MATRIX GUIDELINE FOR DISCIPLINARY ACTIONS

	1st Action	2nd Action	3rd Action
Non ingested error	Letter	Letter	Hearing
Non ingested error	Lotto	Counseling CE +	ricaring
No counseling	\$750.00	\$1000.00	Hearing
Attorney Fees and Costs	Actual	Actual	Actual
Ingested no potential harm	\$500.00	\$1000.00	Hearing
Ingesieu ne peterniai naim	φοσοιοσ	\$1000100	110011119
Ingested with potential harm			
or adverse outcomes	\$1000.00	Hearing	Hearing
Ingested with negative outcome or patient discomfort.			
No institution intervention	Hearing	Hearing	Hearing
Ingested with significant negative health circumstance.			
With institution admit	Hearing	Hearing	Hearing
Ingested with death related to			
inappropriate drug therapy	Hearing	Hearing	Hearing

The investigative committee will review each case individually and may recommend a board hearing, particularly with mitigating circumstances such as inappropriate technician involvement or pharmacist malfeasance.

In certain cases with ingested errors and significant negative health circumstances requiring institutional care, the investigative committee recommendation will be a board hearing.

In all death cases resulting from inappropriate drug therapy a board hearing will occur.

Attorney fees and costs may be added in contested disciplinary actions requiring extensive attorney preparation and presentation and are not described in the above matrix.

The board has directed that ownership may be charged in disciplinary cases. In non-ingested errors copies of admonition letters will be sent to management. Accumulative actions for ownership monitoring will be based upon a 3 year period. All actions including non-ingested errors will be given a case number and monitored.

The Board has the authority to fine from \$0.00 to \$10,000 for each Cause of Action.

		CIPLINE CASES nuary 2020 – July 2020	
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
PTs DS and MY created fraudulent prescriptions and diverted controlled substances from their employing pharmacy.	N/A	Pharmaceutical technician registrations revoked.	N/A
RPH SS failed to maintain Schedule II perpetual inventories and complete invoices for the purchase of controlled substances.	N/A	Voluntary surrender of Nevada pharmacist registration; \$750 administrative fee.	\$3,000 fine; \$750 administrative fee.
Wholesaler WP failed to comply with the requirements of NRS 639.500.	N/A	N/A	Wholesaler license suspended; suspension stayed pending receipt, review and verification of the required background check materials.
AN failed to timely renew his CS registration and wrote 33 prescriptions without a valid registration.	N/A	Letter of reprimand; \$5,000 fine; \$950 administrative fee.	N/A
RPH failed to identify a misbranding error.	N/A	\$250 fine; \$250 administrative fee; two additional CEs on error prevention.	\$3,000 fine; \$250 administrative fee.
RPH DC failed to comply with the 2/12/19 Board Order; failed to timely renew his pharmacist registration and engaged in the practice of pharmacy without a valid registration.	N/A	RPH registration revoked.	N/A
Wholesaler SWS failed to comply with the requirements of NRS 639.500.	N/A	N/A	Wholesaler surrendered license.
KH failed to timely renew her CS registration and wrote 263 prescriptions without a valid registration.	N/A	Letter of reprimand; \$5,000 fine; \$950 administrative fee.	N/A
RPH ST verified the data and final product as correct when it was not and dispensed losartan potassium 25mg tablets rather than the 50 mg. tablets prescribed. ST failed to provide adequate counseling.	N/A	Letter of reprimand; \$1,000 fine; \$1,000 attorney's fees and costs; 2 additional CEs on error prevention.	WG shall pay a \$1,000 fine; \$1,000 attorney's fees and costs.
MDs RB-R and AB pre-signed controlled substance prescriptions that were issued to patients while Respondents were travelling overseas. Respondents allowed APRN DC-L to prescribe controlled substances	N/A	Each respondent shall receive a letter of reprimand; \$5,000 fine; \$2,000 attorney's fees and costs.	N/A

	ANNUAL DISC Reporting Period: Jan		
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
and dangerous drugs prior to being licensed to do so. RPH JA failed to maintain	N/A	JA voluntarily surrendered	DT voluntarily surrendered
perpetual inventories, biennial inventories, records of controlled substance purchases; aided or abetted a person not licensed to practice pharmacy; failed to properly store expired drugs; failure to properly label prescription drugs; continued to practice pharmacy even as his behavior rendered him incompetent, unskillful and neglident. RPH JA and PT FA engaged in unlawful dispensing and sales. PT FA practiced as a registered pharmacist without registration.		pharmacist registration; may not work for any facility licensed by the Board unless he petitions and is grated reinstatement by the Board; if he applies for reinstatement, he shall appear before the Board and he shall successfully complete an evaluation of is competence to practice pharmacy. FA voluntarily surrendered technician registration. She may not work for any facility licensed by the Board unless she petitions and is grated reinstatement by the Board. Respondents are jointly liable and shall pay \$2,500 fine; \$3,000 attorney fees and costs.	pharmacy license and may not operate in any capacity unless it has petitioned the Board and is granted reinstatement.
PT JW's application for registration approved subject to the requirement that he enroll in PRN for one year. JW was terminated from PRN due to lack of attendance.	N/A	Revocation	N/A

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FILED
JUN 1 3 2019

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,) CASE NO. 19-090-CS-S
Petitioner,) NOTICE OF INTENDED ACTION
v.) AND ACCUSATION
KIARASH L. MIRKIA, M.D.,)
Certificate of Registration No. CS15197,)
Respondent.	,

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Kiarash L. Mirkia, M.D., Certificate of Registration No. CS15197 ("Dr. Mirkia") held a Board-issued controlled substance registration.

FACTUAL ALLEGATIONS

II.

