handbook, A Guide for Managers have been referenced and used to develop the State Information Security Program Policy.

- Chapter 3, **Security Administration** policies, focuses on security administration, risk assessment/management, asset management, personnel security, security awareness training, and security plans.
- Chapter 4, **Operational Policies**, focuses on security methods for physical security, environmental security, media control, data integrity, equipment security, security incident management.
- Chapter 5, **Technical Policies**, focuses on security controls that the computer executes including identification/authentication, system/data access control, audit trails, network security, encryption, and patch management

This document contains policies that satisfy minimum security requirements based on industry best practices and federal guidelines.

### 2.2 Document Change Control

Requests for changes to this policy must be presented by the state entity to Enterprise IT Services, Office of Information Security. The requested change will be formally drafted and submitted to the State Information Security Committee for review and approval. Once approved by the committee, the CISO will submit the change through the State Chief Information Officer (CIO) for final approval. Once final approval is granted, the CISO will cause the change to occur in this document and distribute the change to all state entities. It is the state entity's responsibility to communicate the approved changes to their organization.

## **2.3 Roles and Responsibilities**

### **2.3.1 Enterprise IT Services (EITS), Office of Information Security (OIS) has the responsibility to:**

- A. establish, implement, administer and oversee the State Information Security Program;
- B. develop guidance documents for state entities in developing various information security programs and plans;
- C. provide subject matter expertise and assistance to state entities in establishing specific information security programs, development of information security policies, standards, procedures, and plans, information security awareness training, information security risk, vulnerability and physical security assessments;
- D. establish a state Information Security Incident Management program to assist state entities in the determination if a security breach or incident has actually occurred and to provide an initial administrative review of the incident;
- E. chair the State Information Security Committee and provide direction and guidance to the committee in the development of the State Information Security Program, policies and standards;
- F. coordinate and obtain approval of all information security policies and standards from the State Information Security Committee and the State Chief Information Officer;
- G. publish all approved information security policies, standards and procedures;
- H. ensure that the state security policies and standards are reviewed and revised every two years.

### **2.3.2 State Agencies have the responsibility to:**

- A. establish and implement a departmental security program, to include policies, standards and procedures, that is consistent with or exceeds the requirements of this policy and commensurate with the risk and magnitude of harm of state information resources should unauthorized access, use, disclosure, disruption, modification or destruction occur;
- B. ensure information security management processes are integrated with the state entities strategic and operational planning processes;
- C. appoint an Information Security Officer (ISO) for the agency that will establish, administer, implement and oversee an agency Information Security Program;
- D. communicate state and agency security policies, standards and procedures to all agency staff.

### **2.3.3 State agency Information Security Officers have the responsibility to:**

- A. ensure the establishment, implementation, enhancement, monitoring and enforcement of the federal, state and entity information security policies and standards;
- B. provide direction and leadership to his or her management and staff through the recommendation of security policies, standards, procedures, processes and awareness programs to ensure that appropriate safeguards are implemented;
- C. facilitate compliance with state and agency policies, standards and procedures;
- D. represent the agency on the State Information Security Committee.

## **2.4 Exceptions to State Policies or Standards**

- A. In cases where a state agency cannot comply with any section of the State Information Security Program Policy, justifications for the noncompliance must be documented using the Exception Request process provided in Appendix A of this document. The Exception Request must be submitted to EITS, Office of Information Security, Chief Information Security Officer (CISO) for approval.
- B. Resulting risks from a deviation to policy must be documented in the appropriate Information Security Plan.

- C. OIS will provide an overview of the exception list to the committee on an annual basis.

## **2.5 Compliance**

### **2.5.1 EITS, Office of Information Security (OIS):**

- A. has oversight responsibilities to state agencies within the Executive Branch of Nevada State Government. The oversight is to provide a means to review and identify potential new or unaddressed vulnerabilities and to establish a baseline of a state agency and overall statewide security posture to build on to improve the overall security structure;
- B. does not have enforcement authority of state security policies and standards; however, OIS has the responsibility to escalate unaddressed security vulnerabilities as the Chief Information Security Officer (CISO) deems necessary to the State Chief Information Officer (CIO) for resolution per NRS 242.
- C. within the oversight responsibilities, may initiate security assessments of a state agency to identify new or unaddressed risks, threats, vulnerabilities of the State's information processing environments and infrastructures;
- D. must provide the state agency with a written report of an assessment;
- E. can only release the results of an assessment to other compliance or audit organizations upon written approval of the assessed state agency.

### **2.5.2 State Agencies must:**

- A. periodically review implemented security controls to verify compliance with state and agency security policies, standards, procedures and processes;
- B. establish enforcement and consequences for state and agency security controls.

## **2.6 References**

Policies provided in this document are based on industry standards and guidelines provided by:

- International Standard ISO/IEC 27002:2005 (E) – Code of Practice for Information Security Management
- National Institute of Standards and Technology (NIST) – 800 Series
- OMB Circular 130 – Management of Federal Information Resources

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## **CHAPTER 3: SECURITY ADMINISTRATION POLICIES**

This State Information Security Policy is a statement that sets the direction, gives broad guidance and defines the minimum requirements, ethics, responsibilities and accepted behaviors required to establish and maintain a secure environment, and achieve State information security objectives. Compliance with this policy is mandatory. Exception requests can be submitted requesting an exception to a specific policy stated within this document but must be approved by the State Chief Information Security Officer (CISO).

### **3.1 Organizational and Functional Responsibilities**

#### **3.1.1 State Agencies:**

- A. Establish a framework to initiate and control the implementation of information security within their area of authority.
- B. Appoint an Information Security Officer (ISO) for the state agency. The appointment may be based on the size of an agency, with individual ISO's appointed for each sub-organization within the agency, if the agency is large. The agency may also choose one ISO to represent and fulfill the ISO responsibilities for an entire agency or to serve as the agency's lead ISO, to coordinate with all agency ISOs on behalf of the agency.
- C. Establish a process to determine information sensitivity, based on best practices, State directives, legal and regulatory requirements and identified security risks and vulnerabilities to determine the appropriate level of protection for the information and the operational environment of the agency.
- D. Ensure the agency structure is in place for the:
  - 1) establishment and implementation of agency specific information security program to include policies, standards and procedures;
  - 2) assigning information security responsibilities;
  - 3) implementation of a security awareness program;
  - 4) monitoring significant changes in the exposure of information assets to major threats, legal or regulatory requirements;
  - 5) coordination of security incidents with EITS, Office of Information Security;
  - 6) consideration and planning of major initiatives to enhance information security within the agency;
  - 7) ensure information security is included in the design of all automated applications;
  - 8) communicating requirements of this policy and associated agency specific information security policies and standards to third parties and addressing third party agreements.

#### **3.1.2 State Agency Information Security Officer (ISO):**

The state agency Information Security Officer (ISO) is responsible for the overall development, implementation, enhancement, monitoring and enforcement of the agency specific Information Security Program policies, standards and procedures.