In April 2018, Dr. Mirkia owned and was the Medical Director of Mirkia IV, PLLC ("Mirkia IV").

III.

Mirkia IV provided intravenous rehydration treatments to patients in the Las Vegas area using registered nurses who work for the company either directly or on a contract basis.

IV.

Dr. Mirkia allowed Mirkia IV's office staff, including office manager Alex Zukovski ("Zukovski"), who is not a practitioner or registered nurse, to possess the information and keys necessary to access Mirkia IV's inventory of dangerous drugs.

V

Under Dr. Mirkia's direction, Zukovski or other Mirkia IV office staff accessed and possessed Mirkia IV's inventory of dangerous drugs and provided supplies of dangerous drugs to registered nurses without a practitioner on site, without a practitioner's direct supervision, before Dr. Mirkia or any other practitioner examined the patient, and before there was a patient-specific and medication-specific written order for the patient and/or the mediation.

VI.

Dr. Mirkia directed the registered nurses who were employed by or contracted with Mirkia IV to possess and control dangerous drugs from Mirkia IV's inventory, including storing them at their homes, without a practitioner on site, without direct practitioner supervision, without a patient-specific and medication-specific written order for the patient and/or medication. Dr. Mirkia allowed those nurses to possess and store dangerous drugs from Mirkia IV's inventory for up to three days at a time in anticipation that Dr. Mirkia might examine a patient and issue an order for administration.

VII.

Dr. Mirkia allowed registered nurses to transport the dangerous drugs he put into their possession and control without a patient-specific and medication-specific order.

VIII.

Dr. Mirkia generally had no contact—did not examine and did not establish a bona fide therapeutic relationship with the patient—until after one of Mirkia IV's registered nurses transported the dangerous drugs in his/her possession to the patient's location.

IX.

After completing an "examination" of the patient by telephone, Dr. Mirkia would approve, deny or modify a pre-determined order authorizing the patient to receive treatment using an electronic medical record ("EMR") system.

X

After Dr. Mirkia issued an order to administer medication to the patient, the registered nurse purportedly performed his/her own assessment.

XI.

Mirkia IV's nurses were directed to upsell, and often upsold, additional medications to the patient beyond what Dr. Mirkia initially ordered.

XII.

When an RN was successful in upselling additional dangerous drugs to a patient, an "on call" practitioner purportedly was available to amend the patient's order prior to administration.

XIII.

Dr. Mirkia purchased sterile compounded dangerous drugs from Fusion IV Pharmaceuticals, Inc., *dba* Axia Pharmaceuticals ("Fusion"), in Los Angeles, California.

XIV.

Fusion sold compounded sterile products to practitioners in Nevada, including Dr. Mirkia and/or Mirkia IV.

XV.

Fusion is not licensed in Nevada.

APPLICABLE LAW

XVI.

No person may possess a dangerous drug in Nevada without specific statutory authority to do so. *See* NRS 454.213, NRS 454.316, NRS 454.321.

XVII.

A practitioner can give a registered nurse limited authority to possess and administer dangerous drugs without the practitioner onsite by way of NRS 454.213(1)(c), which says in relevant part:

a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

NRS 454.213(1)(a)(emphasis added); see also NRS 639.100.

XVIII.

Chart orders must be written (NRS 454.223) and are patient-specific and medication-specific.¹

XIX.

"Except as otherwise specifically provided, every person who violates any provision of NRS 454.181 to 454.371, inclusive, is guilty of a misdemeanor." NRS 454.356.

XX.

A practitioner must first establish a *bona fide therapeutic relationship* with a patient by examination before he or she can determine that a medication is medically necessary and direct and/or authorize a RN to possess and administer a dangerous drug on-site or issue a chart order for off-site administration of a dangerous drug to treat the patient's medical condition. *See* NAC 639.945(1)(o) and NRS 454.213(1)(a).

¹ See NRS 639.004 "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

XXI.

[A] bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics . . . by the practitioner within the 6 months immediately preceding the date the practitioner . . . prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed.

NRS 639.945(3).

XXII.

An outsourcing facility that is engaged in the compounding of sterile drugs in this State [Nevada] or for shipment into this State shall:

- 1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;
- 2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and
 - 3. Comply with all the requirements of 21 U.S.C. § 353b.

NAC 639.6915

XXIII.

"Supplying . . . medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(g).

XXIV.

A licensee "[p]erforming any of his or her duties as the holder of a license, certificate or registration issued by the Board . . . in an incompetent, unskillful or negligent manner" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(i).

XXV.

"Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(k).

XXVI.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

XXVII.

Engaging in conduct that constitutes unprofessional conduct or that is contrary to the public interest is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

XXVIII.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION Unlawful Access and Possession of Dangerous Drugs - Statutory Violations XXIX.

By allowing Mirkia IV's staff, including its office manager and its registered nurses, none of whom were practitioners and none of whom were licensed to possess or prescribe dangerous drugs, to operate Mirkia IV and/or to obtain, access, possess and store dangerous drugs when he was not on site, before he examined the patient and before he wrote a patient-specific order, Dr. Mirkia violated, or assisted and abetted his staff in violating, NRS 454.213(1), NRS 454.316 and/or NRS 454.356. Because of that conduct, which violates Nevada law and is

inconsistent with the public interest, Dr. Mirkia's controlled substance registration, Certificate of Registration No. CS15197, is subject to discipline pursuant NRS 639.210(12), NRS 453.236(1)(d) and NRS 453.241(1).

SECOND CAUSE OF ACTION Unlawful Access and Possession of Dangerous Drugs – Unprofessional Conduct XXX.

By allowing Mirkia IV's staff, including its office manager and its registered nurses, none of whom were practitioners and none of whom were licensed to possess or prescribe dangerous drugs, to operate Mirkia IV and/or to obtain, access, possess and store dangerous drugs when he was not on site, before he examined the patient and before he wrote a patient-specific order, Dr. Mirkia engaged, or assisted and abetted his staff to engage, in unprofessional conduct as defined in NAC 639.945(1)(g), (i), and (k). For that conduct, Dr. Mirkia's controlled substance registration, Certificate of Registration No. CS15197, is subject to discipline pursuant to NRS 639.210(4), NRS 453.236(1)(d) and/or NRS 639.255.

THIRD CAUSE OF ACTION Purchasing Sterile Compounded Drugs from an Unlicensed Pharmacy XXXI.

By purchasing sterile compounded dangerous drugs from a pharmacy not licensed with the Board, Dr. Mirkia violated, or assisted and abetted that pharmacy in violating, NRS 639.233, NRS 639.285 and/or NAC 639.6915. Because of that conduct, Dr. Mirkia's controlled substance registration, Certificate of Registration No. CS15197 is subject to discipline pursuant to NRS 639.210(4) and (12), NRS 453.236(1)(d); NRS 453.241(1) and/or NRS 639.255.

[THIS SPACE INTENTIONALLY LEFT BLANK]

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 17 day of June 2019.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

)	CASE NO. 19-090-CS-S
)	
)	
)	STATEMENT TO THE
)	RESPONDENT
)	NOTICE OF INTENDED ACTION
)	AND ACCUSATION
/	RIGHT TO HEARING
)))))) /

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 17, 2019, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 13 day of June, 2019.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of June, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Kiarash L. Mirkia, MD 1878 Morro Vista Drive Las Vegas, NV 89135

SHIRLEY HUNTING

MAR **2 0** 2020

NEVADA STATE BOARD OF PHARMACY

ANSWER AND NOTICE OF DEFENSE

LEWIS BRISBOIS BISGAARD & SMITH LLP KEITH A. WEAVER Nevada Bar No. 10271 MELANIE L. THOMAS Nevada Bar No. 12576

6385 S. Rainbow Boulevard, Suite 600

4 Las Vegas, Nevada 89118 Telephone: 702.893.3383 5 Facsimile: 702.893.3789

Attorneys for Kiarash L. Mirkia, M.D.

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF CASE NO. 19-090-CS-S PHARMACY.

Petitioner,

VS.

KIARASH L. MIRKIA, M.D., Certificate of Registration No. CS15197,

Respondent.

KIARASH L. MIRKIA, M.D. ("Dr. Mirkia"), by and through his counsel LEWIS BRISBOIS BISGAARD & SMITH, LLP hereby submits his Answer and Notice of Defense.

JURISDICTION

I. Answering Paragraph I, Respondent objects to this paragraph as it calls for a legal conclusion; notwithstanding, Respondent admits that he held a Board-issued controlled substance registration, Certificate of Registration No. CS15197.

FACTUAL ALLEGATIONS

- II. Answering Paragraph II, Respondent admits that he was the owner of Mirkia IV, PLLC, but denies the remainder of the allegations.
- III. Answering Paragraph III, Respondent admits that Mirkia IV provided intravenous rehydration treatments to patients in the Las Vegas area using registered nurses who are independent contractors paid by 1099s, and denies that the registered nurses were directly employed.

4838-1960-6967.1

LEWIS BRISBOIS BISGAARD & SMITH LLP IV.

V.

office staff.

VI.

VII.

VIII.

IX.

required to return it to Mirkia IV.

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¹ The regimens were set forth on the

approved of the desired regimen.

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Answering Paragraph IV, Respondent admits that Alex Zukovski was the

Answering Paragraph V, Respondent admits that Zukovski accessed and

office manager of Mirkia IV, and had information and keys necessary to access Mirkia

provided supplies to registered nurses after notifying Respondent, who was at times

supervising remotely through the use of onsite cameras and a logbook, before

Respondent or any other practitioner examined the patient and before there was a

patient-specific and medication-specific written order for the patient and/or medication.

Respondent denies the remainder of the allegations, including those related to other

Answering Paragraph VI, Respondent denies these allegations.

permitted to possess and transport inventory up to the end of their shift when they were

videoconference with the patient and nurse listening, would obtain past medical history,

current medications, allergies and symptoms, would approve certain supplements. The

nurse would provide the vital signs and run down on the patient. The application

patients by telephone, but admits performing exams on video-conference with the patient

and nurse present, and afterwards would approve, deny or modify the regimen the patient

selected when requesting the IV services. 1 Respondent admits that patients would select

packages for a desired regimen, but there would not be an order given until Respondent

WhatsApp was utilized to perform these functions because it is encrypted.

Answering Paragraph VII, Respondent admits that registered nurses were

Answering Paragraph VIII, Respondent admits that he would be on

Answering Paragraph IX, Respondent denies that he examined the

IV's inventory, and denies the remainder of the allegations as to any other office staff.

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- XI. Answering Paragraph XI, Respondent denies nurses were directed to upsell, and often upsold, additional medications to the patient beyond what Respondent ordered. If a registered nurse believed that additional treatment was needed, they would contact Respondent for additional orders or receive direction to call emergency services.
 - XII. Answering Paragraph XII, Respondent denies these allegations.
- Answering Paragraph XIII, Respondent admits to purchasing from Fusion IV XIII. Pharmaceuticals on behalf of Mirkia IV, PLLC for a period of time before learning from the Board of Pharmacy that they were not licensed in Nevada, at which time Respondent discontinued the relationship.
- XIV. Answering Paragraph XIV, Respondent admits that Fusion sold products to Mirkia IV, but denies that products were sold to Dr. Mirkia individually. Respondent is without sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained therein as it relates to other "practitioners in Nevada," and on that basis denies those allegations.
- Answering Paragraph XV, Respondent admits that he became aware through the Board of Pharmacy that Fusion is not licensed in Nevada.