The appointed state agency ISO is responsible for:

- A. providing direction and leadership to the agency management and staff through the recommendation of security policies, standards, processes and security awareness programs to ensure that appropriate safeguards are communicated, implemented and to facilitate compliance with the state and agency specific information security controls;
- B. report and coordinate with EITS, Office of Information Security, security breaches or investigations;
- C. coordinate and oversee agency security program activities and reporting processes in support of this State Information Security Program Policy and other security initiatives.

### **3.1.3 Agency Management:**

- A. Agency management is responsible to support and provide resources needed to enhance and maintain a level of control consistent with the State and state agency Information Security Program Policies based on the level of identified risks.
- B. Agency management has the following responsibilities in relation to the security of information:
  - 1) ensure processes, policies and requirements are identified and implemented relative to security requirements defined by the agency's business;
  - 2) ensure the proper controls of information are implemented for which the state agency business have assigned ownership responsibility based on the identified classification designation;
  - 3) ensure the participation of the state agency ISO and technical staff in identifying and selecting appropriate and cost-effective security controls and procedures and in protecting information assets;
  - 4) ensure participation of the state agency ISO in the development, selection and implementation of all Request for Proposals and Contracts involving information technology resources;
  - 5) ensure appropriate security requirements for user access to automated information are defined for files, databases and physical devices assigned to their areas of responsibilities;
  - 6) ensure critical data and recovery plans are backed up and kept at a secured off-site storage facility and that recovery of backed-up media will work if and when needed.

### **3.1.4 State Employees:**

- A. All state employees have the responsibility to protect state information and resources, including passwords, and to comply with the State and employee state agency Information Security Program Policies, Standards and Procedures.
- B. All state employees must report suspected security incidents to the appropriate manager and to their agency's Information Security Officer (ISO).

## **3.2 Information Security Policy**

### **3.2.1 General**

- A. All information, regardless of the form or format, which is created, acquired, stored or used in support of state agency's business activities, must only be used for official state business. State information is an asset and must be protected from its creation, through its useful life, and to its authorized disposal.
- B. State information must be maintained in a secure, accurate and reliable manner and be readily available for authorized use.
- C. State information/data must be classified and protected based on its importance to the business activities and risks to any given state agency.
- D. Access to state information and information systems must be granted to an individual for only that information or systems required to accomplish the duties of their position.

### **3.2.2 Individual Accountability**

Individual accountability is the cornerstone of any security program. Any person having authorized access to state information must:

- A. be assigned unique user-id(s) and password(s) for access into state information systems. The original recipient of the user-id(s) and password(s) must not share their user id or password;
- B. only use state information for official business;
- C. only access IT systems and information for which they are authorized;
- D. be responsible to reasonably protect against unauthorized activities performed under their user-id;
- E. report suspected or actual security breaches or incidents, inappropriate content or system access/activity to the state entity's management and ISO or to the EITS, Office of Information Security.

### **3.2.3 Confidentiality – Integrity – Availability**

All state entity information must be protected from unauthorized access to help ensure the information's confidentiality and maintain its integrity. State entities must:

- A. classify and secure information within their jurisdiction based on the information's value, sensitivity to disclosure, consequences of loss or compromise and ease of recovery.
- B. define appropriate processes and develop recovery plans and implement those processes to ensure the reasonable and timely recovery of all state entity information, applications, systems and security regardless of computing platform, should that information become corrupted, destroyed or unavailable for a defined period.

### **3.2.4 State Entity Security Program**

- A. State entities must approve, adopt, publish and communicate to all employees a statement on Information Security detailing management commitment and organizational approach to managing information security within the entity.
- B. State entities must periodically review the statement at established intervals or when significant changes occur to update, reinforce and ensure the continued management commitment and approach for the entity's information security program.



### **3.3 Organizational Security Policy**

#### **3.3.1 Management Commitment to Information Security**

- A. Management must actively support security efforts within the entity through clear direction, demonstrated commitment, and explicit assignment of information security responsibilities to the entity ISO.
- B. Information security initiatives and activities should be coordinated with representatives from different areas within the entity with relevant roles and job functions. All information security responsibilities should be clearly defined.

#### **3.3.2 Information Security Function**

The purpose and mission of the Information Security function is to:

- A. develop, deploy and maintain an information security architecture that will provide security policies, mechanisms, processes, standards and procedures that meet current and future business needs of the state entity;
- B. provide information security consulting to the state entity regarding security threats that could affect the entity's computing and business operations, and make recommendations to mitigate the risks associated with those threats;
- C. assist management in the implementation of security measures that protect the IT infrastructure, while at the same time meet the business needs of the state entity;
- D. develop and implement security training and awareness programs that educate employees, contractors and vendors with regard to the entity's information security requirements;
- E. participate in the development, implementation, maintenance and testing of Continuity of Operations Plans (COOP), processes and techniques to ensure the continuity of the entity's business and security controls, in the event of an extended period of computing resource unavailability;
- F. report to management and the EITS, Office of Information Security breaches of security controls, and implement additional compensating controls when necessary to help ensure security safeguards are maintained.

#### **3.3.3 Role and Responsibility of the State Entity Information Security Officer**

The state entity Information Security Officer (ISO) is responsible for performing, at a minimum, the following tasks;

- A. develop or coordinate the development and implementation of state entity information security plans, policies, standards, procedures, and other control processes that meet the business needs of the state entity;
- B. provide security consultation to the state entity management with regard to information security practices and controls;
- C. work closely with entity management to ensure security measures are implemented to meet policy requirements;

- D. evaluate new security threats and countermeasures that could affect the state entity and make appropriate recommendations to management of the state entity to mitigate the risks;
- E. inform and coordinate reports of suspected information security incidents or breaches, unauthorized use and unauthorized disclosure of state information or personal identification information with state entity management and the EITS, Office of Information Security (OIS). OIS will provide support to all state entities suspecting a breach or incident by performing an initial administrative investigation of the associated IT resource(s), maintain the required chain of custody of all materials, equipment, and evidence and provide a neutral independent third party review and report to management to assist in making informed decisions on further actions;
- F. ensure appropriate follow-up to security violations is conducted;
- G. establish and provide appropriate security awareness and education to all state entity employees and where appropriate third party contractors;
- H. be aware of laws and regulations that could affect the security controls and classification requirements of the state entity's information;
- I. support, develop and accomplish actions required by the state entity ISO as defined in other parts of this State Information Security Program Policy;
- J. represent the entity on the State Information Security Committee.

### **3.4 Personnel Security**

#### **3.4.1 General**

The Personnel Security process begins with a review of the user's position needs, relevant policies, regulations, standards and threats for a defined environment.

- A. All state entities must comply with existing state and federal laws, and regulations that impose significant responsibilities on employees for the security of information.
- B. All state entities must establish an Acceptable Use Policy and obtain a signature from the employee indicating acknowledgement of the rules prior to access being granted to information or information systems.