APPLICABLE LAW

- Answering Paragraph XVI, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.
- XVII. Answering Paragraph XVII, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.
- XVIII. Answering Paragraph XVIII, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.
- XIX. Answering Paragraph XIX, Respondent objects to this paragraph as it calls for a legal conclusion, for which no response is required.

generally and specifically.

THIRD CAUSE OF ACTION

Purchasing Sterile Compounded Drugs from an Unlicensed Pharmacy

XXXI. Answering Paragraph XXXI, Respondent objects to the extent that this paragraphs calls for a legal conclusion, and denies the remainder of the allegations generally and specifically.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Board's Complaint fails to state a claim on which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

The Board's Complaint, and each cause of action therein, is barred by the doctrine of laches, estoppel, and the doctrine of unclean hands.

THIRD AFFIRMATIVE DEFENSE

Respondent denies each and every allegation of the Board's Complaint not specifically admitted or otherwise pled to herein.

WHEREFORE, Respondent prays for judgment as follows:

- That all charges against him be dismissed;
- 2. For such other and further relief as may be deemed just and proper in these premises.

DATED: March 20, 2020

Respectfully submitted,

KEITH A. WEAVER MELANIE L. THOMAS

LEWIS BRISBOIS BISGAARD & SMITH LLP

/s/ Melanie L. Thomas

By:

Attorneys for Kiarash L. Mirkia, M.D.

WIS 2



AUG 1 4 2020

NEVADA STATE BOARD OF PHARMACY

LEWIS BRISBOIS BISGAARD & SMITH LLP

KEITH A. WEAVER

Nevada Bar No. 10271 MELANIE L. THOMAS

Nevada Bar No. 12576

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE **BOARD** OF CASE NO. 19-090-CS-S PHARMACY,

Petitioner.

VS.

KIARASH L. MIRKIA, M.D., Certificate of Registration No. CS15197.

Respondent.

KIARASH L. MIRKIA, M.D.'S PRE-**HEARING MOTION TO DISMISS**

[Oral Argument Requested on the Record]

KIARASH L. MIRKIA, M.D. ("Dr. Mirkia"), by and through his counsel LEWIS BRISBOIS BISGAARD & SMITH, LLP hereby submits his Pre-Hearing Motion to Dismiss

19 DATED: August 13, 2020

pursuant to NRS 622A.360(2)(e).

Respectfully submitted.

KEITH A. WEAVER MELANIE L. THOMAS

LEWIS BRISBOIS BISGAARD & SMITH LLP

/s/ Melanie L. Thomas

By:

Attorneys for Kiarash L. Mirkia, M.D.

4814-8352-6599.1

KIARASH L. MIRKIA, M.D.'S PRE-HEARING MOTION TO DISMISS

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INTRODUCTION

This case was initiated as a result of Jason Burke, M.D., Dr. Mirkia's competitor, filing a complaint on January 26, 20181-not as a result of any specific patient care complaint. It would be seemingly prudent for the Board to cast a jaundiced eye toward a competitor's complaint, where there was no accompanying patient complaint(s). Particularly, diligence encompasses consideration of the motivation behind accusing a professional peer of felonious activity when unclear whether a violation has occurred.

The Board's regulations regarding this subject matter were so vague and ambiguous that it clarified them by way of advisory opinion letter to the Complainant, Dr. Burke, on May 23, 2018 (five months after the Complaint was filed against Dr. Mirkia). (Exhibit A).2 Dr. Burke sought regulatory interpretation of the very statutes at issue, in a correspondence to the Board dated two days prior to filing his Complaint against Dr. Mirkia. Id. Dr. Burke was uncertain of the law and chose to resolve that uncertainty first for himself, by seeking an advisory opinion; but also, for Dr. Mirkia-with a subsequent accusation of criminal conduct amounting to a felony before their shared licensing board. Strange. Definitely unfair. Almost certainly unconstitutional.

Clearly, Dr. Burke was confused about the statutory construction and its implications on the very industry in which he offered services-IV hydration. Upon information and belief, Dr. Burke owns, operates, or is in some way affiliated with the website "badrn.com," where it is provided:

> The previous model that has existed in Las Vegas for IV hydration where a doctor gives medications/saline to RNs to keep at home for use on random patients in the future has been declared illegal by the Nevada Board of Pharmacy.3

The Complainant's Petition for Regulatory Interpretation to the Nevada Board of

¹ See Pharmacy Board Case File, at Mirkia0004.

² Response from Nevada State Board of Pharmacy to Petition for Regulatory Interpretation to the Nevada Board of Pharmacy (May 23, 2018).

³ https://www.badrn.com/ [last accessed Aug. 10, 2020] [emphasis in original].

Pharmacy was answered by the Board by way of what can only be fairly considered an advisory opinion, given that the "previous model that has existed in Las Vegas" having been subsequently declared "illegal." The NRS and NAC provisions have not changed during the pendency of this action, arguably Dr. Burke interpreted the Board's advisory opinion to be the subsequent declaration of illegality that terminated the "previous model." Id.; see also Exhibit A.

NRS 622A.300 governs the initiation of this action, and provides in relevant part, that cases heard by regulatory bodies such as the Nevada Board of Pharmacy. As a preliminary matter, the Accusation does not contain sufficient factual allegations to state a claim against Dr. Mirkia in law or in fact. Pursuant to NRS 622A.330, Dr. Mirkia requested and received the "case file." (Exhibit B).4 NRS 622A.330 provides in relevant part:

Discovery; limitations on interrogatories and depositions.

- 1. At any time after being served with the charging document, the licensee may file with the regulatory body [...] a written discovery request for a copy of <u>all documents and other evidence intended to be presented</u> by the prosecutor <u>in support of the case</u> and a list of proposed witnesses.
- 2. The investigative file for the case is not discoverable unless the prosecutor intends to present materials from the investigative file as evidence in support of the case. The investigative file for the case includes all communications, records, affidavits or reports acquired or created as part of the investigation of the case, whether or not acquired through a subpoena related to the investigation of the licensee.
- 3. A party may not serve any interrogatories on another party or take any depositions relating to the case, unless permitted by the regulations of the regulatory body

[emphasis added]. NRS 622A.330. The case file does not contain evidence to support the allegations against Dr. Mirkia. Specifically, the materials contained therein do not establish the allegations in this case. Dr. Mirkia did not improperly provide or allow to be

⁴ See August 5th E-Mail from B. Kandt, Esq. and S. Hunting ("In response to your request made pursuant to NRS 622A.330... scanning case file for production[.]"). A witness list was also provided. *Id.*

provided any dangerous drugs in violation of the laws of the State of Nevada, or any other applicable statutory or regulatory provisions. There is no evidence to the contrary.

Dr. Mirkia denies the allegations in the Accusation that his conduct violated the law. The Board's subsequent advisory opinion demonstrates that any ambiguity or confusion created by the NRS provisions should be resolved in favor of Dr. Mirkia as the "scenarios" for which the Complainant sought and received clarification from the Board are the <u>identical</u> scenarios and statutes upon which the Complaint was filed. *See Complaint Form* (Mirkia0004); *see also* Exhibit A. It would be inequitable for the Board to punish Dr. Mirkia for violating unclear statutory provisions that the Complainant himself petitioned the Board to interpret. Therefore, Dr. Mirkia respectfully requests that this case be dismissed in its entirety.

II. STATEMENT OF FACTS

The case file and supplemental case file produced by the Board (Mirkia0001-Mirkia0090) does not contain any invoices post January 18, 2018 (six (6) days before Dr. Burke petitioned the Board to interpret the subject regulations). The invoices in the case file do not support Dr. Burke's allegations that Dr. Mirkia prescribed Zofran. *See* Mirkia0004, Mirkia0019-0028. The case file does not cite to any specific instance, specific patient, specific independent contractor(s), or any specific time frame.

III. <u>LEGAL ARGUMENT AND ANALYSIS</u>

NRS 454.201 defines "dangerous drug" as follows:

"Dangerous drug" means any drug, other than a controlled substance, unsafe for self-medication or unsupervised use, and includes the following:

- 1. Any drug which has been approved by the Food and Drug Administration for general distribution and bears the legend "Rx only";
- 2. Procaine hydrochloride with preservatives and stabilizers (Gerovital H3) in injectable doses and amygdalin (laetrile) which have been licensed by the State Board of Health for manufacture in this State but have not been approved as drugs by the Food and Drug Administration; or
- 3. Any drug which, pursuant to the Board's regulations, may be sold only by prescription because the Board has found those drugs to be dangerous to public health or safety.

[emphasis added]. NRS 454.201. The "case file" produced by the Board pursuant to NRS 622A.330, included invoices produced by ResetIV for purchases from October 1, 2017 through January 18, 2018.⁵ Drugs purchased were limited to the following: B-complex vitamins, biotin, ascorbic acid, glutathione, and normal saline. *Id.*, at n.4. Dr. Burke's Complaint references only three drugs:

Drug Prescribed: IV fluid, zofran, vitamins

See Mirkia0004. The Board has not secured evidence that Dr. Mirkia was utilizing Zofran in any way. With regard to the "IV fluid," and "vitamins," these are not dangerous drugs. Normal saline is the chemical name for salt, known generically by sodium chloride. Salt and vitamins are not considered dangerous drugs.⁶ The premise of this case falls way away when no dangerous drugs are involved. Vitamins B and C, biotin, and glutathione, are available without a prescription; and therefore, are not dangerous drugs.⁷

A. DR. MIRKIA DID NOT VIOLATE, OR OTHERWISE OR ABET OTHERS TO VIOLATE ANY NEVADA STATUTORY PROVISIONS

Dr. Mirkia was not in possession of dangerous drugs. Regardless, the drugs ordered by ResetIV were permitted to be placed in the possession and/or administered by registered nurses. As a preliminary matter, there is nothing that would prevent a registered nurse from possessing and/or administering the drugs that are the subject of this action. NRS 454.213(1) provides as follows, in relevant part:

Authority to possess and administer dangerous drug. [Effective through December 31, 2019.]

1. Except as otherwise provided in NRS 454.217, a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be <u>possessed and administered</u> by:

⁵ See Case File, at Mirkia0018-0028.

⁶ Dr. Mirkia purchase the normal saline from Spring Valley Hospital. See Mirkia0023.

⁷ Dr. Burke's Complaint merely provides "IV fluid" and "vitamins," so it is unclear if that is intended to cover these items.

(c) [...] a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, [...] or pursuant to a chart order, for administration to a patient at another location. [...]

(v) A medical assistant, in accordance with applicable regulations of the: (1) Board of Medical Examiners, at the direction of the prescribing physician and under the supervision of a physician or physician assistant.

[emphasis added]. NRS 454.213(1)(c), (v).

Further, there is nothing that would prevent a registered nurse from possessing these drugs without a prescription. NRS 454.316 provides in relevant part:

2. <u>A prescription is not required for possession</u> of a dangerous drug by a person authorized by NRS 454.213, [...] to handle, possess and deal in dangerous drugs <u>if the drugs are in stock containers properly labeled and have been procured from a manufacturer</u>, wholesaler or pharmacy [...].