#### **3.4.2 Employment Screening**

##### **A. STATE EMPLOYEES and IT CONTRACTORS:**

- 1) Fingerprint based background checks must be conducted on all persons hired, promoted or contracted for IT services determined to be sensitive. This requirement is supported by NRS 239B, Disclosure of Personal Information to Governmental Agencies.
- 2) Background checks must be processed through the Department of Public Safety and must consist of a State and a Federal Bureau of Investigation (FBI) fingerprint based background check. A conviction in any jurisdiction of any crime involving moral turpitude or indication of lack of business integrity or honesty, whether denominated a felony or misdemeanor, must be considered to be an unfavorable result of a background check. Any unfavorable results from a background check must be submitted to the State Chief Information Security Officer (CISO).

- 3) Unfavorable results from a background check must not be an automatic cause to refuse employment or cause for termination. The agency head after consult with the State Chief Information Security Officer (CISO) has the final decision on action to be taken or not taken based on the results of the report and disposition of court information.

### **3.4.3 Acceptable Use**

- A. Acceptable Use Policy must be developed for the entity's IT resources, including computers, telecommunications equipment, software and other data/information services. The policy must provide specific rules for the access and use of the entity's IT systems and information to include acceptable use of the Internet, e-mail, personal use of assigned IT systems, and use of mobile devices.
- B. Each employee, contractor and vendor must sign and acknowledge receipt of the Acceptable Use Policy prior to granting access to entity IT systems or information, with annual review and acknowledgement.

### **3.4.4 Separation of Duties**

Identified sensitive positions must have critical functions divided among different individuals, whenever possible, to ensure that no individual has all necessary authority or information access that could result in fraudulent activities and misuse of confidential/privileged information.

### **3.4.5 Resignation/Termination**

- A. A process must be developed to establish, implement and maintain procedures for processing terminations, both voluntary and involuntary, of employees. The procedures for processing termination involving sensitive positions or access to sensitive information must be more restrictive than those in non-sensitive positions.
- B. Involuntary termination of an employee must cause immediate revocation of all system and information access privileges.

## **3.5 Security Awareness**

- 3.5.1 On-going awareness training programs that addresses the security education needs of all state entity employees must be developed and provided.
- 3.5.2 Security awareness training must be developed by the State entity Information Security Officer to supplement the entity's new employee orientation program and must be reinforced at least annually with all entity employees.

## **3.6 Asset Management**

- 3.6.1 State entities must establish and maintain protection of their information technology assets.
- 3.6.2 An inventory of assets must be maintained by state entities. The asset inventory must include:
  - A. Physical assets: computer equipment, communications equipment, removable media and other equipment;
  - B. Software assets: application software, system software, development tools, and utilities;
  - C. Information: entity-defined essential data, system documentation, operational and support procedures; information security plans, contingency and continuity of operations plans.

3.6.3 Updated inventories must be included in the appropriate Information Security and Contingency Plans.

### **3.7 Risk Assessment and Risk Management**

Risk Assessments are the foundation to establish an effective and appropriate Information Security Program to define and establish necessary controls and processes, commensurate with the level of risks, necessary to provide protection to a state entity's information processing infrastructure and information.

#### **3.7.1 Risk Assessments**

- A. A full risk assessment must be conducted at each state entity to determine the risks, threats, and vulnerabilities to their IT systems, applications, information and operational controls and processes. The full risk assessment must include:
  - 1) **security administration assessment** of information security controls, policies, standards, procedures and processes, data classification, information security plans;
  - 2) **vulnerability assessments** of IT systems and applications, to include networks, servers, wireless, web sites, e-mail systems, data access controls;
  - 3) **physical security assessments** of entity offices for physical access and environmental controls.
- B. Initial risk assessments must be conducted by an independent party with expertise in information security and specific technical expertise.
- C. Results of the assessments must be used to determine the level of protection to be provided and to develop, administer, implement and maintain the state entity Information Security Program which must consist of entity specific security policies, standards, procedures, processes, internal controls and continuity of operation plans.
- D. The appropriate assessment must be conducted prior to the introduction of a new system applications or when a major change occurs to the operating environment.

#### **3.7.2 Self-Assessments**

State entities must conduct a self-assessment of their information security controls at least annually and revise their controls according to identified inadequacies or new risks.

#### **3.7.3 Independent Review of State Entity Information Security Program**

State entities must have a periodic independent review of established security controls. The Enterprise IT Services (EITS), Office of Information Security (OIS) should be the first resource considered for the independent reviews.

### **3.8 Information Security Plans**

Each state entity must develop Information Security Plans to document the administrative security controls and the controls for each major application and general support systems.

#### **3.8.1 Administrative Security Plan**

- A. Each state entity must develop and document the administrative security controls established to include but not limited to controls put in place for security management, personnel security, security awareness training.
- B. The Administrative Security Plan must be reviewed and revised at least biennially.

### **3.8.2 Major Application Security Plan**

A major application is defined as an application that is critical to the business function of the state entity and/or requires special attention to security due to the risk and magnitude of impact to the state entity should the application be subject to unauthorized access, manipulation or disclosure of information.

- A. Each state entity must develop and document the security controls designed within each major application of the entity. The plan must include the controls incorporated within the system design and any additional controls.
- B. Major Application Security Plans must be developed prior to any new application being put into production.
- C. Major Application Security Plans must be reviewed at least biennially or when a major change is made to the application.

### **3.8.3 Major Support System**

A major support system is defined as an information system requiring special management attention because of its importance or criticality to the state entity's business and plays a significant role in the administration of the entity critical programs, finances, property or other critical resource.

- A. Each state entity must develop and document the security controls designed within each major support system of the entity. The plan must include the controls incorporated within the system design and any additional controls.
- B. Major Support System Security Plans must be developed prior to any new system being put into production.
- C. Major Support Security Plans must be reviewed at least biennially or when a major change is made to the system.

#### **3.8.4 General Support System Security Plan**

General support systems are defined as one or a combination of multiple systems that support the state entity, such as a Local Area Network (LAN), Wide Area Network (WAN) or email server.

- A. Each state entity must develop and document the security controls established for each general support system of the entity.
- B. General Support System Security Plans must be developed prior to a new system is put into production.
- C. General Support System Security Plans must be reviewed at least biennially or when a major change is made to the system.

### **3.9 Contingency Planning**

State entities must implement and maintain a business continuity management process to minimize the impact on the organization, counteract interruptions to business activities and protect critical business processes from the effects of major failures of information systems.

#### **3.9.1 Major Application Contingency Plan**

- A. State entities must develop a contingency plan for each major application that defines the backup and recovery procedures specific to each application.
- B. Contingency plans must include all pertinent information required to identify any applications that the major application relies on to accomplish processing or any applications that the major application supplies data or processing capabilities to.
- C. State entities must test the procedures defined in the application contingency plans at least biennially or when a major changed to the application has been implemented.

#### **3.9.2 Major System Contingency Plan**

- A. State entities must develop a contingency plan for each major system that defines the backup and recovery procedures specific to each application.
- B. Contingency plans must include all pertinent information required to identify any applications that the major system relies on to accomplish processing or any applications that the major application supplies data or processing capabilities to.
- C. State entities must test the procedures defined in the application contingency plans at least biennially or when a major changed to the application has been implemented.

#### **3.9.3 General Support System Contingency Plan**

- A. State entities must develop a contingency plan for each general support IT system that defines the backup and recovery procedures specific to each system.
- B. Contingency plans must include all pertinent information required to identify all applications that resides on the general support system, operating system, users, datasets, and responsibilities for the backup and recovery of the system.

- C. State entities must test the procedures defined in the general support system contingency plans at least biennially or when a major changed has been implemented.

## **CHAPTER 4: OPERATIONAL SECURITY POLICIES**

### **4.1 Physical Security and Environmental Controls**

#### **4.1.1 Physical Access**

Appropriate controls must be implemented to:

- A. limit access to rooms, work areas/spaces and facilities that contain the entities information systems, networks and data to authorized personnel only;
- B. deter, detect, monitor, restrict and regulate access to sensitive areas at all times;
- C. ensure controls are commensurate with the level of risk and must be sufficient to safeguard the IT resources against possible theft, loss, destruction, accidental damage, hazardous conditions, fire, malicious actions and natural disaster.

#### **4.1.2 Physical Security**

Appropriate controls must be implemented to ensure that rooms, work areas/space and facilities that contain IT resources that process, transmit or store sensitive or privacy information are protected from unauthorized access.

#### **4.1.3 Visitor Access**

- A. Controls must be implemented that restrict and control visitor access at all times to rooms, work areas/spaces and facilities that contain entity IT resources.
- B. Visitor Logs must be established to record visitor access to work areas/spaces that contain sensitive IT equipment such as servers and communications equipment room.

#### **4.1.4 Fire Protection**

All systems and networks must be protected against the danger of water damage due to leakage from building plumbing lines, shut-off valves and other similar equipment through the location of equipment or covers for the equipment.

#### **4.1.5 Supporting Utilities**

- A. An alternate power supply, such as a generator, must be installed to protect large critical IT systems from power spikes, brownouts, or outages.
- B. State entity servers must be protected by an appropriately sized uninterruptible power supply.
- C. Desktop computers supporting critical functions of a state entity must be protected by an uninterruptible power supply.

### **4.2. Equipment Security**

#### **4.2.1 Workstations**

Appropriate controls must be implemented commensurate with the sensitivity level of the data accessed, processed or stored on the workstation.



#### **4.2.2 Laptops and Other Mobile Computing Devices**

Appropriate controls must be implemented to ensure that the storage and transmission of an entity's sensitive data is protected with encryption standards that are commensurate with the sensitivity level of the data.

#### **4.2.3 Personally Owned Equipment and Software**

- A. State entities must control the use of personally owned or non-state equipment and software to process, access, or store state data. Personally owned or non-state equipment and software includes, but is not limited to, personal computers and related equipment and software, Internet service providers, personal e-mail providers (e.g., Yahoo, Hotmail), personal library resources, and handheld or personal digital assistant (PDA) devices.
- B. Personally owned equipment and software must not be used to process, access, or store sensitive information or be connected the state enterprise or state entity's systems or network without the written authorization of the appropriate entity management and/or Information Security Officer.

#### **4.2.4 Hardware Security**

Hardware products must provide dependable, cost-effective security controls and features and preserve the integrity of the security features provided through the system software.

#### **4.2.5 Hardware/Software Maintenance**

- A. Entity hardware and software must be tested, documented and approved prior to being placed into production.
- B. Maintenance must only be provided by authorized personnel.

### **4.3 Media Control**

Entities must establish procedures to protect media input/output data and system documentation from unauthorized disclosure, modification, removal and destruction.

#### **4.3.1 Media Protection**

Electronic media (e.g., disk drives, CDs, internal and external hard drives and portable devices) must be protected including backup media, removable media and media containing sensitive information from unauthorized access.

#### **4.3.2 Media Marking**

Media containing data must be marked and labeled to indicate the sensitivity level of the data.

#### **4.3.3 Sanitization and Disposal of Information**

Methods must be developed and documented to ensure that sanitization and disposal of media is commensurate with the sensitivity and criticality of the data residing on the storage devices, equipment and hardcopy.

#### **4.3.4 Input/Output Controls**

Physical, administrative and technical controls must be established and implemented to prevent unauthorized entry into office suites, operations, data storage, library and other restricted areas to restrict the unauthorized removal of media.

### **4.4 Data Integrity**

State entities must establish formal procedures for backup, recovery and storage of data and related software.

#### **4.4.1 Controls**

Systems and networks must be equipped with data integrity and validation controls to provide assurance that information has not been altered.

#### **4.4.2 Documentation**

Documentation for all systems, networks, and applications must be developed, readily available to appropriate personnel, secured and up to date for routine security audits, tests and unexpected events such as system disruptions, failures or outages.

### **4.5 Configuration Management**

4.5.1 Controls must be established, implemented and enforced on all state entity systems and networks that process, store, or communicate sensitive information.

4.5.2 Controls must include processes for the request, approval, implementation and documentation of all configuration changes.

### **4.6 Software Security**

State entities must establish controls to ensure that only state approved and properly licensed software is installed on state systems.

### **4.7 Software Development and Maintenance**

4.7.1 Separate development, test and production environments must be established on state systems.

4.7.2 Processes must be documented and implemented to control the transfer of software from a development environment to a production environment.

4.7.3 Development software and tools must be maintained on computer systems isolated from a production environment.

4.7.4 Access to compilers, editors and other system utilities must be removed from production systems.

4.7.5 Controls must be established to issue short-term access to development staff to correct problems with production systems allowing only necessary access.

4.7.6 Security requirements and controls must be identified, incorporated in and verified through out the planning, development, testing phases of all software development projects. Security staff must be included in all phases of the System Development Lifecycle (SDLC) from the requirement definition phase through implementation phase

4.7.7 Vulnerability testing must be conducted on all systems prior to being placed into production.

#### **4.8 Security Incident Management**

- 4.8.1 State entities must establish and maintain an incident response capability to include preparation, identification, containment, eradication, recovery and follow-up capabilities to ensure effective recovery from incidents.
- 4.8.2 State entities must adhere to a standard methodology for resolving information security events to ensure a consistent and effective method is applied.
- 4.8.3 A process of evaluation and continual improvement must be applied to information security events after completion.
- 4.8.4 Individual must report any observed or suspected information security events or weaknesses to their manager or entity Information Security Officer.
- 4.8.5 A formal report must be developed following the discovery of an event or weakness, to allow for timely corrective action.
- 4.8.6 A security incident involving the disclosure of personal identifiable information (PII) must follow the notification rules of NRS 603A.220, Disclosure of Breach of Security of System Data, Methods of Disclosure.
- 4.8.7 State entities must promptly notify the EITS, Office of Information Security of a suspected or actual disclosure of Personal Identifiable Information. The EITS, OIS must be included in the investigation and corrective actions.

## **CHAPTER 5: TECHNICAL SECURITY POLICIES**

### **5.1 Identification and Authentication**

Users of state IT systems and networks must be individually identified and accountable for all actions on those systems accessed by that identification

#### **5.1.1 Identification**

Each authorized user of state systems and networks must have a unique UserID.