[emphasis added]. NRS 454.316(2). The registered nurses contracted to provide services for ResetIV, were licensed sufficiently to satisfy to provisions of NRS 454.213(1), and there has been no evidence produced that would prove that the drugs were in anything other than properly labeled, stock containers, procured from FusionIV Pharmaceuticals, Inc., a section 503(b) registered, outsourcing facility. *Id*.

The Board has disclosed no evidence in its case file that any unlicensed and/or unauthorized persons possessed any dangerous drugs.

The Board has disclosed no evidence in its case file that any unlicensed and/or unauthorized persons prescribed any dangerous drugs. In fact, there are no prescriptions in the Board's case file, *i.e.* "all documents and other evidence intended to be presented by the prosecutor in support of the case." [emphasis added]. NRS 622A.330.

The Board has disclosed no evidence in its case file that any unlicensed and/or unauthorized persons accessed any dangerous drugs when Dr. Mirkia was not onsite. In fact, the <u>only</u> evidence in this case is to the contrary.

The Board has disclosed no evidence in its case file that any dangerous drugs were improperly stored on site. In fact, the <u>only</u> evidence in this case is to the contrary.

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4814-8352-6599.1

In the absence of both a legal and factual basis for the claim that Dr. Mirkia violated statutory provisions with regard to access and possession dangerous drugs, the Board's First Cause of Action must be dismissed.

B. DR. MIRKIA DID NOT ENGAGE IN UNPROFESSIONAL CONDUCT

In its Second Cause of Action, the Board regurgitates identical allegations as those in its First Cause of Action, and accuses Dr. Mirkia of "unprofessional conduct as defined in NAC 639.945(1)(g), (i), and (k)[,]"8 which provide as follows:

NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.

- 1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest: [...]
- (g) Supplying or diverting drugs [...] which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles. [...]
- (i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. [...]
- (k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.

[emphasis added]. NAC 639.945(1)(g), (i), and (k).

The Board has disclosed no evidence in its case file that any unlicensed and/or unauthorized persons were supplied drugs to circumvent the laws related to the sale. In fact, no drugs were ever sold to anyone; rather, a service was provided to patients by appropriately licensed individuals. As demonstrated by the Board's own evidence, all drugs were lawfully acquired through a section 503(b) outsourcing facility by ResetIV and/or Dr. Mirkia. The Board has failed to state a claim pursuant to NAC 639.945(1)(g).

8 See Accusation, at 7.

The Board has disclosed no evidence in its case file that Dr. Mirkia performed his duties in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i). These allegations are based on the Board's contention that Dr. Mirkia violated various Nevada statutory provisions, which as outlined herein are either inapplicable or were otherwise clearly followed. There is no evidence to the contrary. The Board has failed to state a claim pursuant to NAC 639.945(1)(i).

The Board has disclosed no evidence in its case file that any unlicensed persons performed any act, task or operation for which a license was required. In fact, the <u>only</u> evidence in this case is to the contrary. The Board has failed to state a claim pursuant to NAC 639.945(1)(k).

It should be noted that the Complaint against Dr. Mirkia was filed by his competitor, Jason Burke, M.D., who himself was so unclear on the legal obligations imposed upon providers of IV hydration services that he petitioned and received from the Board an advisory opinion related to the very issues. Dr. Mirkia did not have the benefit of a detailed opinion from the Board regarding its interpretation of the NRS and NAC. It would be inequitable to punish him for violations for which the Board felt the need to clarify to the individual alleging the violations. (Exhibit A). In the absence of both a legal and factual basis for the claim that Dr. Mirkia violated statutory provisions with regard to access and possession dangerous drugs, the Board's Second Cause of Action must be dismissed.

C. FUSIONIV PHARMACEUTICALS, INC. IS NOT REQUIRED TO BE LICENSED IN NEVADA

The Board alleges that Dr. Mirkia assisted or aided and abetted FusionIV Pharmaceuticals, Inc. in violating Nevada law, "[b]y purchasing sterile compounded dangerous drugs from a pharmacy not licensed with the Board[.]" See Accusation, at 7, ¶ XXXI. While it is true that FusionIV was not licensed by the Board, no such licensure was required as this is a section 503(b) outsourcing facility. The Food and Drug Administration (FDA) is responsible for ensuring the safety and efficacy of all human and

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veterinary drugs and biological products, whether large pharmaceutical companies, contract research organizations, or outsourcing facilities produce them.

The Drug Quality and Security Act was signed into law in November 2013. This law outlines specific regulations and guidelines that must be followed by outsourcing facilities engaged in non-prescription anticipatory manufacturing to ensure that the products they prepare and distribute are safe and of high quality. The FDA has urged healthcare providers to use only registered and approved outsourcing facilities.

A. Statutory Framework

Section 503B(d)(4)(A) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that:

- Is engaged in the compounding of sterile drugs;
- · Has elected to register as an outsourcing facility; and
- Complies with all of the requirements of section 503B.

An outsourcing facility is not required to be a licensed pharmacy, and it may or may not receive prescriptions for identified individual patients. Sections 503B(d)(4)(B) and (C) of the FD&C Act.

(Exhibit C).9

Nevada law does not require outsourcing facilities to register as a pharmacy. "[A]n outsourcing facility is not required to be licensed as a pharmacy." NAC 639.6916(1). FusionIV Pharmaceuticals has been registered with the FDA as an outsourcing facility pursuant to section 503(b), since January 2017.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility ¹	Date of Most Recent Registration as an Outsourcing Facility ¹
Fusion IV Pharmaceuticals, Inc., dba Axia Pharmaceutical, Los Angeles, CA	Navid Vahedi 877-685-8222	1/6/2017	1/15/2020

⁹ Outsourcing Facility Information, at 3, Center for Drug Evaluation and Research, U.S. Food & Drug Administration (Sept. 2017).