#### **5.1.2 Password**

- A. Logical password controls must be used in conjunction with a unique UserID.
- B. Each authorized user of state systems and networks must have a unique password that is to remain confidential, not to be shared with other users, system maintenance personnel and/or contractors.
- C. Passwords granting access to sensitive data or elevated access to the system must not be saved, stored or hard-coded in any system or application.

### **5.2 Data Access Controls**

State IT systems and networks must have logical access controls to provide protection from unauthorized access, alteration, loss, disclosure and availability of information.

#### **5.2.1 Review and Validation of System User Accounts**

User accounts must be reviewed quarterly to ensure the continued need for access to a system and that transferred or resigned users have been deleted.

#### **5.2.2 Automatic Account Lockout**

State IT systems and networks must have automatic account lockout after a third failed attempt to log-in to the system or network.

#### **5.2.3 Automatic Session Timeout**

State IT systems must have automatic session timeout and re-authentication to re-establish or unlock. The timeout setting will be determined by the entity ISO consistent with the sensitivity of the data and security of the work area.

#### **5.2.4 Warning Banner**

State IT systems and network must display an entity or State Attorney Generals' Office approved sign-on warning banner at all system access points.

### **5.3 Audit Trails**

- 5.3.1 All IT systems and networks must generate audit logs that show addition, modification and/or deletion of information.
- 5.3.2 Audit logs must be recorded, retained and regularly analyzed to identify unauthorized activity.

## **5.4 Network Security**

### **5.4.1 Network Management**

Network infrastructure must be managed and controlled to protect systems and applications using the network including information in transit.

### **5.4.2 Remote Access and Dial-In**

Remote access and dial-in security controls must be implemented and enforced to provide protection for information stored, accessed, transmitted and received across public and private networks.

### **5.4.3 Network Security Monitoring**

All state systems and networks must have security event-monitoring.

### **5.4.4 Firewalls**

All incoming and outgoing connections from state systems and networks to the Internet and extranets must always be made through a firewall.

### **5.4.5 Internet Security**

Connectivity of state systems and networks to the Internet must be within a framework of effective technical security controls using firewalls and gateways that provide external network access via Internet Service Providers (ISP) and other public or designated external entities.

### **5.4.6 E-Mail Security**

- A. State e-mail services must have security controls implemented to protect against malicious code attacks and ensure that e-mail services are not used to relay unauthorized messages.
- B. State e-mail services must be used for only official state business.

### **5.4.7 Personal E-Mail Accounts**

Personal e-mail accounts must not be accessed using state systems and networks without the entity management approval.

### **5.4.8 Security Testing and Vulnerability Assessment**

All state systems and networks must have vulnerability scans and/or penetration tests to identify security threats prior to the initiation of a new system or network and at least annually for existing systems or networks.

## **5.5 Malicious Code Protection**

All state systems and networks must have protection programs to minimize the risk of intruding malicious code (e.g., viruses, worms, Trojan horses).

## **5.6 System-to-System Interconnection**

Each state entity must implement a plan or schedule to establish, maintain and terminate interconnections among state entity systems and networks that are operated by different state or federal organization.

## **5.7 Patch Management**

State entities must establish and implement patch management to all systems and networks in a manner that ensures maximum protection against security vulnerabilities and minimize impact on entity business operations.

Patch management must contain a systematic process of identifying, prioritizing, acquiring, implementing, testing and validating security patches necessary for each system or network.

A risk-based decision must be documented if security patches are not applied to a system or network.

## **5.8 Communications Security**

### **5.8.1 Voice Communications**

Security controls must be implemented to provide adequate protection at the system and environmental levels.

### **5.8.2 Data Communications**

Controls must be established to ensure that sensitive data is protected from unauthorized access during transmission.

### **5.8.3 Wireless Communications**

- A. Wireless networks must not be connected to wired networks except through appropriate controls (e.g., Virtual Private Network (VPN) port).
- B. Wireless LANS must not be used to transmit, process, or store sensitive information unless protected with encryption standards that are commensurate with the sensitivity level of the data.

### **5.8.4 Peer-to-Peer File Sharing**

Peer-to-Peer file sharing must only be permitted internally between state entities.

### **5.8.5 Instant Messaging**

Instant messaging is only permitted internal to state systems and networks.

### **5.8.6 Video Conferencing**

Adequate controls must be implemented to ensure that appropriate transmission protections are in place commensurate with the highest sensitivity of the information to be discussed over the video conference.

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**APPENDIX A**

**REQUIREMENTS AND PROCEDURE  
FOR  
REQUESTING EXCEPTION**

**TO  
STATE INFORMATION SECURITY  
POLICIES AND STANDARDS**



## Requirements and Procedure for Exception Requests

### 1.0 PURPOSE

State information security policies and standards provide guidance for the security and effective planning and use of information technology (IT) resources. In the diverse State IT infrastructure, there may be occasions when compliance with a policy or standard cannot be accomplished; justifications for the noncompliance must be documented.

This policy establishes a mechanism to address requests for an exception to State Information Security policies or standards.

### 1.1 REQUIREMENTS

- 1.1.1 State entities that are unable to comply with a State Information Security Policy or Standard must formally request an exception when there is a legitimate reason and reasonable alternatives to meet the policy or standard are not viable.
- 1.1.2 Exceptions will be evaluated and granted on a case by case basis and consider the nature of the request, systems impacted, security risks, and mitigation alternatives.
- 1.1.3 Request for exception must be submitted by the appropriate state entity manager, IT manager, Information Security Officer (ISO) or their designee.
- 1.1.4 Requests must be submitted utilizing the formalized exception request process defined in this document.
- 1.1.5 Request for an exception must be submitted to the Enterprise IT Services (EITS), Office of Information Security (OIS) for review. OIS will provide the requestor with written notification of the results of any exception request.
- 1.1.6 Exception requests that are denied by the OIS, Chief Information Security Officer (CISO) may be appealed to the State Chief Information Officer (CIO).
- 1.1.7 Approved exception requests must be kept on file for audit purposes.
- 1.1.8 All exceptions requests are temporary and must be reviewed annually.

### 1.2 PROCEDURE

- 1.2.1 A request for exception must use the Exception Request Form. The exception request must include the following:
  - A. the number and title of the policy or standard the exception request is covering;
  - B. the business and technical reasons for the exception – requests without specific business or technical reasons identified in the justification will be denied and returned for resubmission;
  - C. the source and destination addresses and specific ports that require exception if applicable;
  - D. the specific, temporary length of time the exception will be required;

- E. the actions that will be taken to eliminate the exception;
- F. the timeframe to eliminate the exception.

- 1.2.2 The Exception Request Form must be submitted to OIS and assigned to an OIS staff member for review. The request will be evaluated and presented with comments and a recommendation to the CISO for review.
- 1.2.3 The CISO must evaluate the request, consider the OIS staff recommendation, and grant or deny the request as appropriate. The assigned OIS staff will notify the requestor via e-mail of the decision.
- 1.2.4 The assigned OIS staff will provide a copy of the final decision to the requestor via inter-departmental mail.
- 1.2.5 OIS will maintain a copy of all Exception Requests with decision on file.
- 1.2.6 Granted exception requests will be reviewed annually, in January, by OIS.
- 1.2.7 The decision of the CISO related to this procedure may be appealed to the CIO. The process to appeal the CISO decision is:
  - A. Send the original exception request forms with a memo to the CISO directly, stating the reason(s) why the exception should be approved from the state entity's perspective.
  - B. The CISO will re-evaluate the exception and submit it to the EITS senior security team (e.g., consist of the CIO, CISO and Deputy CISO) for final decision.
  - C. The CISO will return the decision of the EITS senior security team to the requestor.

## **NEVADA STATE BOARD OF PHARMACY IT ACCEPTABLE USE AGREEMENT**

### **INTRODUCTION**

This acceptable use agreement governs the use of computers and mobile devices, networks, and other information technology (IT) resources for the Nevada State Board of Pharmacy (Board). This statement applies to all Board members, employees and contractors, and all other persons who may legally or illegally use or attempt to use IT resources owned or managed by the State, and/or is connected by any means to the state SilverNet Network. As a user of these IT resources, you are responsible for reading and understanding this agreement.

IT resources at the Board are to be used in a manner that supports the mission of the Board. IT resources refer to all equipment, hardware, software or network (including wireless networks) and includes computers and mobile devices, e-mail applications and state internet and intranet access (including when accessed through personally owned computers). IT resources range from multi-user systems to single-user terminals and personal computers, whether free-standing or connected to networks.

### **ACCEPTABLE/UNACCEPTABLE USE**

1. All users must safeguard the confidentiality, integrity, and availability of Board IT resources, including password login, access codes, network access information and log-on IDs from improper access, alteration, destruction, or disclosure. Users shall only access or use Board IT resources when authorized. Users must abide by Board policies and other State policies regarding the protection of data and information stored on these IT resources.
2. When personally-owned IT resources are used for Board business, the Board retains the right to any Board records or materials developed for Board use. Also, any materials must be appropriately safeguarded according to applicable standards including, but not limited to, virus protection, protected access and backups.
3. Users must not use Board IT resources to engage in activities that are unlawful or violate federal or state laws, State or Board security policies or in ways that would:
  - a. Be disruptive, cause offense to others, or harm morale.
  - b. Be considered harassing or discriminatory or create a hostile work environment.
  - c. Result in State or Board liability, embarrassment, or loss of reputation.
4. Users must maintain the integrity of information and data stored on Board IT resources by:
  - a. Only introducing data that serves a legitimate business purpose.
  - b. Only acquiring, using, altering, disposing of, or destroying data or information with proper authorization.
  - c. Protecting data and information stored on or communicated across Board systems and accessing appropriate data or information only when authorized.
  - d. Protecting data and information communicated over internal or public networks to avoid compromising or disclosing nonpublic information or communications.
5. While Board IT resources are primarily intended for business purposes, limited (incidental and occasional) personal use may be permissible when authorized by management and it does not:
  - a. Interfere with work responsibilities or business operations.
  - b. Involve interests in personal outside business or other non-authorized organizations or

- activities (which may include, but are not limited to, selling personal property, soliciting for or promoting commercial ventures, or soliciting for or promoting charitable, religious, or political activities or causes).
- c. Violate any of the federal or state laws or State or Board security policies.
  - d. Lead to inappropriate cost to Board functional units. Excessive non-work-related surfing and utilizing streaming services such as listening to music or watching videos is prohibited.
  - e. External Internet based instant messaging is forbidden.
  - f. Peer-to-peer file sharing is specifically forbidden.
6. Users must check all electronic media, such as software, diskettes, CDs and files for viruses when acquired through public networks (e.g., internet sites) or from outside parties by using virus detection programs prior to installation or use. If users suspect a virus, the applicable system(s) or equipment must not be used until the virus is removed. The matter must be immediately reported to the applicable manager or the Board (ISO).
  7. Only Board-approved and properly licensed software will be used or installed on Board computers and mobile devices and will be used according to the applicable software license agreements. Security awareness training must be reinforced annually for all users of State information and information technology.
  8. Users must ensure that any nonpublic information, data or software that is stored, copied, or otherwise used on Board IT resources is treated according to the State and Board standards regarding nonpublic information and applicable agreements and intellectual property restrictions.
  9. Whenever a user ceases to be an employee, contractor, or other authorized user of Board IT resources, such user shall not use Board facilities, accounts, access codes, privileges, or information for which he/she is no longer authorized. This includes the return of all Board IT resources including hardware, software, data, and peripherals.
  10. Inappropriate use of e-mail includes, but is not limited to, sending and forwarding:
    - a. Messages, including jokes or language, that may be considered discriminatory, harassing, unlawful, defamatory, obscene, offensive, insensitive, or otherwise inappropriate (for example, messages about age, race, gender, disability, sexual orientation, national origin or similar matters).
    - b. Pornographic or sexually explicit materials.
    - c. Chain letters.
    - d. Information related to religious materials, activities, or causes, including inspirational messages.
    - e. Charitable solicitations unless sanctioned by the State or Chief Information Officer (CIO).
    - f. Auction-related information or materials unless sanctioned by the State or CIO.
    - g. Software or copyrighted materials without a legitimate business or instructional purpose.
    - h. Large personal files containing graphics or audio files (such as photographs and music).
    - i. Materials related to personal commercial ventures or solicitations for personal gain.
    - j. Information related to political materials, activities, or causes unless sanctioned or permitted by the State or CIO.
    - k. Unauthorized or inappropriate mass distribution or communication.

1. Any other materials that would be improper under this policy or other State or Board policy.
11. Inappropriate use of the internet includes, but is not limited to, accessing, sending, or forwarding information about, or downloading from:
- a. Sexually explicit, harassing, or pornographic sites.
  - b. "Hate sites" or sites that can be considered offensive or insensitive.
  - c. Auction or gambling sites.
  - d. Games, software, audio, video, or other materials that the Board is not licensed or legally permitted to use or transmit, or that are inappropriate or not required by State or Board business.
  - e. Offensive or insensitive materials, such as sexually or racially oriented topics.
  - f. Any other materials that would be improper under other State or Board policies.
  - g. Intentional importation of viruses, keyloggers, Trojans, or any other software that could be classified as malware or spyware.

### **CONSEQUENCES**

Any inappropriate use of Board IT resources may be grounds for discipline up to and including dismissal. Should disciplinary action be required, the State of Nevada, progressive disciplinary procedures will be followed.

## NEVADA STATE BOARD OF PHARMACY

### ACCEPTABLE USE AGREEMENT ACKNOWLEDGEMENT

This is to certify that I have read and agree to abide by the guidelines set forth within the Board Acceptable Use Agreement. As a member, employee or contractor of the Board, I fully intend to comply with this policy realizing that I am personally liable for intentional misuse or abuse of the Board's IT resources. If I have any questions about this policy, I understand that I need to ask the Executive Director or his/her authorized agent for clarification.