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https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

[last accessed Aug. 11, 2020]. Because FusionIV Pharmaceuticals, Inc. is a section 503(b) registered outsourcing facility, it was not required to be licensed as a pharmacy in the State of Nevada; therefore, it is factually impossible for Dr. Mirkia to have assisted or aided and abetted FusionIV Pharmaceuticals, Inc. in violating Nevada law, "[b]y purchasing sterile compounded dangerous drugs from a pharmacy not licensed with the Board[.]" *See Accusation*, at 7, ¶ XXXI. There can be no violation, where there is expressly no requirement. As such, there is no legal basis to proceed on the Third Cause of Action (Purchasing Sterile Compounded Drugs from an Unlicensed Pharmacy), and Dr. Mirkia respectfully requests dismissal of this claim.

IV. <u>CONCLUSION</u>

There is no basis for the claims against Dr. Mirkia. The motivation behind the Complaint appears to be personal and self-motivated by Dr. Mirkia's then-competitor Dr. Burke. The Board has produced no evidence in its case file that would support that allegations against him. The Accusation fails to state a claim for relief both in law and fact. Dr. Mirkia's conduct conformed to the law at all times relevant herein, including in the provision of IV hydration services and with regard to alleged dealings with a section 503(b) registered outsourcing facility. Accordingly, this case should be dismissed in its entirety.

DATED: August 13, 2020

Respectfully submitted,

KEITH A. WEAVER MELANIE L. THOMAS

LEWIS BRISBOIS BISGAARD & SMITH LLP

/s/ Melanie L. Thomas

Ву:

Attorneys for Kiarash L. Mirkia, M.D.

WIS 2

EXHIBIT A

2018.05.22 Resp Pet Interp Burke



Nevada State Board of Pharmacy

431 W. Plumb Lane® Reno, NV 89509 (775) 850-1440 • 1-800-364-2081® FAX (775) 850-1444 E-mail: pedwards@pharmacy.nv.gov • Web Page: bop.nv.gov

May 23, 2018

Jason Burke, M.D. Hangover Heaven, LLC 3281 S. Highland Dr., #806 Las Vegas, Nevada 89109

Dear Dr. Burke:

I am responding on behalf of the Nevada State Board of Pharmacy (Board) to two "scenarios" you presented in your January 24, 2018 Petition for Regulatory Interpretation to the Nevada Board of Pharmacy. Those scenarios can be reduced to two questions, as indicated in your April 6, 2018 email to the Board. The plain language of existing statutes answer both of those questions such that no Board interpretation is necessary. Those statutes give practitioners general authority to possess and administer prescription medications in conformity with the applicable standard of care. A registered nurse (RN), however, may possess a prescription medication for off-site administration only pursuant to an existing patient-specific chart order.

Legal Framework:

No person may possess a controlled substance or a dangerous drug (collectively a prescription medication) in Nevada without specific statutory authority to do so.² The Nevada Legislature granted practitioners³ that authority in NRS chapters 453 and 454.⁴ RNs do not enjoy such broad authority.

¹ NRS 632.019 "Registered nurse" means a person who is licensed to practice professional nursing.

² See NRS 453.336, NRS 453.338, NRS 454.316, NRS 454.321.

³ NRS 454.00958 Practitioner" means:

^{1.} A physician, dentist, veterinarian or podiatric physician who holds a valid license to practice his or her profession in this State.

^{2.} A pharmacy, hospital or other institution licensed or registered to distribute, dispense, conduct research with respect to or to administer a dangerous drug in the course of professional practice in this State.

^{3.} When relating to the prescription of poisons, dangerous drugs and devices:

⁽a) An advanced practice registered nurse who holds a certificate from the State Board of Pharmacy permitting him or her so to prescribe; or

⁽b) A physician assistant who holds a license from the Board of Medical Examiners and a certificate from the State Board of Pharmacy permitting him or her so to prescribe.

An optometrist who is certified to prescribe and administer dangerous drugs pursuant to NRS 636.288 when the optometrist prescribes or administers dangerous drugs which are within the scope of his or her certification.
 See NRS 453.375(1)(a); NRS 454.213(1)(a).

Regarding controlled substances, NRS chapter 453 states in relevant part:

- . 1. A controlled substance may be possessed and administered by the following persons:
 - (a) A practitioner.
- (b) A registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a physician, physician assistant, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

NRS 453.375(1)(a) and (b) (emphasis added). Similarly, as to dangerous drugs, NRS chapter 454 says:

- 1. A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by:
 - (a) A practitioner.
- (c) Except as otherwise provided in paragraph (d), a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

NRS 454.231(1)(a) and (c) (emphasis added).

By way of those statutes, the Nevada Legislature gave practitioners general authority to possess and administer prescription medications.⁵ That authority is broad such that a practitioner can possess and maintain an inventory of prescription medications for the future needs of his or her practice.⁶

Conversely, the Legislature used qualifying language to describe instances where a RN may possess and administer a prescription medication. A RN may possess and administer a prescription medication only "at the direction" of a practitioner, which usually occurs in a facility setting where the practitioner is located. A RN may also possess and administer a prescription medication "pursuant to a chart order, for administration to a patient at another

⁵ See NRS 453.375(1)(a); NRS 454.213(1)(a).

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⁷ NRS 453.375(1)(b); NRS 454.213(1)(c).

2018 05.22 Resp. Pet. Interp. Burke

location." Chart orders are patient-specific and medication-specific. The Legislature did not grant RNs authority to possess a prescription medication (or an inventory of prescription medications) absent an existing chart order in anticipation of a yet-to-be-written chart order.