*\*If I refuse to sign this acknowledgement form, the Executive Director or his/her authorized agent will be asked to sign this form indicating that I have been given time to read and have had questions answered about this agreement. The Executive Director or his/her authorized agent will read this statement to me prior to signing the document and advise me that by not signing this document my rights to use the Board's IT resources may be denied and may affect my ability to fulfill my duties.*

NAME (please print)	
SIGNATURE	
TITLE/POSITION	
DATE	

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*EXECUTIVE SECRETARY'S SIGNATURE	
COMMENTS	
DATE OF NEXT REVIEW AND AGREEMENT	

*Date of next review should coincide with date of next Performance Evaluation, contract renewal, or re-appointment to the Board, as applicable.*

## Nevada Executive Branch Employees Acknowledgment of Ethical Standards

### Employee Information

<b>Name:</b>		<b>Employee ID #:</b>	
<b>Department:</b>		<b>Agency #:</b> (3 digit, e.g. 070)	
<b>Division:</b>		<b>Home Org. #:</b> (4 digit, e.g. 1363)	
<b>Date Hired:</b>		<b>Class Code:</b>	

NRS 281A.500(2) requires that each new public employee receive information regarding Nevada Ethical Standards. The Nevada Ethics In Government Manual and a link to NRS 281A can be located on the Nevada Commission on Ethics website at the following: <http://ethics.nv.gov> or on the Division of Human Resource Management's website at: <http://hr.nv.gov/Resources/Forms/Ethics/Ethics/>.

By signing this form, I acknowledge that I have been provided information on Ethics as required by NRS 281A.500(2) and I acknowledge that I must familiarize myself with the Ethics in Government laws as they pertain to my conduct as a public employee.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Distribution:**   **Original - Division of Human Resource Management, Central Records**  
                           Copy – Employee  
                           Copy – Agency file

Note: Form must be completed within 30 days of new hire date.

**NEVADA STATE BOARD OF PHARMACY  
POLICY FOR SCREENING OF STAFF TO AVOID CONFLICTS OF INTEREST**

These policies and procedures are implemented pursuant to NRS 622.210 and the Nevada Ethics in Government Law, NRS Chapter 281A.

All employees of the Nevada State Board of Pharmacy (Board) shall consent to these policies and procedures as a condition of employment; evidence of such consent shall be made by execution of a copy of these policies and procedures below.

Board employees have a duty to carry out and enforce the provisions of Nevada law to protect the health, safety and welfare of the public. *See* NRS 622.080, NRS 639.070(1)(a), NRS 639.213 and NRS 639.2171(1).

NRS 281A.020(1) provides:

It is hereby declared to be the public policy of this State that:

(a) A public office is a public trust and shall be held for the sole benefit of the people.

(b) A public officer or employee must commit himself or herself to avoid conflicts between the private interests of the public officer or employee and those of the general public whom the public officer or employee serves.

Board employees have a duty to avoid any real or perceived conflict of interest in any transaction or matter over which the Board has supervision, control, jurisdiction or advisory power. *See* NRS 281A.400 - .430.

In any transaction or matter in which the Executive Secretary has a real or perceived conflict of interest, including, without limitation, any transaction or matter involving an immediate relative as defined in NRS 622.020, upon discovery of the conflict the Executive Secretary shall immediately recuse him/herself from participating in the transaction or matter, including by refraining from attempting to influence any deliberation or action on the transaction or matter, and not be privy to any non-public information relating to the transaction or matter. In the event of such a recusal, the Deputy Executive Secretary shall have exclusive management authority over the transaction or matter and shall take all necessary action to sequester the Executive Secretary from the transaction or matter, subject only to the oversight of the Board.

In any transaction or matter in which any Board employee other than the Executive Secretary has a real or perceived conflict of interest, including, without limitation, any transaction or matter involving an immediate relative as defined in NRS 622.020, upon discovery of the conflict the employee shall immediately recuse him/herself from participating in the transaction or matter, including by refraining from attempting to influence any deliberation or action on the transaction or matter, and not be privy to any non-public information relating to the transaction or matter. In the event of such a recusal, the Executive Secretary shall take all necessary action to sequester the employee from the transaction or matter.

The recusal and sequestration of any Board employee from a transaction or matter real or perceived conflict of interest shall be documented by the Office of General Counsel.

**I hereby acknowledge that I have read, understand and consent to these policies and procedures:**

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**SIGNATURE**

**PRINT NAME**

**DATE**



## **NEVADA STATE BOARD OF PHARMACY OPERATING RESERVE POLICY**

1. **PURPOSE:** It is the fiduciary responsibility of the Nevada State Board of Pharmacy to safeguard the administration of the funds collected and expended in regulating the practice of pharmacy in the State of Nevada. This policy is written to ensure the ongoing financial integrity of the Nevada State Board of Pharmacy.
2. **POLICY STATEMENT:** Reserves provide a gauge of the financial strength of an agency. Reserves, or undesignated fund balances, are those unrestricted assets which are reasonably liquid and not otherwise budgeted for expenditures. The undesignated fund balance will include an operating reserve to protect the Nevada State Board of Pharmacy when revenues fall short of expenses. To ensure continued and future reliability, this policy proposes to identify a target balance or threshold for the operating reserve.
3. **PROCEDURE:** The Board will establish an operating reserve out of the undesignated fund balance in an amount not less than six months' operating expenses of the preceding year's budget and not to exceed two years' operating expenses of the preceding year's budget.
4. **REVIEW:** The operating reserve will be reviewed by the Board on an annual basis and adjusted as necessary. The balance in the operating reserve will be reviewed routinely by the Executive Secretary.
  - a. When the balance in the operating reserve approaches the six-months' threshold, the Executive Secretary will conduct an evaluation to identify appropriate measures to ensure the continued financial efficacy of the Board. The findings of this evaluation will be submitted at the next regularly scheduled Board meeting. The evaluation will include:
    - An examination of the forces affecting funding including a decrease in licensee population, increased services and programs or changes in the regulatory environment.
    - A review of expenses to identify if costs can be reduced.
    - An evaluation of existing and future potential funding sources.
  - b. When the balance in the operating reserve approaches the two years' threshold, the Executive Secretary will conduct an evaluation to identify appropriate measures to ensure the threshold is not exceeded. The findings of this evaluation will be submitted at the next regularly scheduled Board meeting. The evaluation will include:
    - A review of fee structures.
    - An evaluation of expanding services to the extent permitted by law.

## **EXECUTIVE SECRETARY REPORT – JULY, 2018**

- **FINANCIAL REPORT**
- **TEMPORARY LICENSES**
- **STAFF ACTIVITIES**
  - AG's Substance Abuse Committee (6/20) - Larry
  - Interim Health Committee (7/17) - Dave
  - Legislative Commission on Regulations (6/26) – Dave, Brett
  - Nevada Health Care Roundtable – Dave, Darla
- **REPORT TO BOARD**
- **BOARD RELATED NEWS**
- **ACTIVITIES REPORT**

## 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
639 Veterinarians dispensing through consignment	09/07/17 10/19/17 12/06/17	12/12/17	R146-17	02/01/18	02/01/18	03/07/18	04/05/18	05/16/18
639.010 Definition of Designated Agent	10/19/17 12/06/17							
639.670 USP 800	10/19/17	Close – Adopting USP 800						
639.879 APRN Dispensing	10/19/17	11/02/17	R132-17	12/01/17		03/07/18	03/28/18	05/16/18
639 NEW Prescription Readers	10/19/17	11/02/17	R131-17	12/05/17	01/24/18 03/13/18 05/03/18	03/07/18 04/12/18 06/07/18	06/15/18	06/26/18
639 PMP Registration/Access	01/11/18	01/12/18	R013-18	04/30/18	05/03/18	06/07/18	06/15/18	06/26/18
639 Show Cause	01/11/18	01/12/18	R014-18	02/27/18	03/13/18	04/12/18	04/17/18	05/16/18
639.742 Vet Dispensing 639.220 Schedule of Fees	01/11/18	01/12/18	R015-18	03/09/18	03/13/18	04/12/18	04/17/18	05/16/18
639.NEW Dispensing of CS in conformance with AB 474	03/07/18	03/13/18	R047-18	04/17/18 05/04/18	05/08/18	06/07/18	06/15/18	06/26/18
453.510 Schedule I – Adding New Substances (Fentanyl)	03/07/18	03/15/18	R048-18					
639.NEW (2) – Further defines CS prescribed for pain (AB474)	06/07/28	06/15/18	R144-18					

## 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
639.955 Penalty for failing to transmit information required by NAC 639.926	03/02/16	03/11/16	R036-16	04/08/16	04/27/16	06/01/16	06/16/16	06/28/16
639.921 Sharing information between systems.	03/02/16	03/11/16	R035-16	04/08/16	06/15/16	07/20/16	Denied 07/21/16	
453.NEW Naloxone	01/13/16	04/07/16	R058-16	05/04/16	06/15/16	07/20/16	08/05/16	09/09/16
639.7102 Use of computer system for issuance and transmission of prescription 639.7105 Electronic transmission of prescription	07/21/16 09/08/16 10/13/16	10/25/16	R154-16	07/05/17	08/02/17	09/07/17	09/27/17	10/31/17
NAC 453.510 Schedule I add MAB-CHMINACA, AB-FUBINACA and ADB-PINACA	09/08/16	09/20/16	R151-16	Withdrawn – Duplicates R080-15				
453.540 Schedule IV add Eluxadoline	09/08/16	09/20/16	R150-16					
453.550 Schedule V add Brivaracetam	09/08/16	09/20/16	R149-16					
453.NEW Naloxone recordkeeping	10/13/16	10/25/16	R157-16	06/15/17	08/02/17	09/07/17	09/27/17	10/31/17
453.460 Partial Filling of Prescriptions	03/01/17 10/19/17	03/21/17	R007-17	06/22/17	08/02/17	09/07/17 01/11/18	01/30/18	02/27/18
	10/31/17: LCB drafting changes from 10/19/17 WS							
453.510 Schedule I adding certain controlled substances	04/13/17	05/03/17	R011-17	06/29/17	08/02/17	09/07/17	09/27/17	10/31/17
453.530 Schedule III HCG in non-humans	06/01/17	06/07/17	R013-17	06/14/17	08/02/17	09/07/17	09/27/17	10/31/17
453.440 DEA/ICD-10 Requirements	07/20/17	07/28/17	R046-17	09/05/17	11/01/17	12/06/17	12/13/17	02/27/18
639.926 Days Supply/Schedule V Reporting	07/20/17	07/28/17	R045-17	09/05/17	11/01/17	12/06/17	12/13/17	02/27/18

TEMPORARY LICENSES  
(Issued since last board meeting)  
Updated 7/3/18

Walgreens

Catherine Cahill

Mesa View Regional Hospital

Aviva Bodek

Sunrise Hospital

Lorne Roby

Walmart

Robert Jarecki



# Nevada State Board of Pharmacy

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## NEVADA STATE BOARD OF PHARMACY

### ACTIVITIES REPORT

#### JUNE 6-7, 2018 BOARD MEETING HELD IN RENO, 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 June 2018 Board meeting.

#### Licensing Activity:

- 21 licenses were granted for Out-of-State MDEG (Medical Devices, Equipment and Gases) companies and 1 granted for a Nevada MDEG company.
- 35 licenses were granted for Out-of-State pharmacies; pending receipt of a favorable inspection for all compounding pharmacies.
- 23 licenses were granted for Out-of-State wholesalers.
- 10 licenses were granted for Nevada pharmacies.
- 3 licenses were granted for Out-of-State Outsourcing Facilities & 1 application was tabled.
- 3 licenses were renewed and 1 denied for pharmacists with disciplinary issues in other states.
- 1 license was granted for a tech in training with past discipline as was 1 granted for a pharmacist (not working in Nevada) with discipline from another state.
- 1 intern license was tabled until the applicant successfully begins pharmacy school as required by law.

#### Disciplinary Actions:

- Pharmacist NZ (revoked last meeting for creating, filling and sending a prescription out of state to her sister without authorization from a prescriber) was granted reconsideration of her discipline. The Board made no changes to her original order.
- Pharmacy Technician CM was revoked for working in a pharmacy without a pharmacist present on several occasions.

#### 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.
- The Board discussed vaccination by pharmacists pursuant to a prescription. Statute allows such activity only by protocol, so there was no action.
- Personnel evaluations were held.
- A training session was conducted on the use of meeting materials in electronic format.

#### Workshop:

- A. **Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the prescribing or dispensing of controlled substance for the treatment of pain in conformance with Assembly Bill 474 from the 2017 Nevada Legislative Session;** To further define "controlled substance" as it relates to a "written informed consent" and "medication agreement". To clarify the application of Section 55;

where it says “ require the patient to complete an assessment of the patient’s risk for abuse, dependency and addiction.”

**Public Hearing:**

- A. Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the dispensing of drugs with prescription readers.** Enacts provisions of Senate Bill 131 (79th Session 2017) requiring certain pharmacies to, upon request, provide a prescription reader or advice on obtaining a prescription reader. (LCB File No. R131-17)
- B. Amendment of Nevada Administrative Code Chapter 453 to add a new section thereto relating to practitioner access to the Prescription Monitoring Program (PMP) database established pursuant to NRS 453.162.** (LCB File No. R013-18) requiring practitioners to register with the Board to access the PMP database. To allow a practitioner to designate members of his or her staff to act as delegates for the purposes of accessing the PMP database. To provide for the suspension or termination of access to the PMP database if the Board has probable cause to believe that the PMP database has been intentionally accessed by a person or for a purpose not authorized by law.
- C. Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the prescribing or dispensing of controlled substances for the treatment of pain in conformance with Assembly Bill 474 from the 2017 Nevada Legislative Session.** (LCB File No. R047-18) The proposed amendments further define “acute pain” and “course of treatment;” clarify “initial prescription” as defined in section 51 of AB 474; clarify “written informed consent” in sections 53 and 54 of AB 474 for practice groups; clarify “making a good faith effort to obtain and review the medical records of the patient” in paragraph (c) of subsection 1 of section 54 of AB 474; clarify the application of section 57 of AB 474 requiring a practitioner, other than a veterinarian, to consider certain factors before prescribing a controlled substance listed in schedule II, III or IV. (LCB File No. R047-18)