As with any prescription medication, a practitioner must first establish a bona fide therapeutic relationship with the patient before directing a RN to possess and administer a prescription medication on-site or issuing a chart order for off-site administration: "[A] bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics . . . by the practitioner within the 6 months immediately preceding the date the practitioner . . . prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed."

From that legal framework the two "scenarios" or questions you present in your Petition may be analyzed.

Scenario 1:

Your Scenario 1 asks whether, after establishing a bona fide therapeutic relationship with the patient, the practitioner has to physically give any prescription medication the practitioner ordered through a chart order to the RN for off-site administration to the patient?

Response to Scenario 1:

Yes, a RN must receive a prescription medication for off-site administration pursuant to a chart order directly from a practitioner. A RN does not have authority to possess a prescription medication that is not specifically ordered in an existing chart order.

Scenario #2:

The second scenario presented in your Petition asks whether a RN may keep medications at home or in the car in preparation for going out on house calls.

⁸ Id.

⁹ See NRS 639.004 "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

¹⁰ See NAC 639.945(1)(o).

¹¹ NRS 639.945(3).

2018.05.22.Resp.Pet.Interp.Burke

Response to Scenario #2:

No. A RN may possess a prescription medication-"for administration to a patient at another location" "pursuant to a chart order." The statutes do not authorize a RN to possess an inventory of a prescription medication without a chart order. If an RN had access to or possessed a prescription medication without a chart order for that medication, the RN would possess the prescription medication unlawfully and could be found criminally liable. 13

Finally, it should be noted that a RN, after administering a prescription medication to a patient pursuant to chart order, may not leave any prescription medication with the patient, even if the RN anticipates making a house call to the patient in the future. Leaving medication with the patient constitutes dispensing, 14.15 which NRs are not authorized to do. 16

You may access the statutes cited herein by way of the Board's website at bop.nv.gov, or you may request a copy from my office.

Sincerely,

S. PAUL EDWARDS, ESO.

General Counsel

Nevada State Board of Pharmacy

¹² NRS 453.375(1)(b); NRS 454.213(1)(c).

¹³ See NRS 453.336, NRS 453.338, NRS 454.316, NRS 454.321.

¹⁴ NRS 453.056 "Dispense" defined.

Except as limited by subsection 2, "dispense" means to deliver a controlled substance to an ultimate user, patient or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

^{2.} The term does not include the furnishing of a controlled substance by a hospital pharmacy for inpatients.

15 NRS 454.211 "Dispense" defined.

^{1. &}quot;Dispense" means the furnishing of a dangerous drug in any amount greater than that which is necessary for the present and immediate needs of the ultimate user.

The term does not include the furnishing of a dangerous drug by a hospital pharmacy for inpatients.
 NRS 453.377, NRS 454.215.

EXHIBIT B

Thomas, Melanie

From:

Shirley Hunting <shunting@pharmacy.nv.gov>

Sent:

Wednesday, August 5, 2020 3:24 PM

To:

Thomas, Melanie

Cc:

Brett Kandt; Dena M. McClish

Subject:

[EXT] RE: Kiarash Mirkia, M.D. Case No. 19-090-CS-S

Attachments:

CASE FILE 19-090-CS-S - Mirkia, Kiarash.pdf

External Email

Ms. Thomas,

Attached please find the case file in Case No. 19-090-CS-S Kiarash Mirkia, M.D.

Please contact Mr. Kandt if you have any questions.

Thank you.

Shirley Hunting
Board Coordinator
Custodian of Records
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy., Ste. 206
Reno, NV 89521-4881

Phone: 775-850-1440 Fax: 775-850-1444

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From: Brett Kandt

Sent: Wednesday, August 05, 2020 2:18 PM

To: Thomas, Melanie < Melanie L. Thomas@lewisbrisbois.com >

Cc: Dena M. McClish dena M. McClish <a href="m

Subject: RE: Kiarash Mirkia, M.D. Case No. 19-090-CS-S

Melanie-

Per our discussion this morning and in response to your correspondent in this matter, attached please find the notice of hearing for September 2, 2020. The hearing will be held in conformance with NRS 241.020(2),

Sections 7 and 10 of Governor's Declaration of Emergency Directive 021, and social distancing guidelines promulgated by the Centers for Disease Control and Prevention.

The Board does not utilize hearing officers and will hear the case pursuant to NRS 639.247. In response to your request made pursuant to NRS 622A.330 my assistant is scanning the case file for production and the prosecution's proposed witness list is:

Dena McClish, Board Investigator Joe Dodge, Board Inspector Daniel Rubenstein - Chief Executive Officer, Reset IV Kris Riley - Administrator, Reset IV Jenny Reed **Abby Souza** Cheri Niemiec **Brent Maxfield** Ryan Sittler **Brittany Loveland** Bianca Aguila Chimezie Maduka Brian Paonessa Mohammad Alyousef Matthew Manfra Christa Dodgen Kiarash Mirkia, MD Kim Snow - Nurse Practitioner Leslie Echols-Nurse Practitioner Violeta Aguirre- Nurse Practitioner Alex Zukovski- Office Manager Jason Burke, MD

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy
775-850-1440
bkandt@pharmacy.nv.gov



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From: Thomas, Melanie < MelanieL. Thomas@lewisbrisbois.com >

Sent: Wednesday, August 5, 2020 6:39 AM
To: Brett Kandt < bkandt@pharmacy.nv.gov>

Cc: Weaver, Keith < Keith A. Weaver@lewisbrisbois.com >; Gonzales, Emma < Emma.Gonzales@lewisbrisbois.com >;

Krestyn, Michelle < Michelle.Krestyn@lewisbrisbois.com > Subject: RE: Kiarash Mirkia, M.D. Case No. 19-090-CS-S

Good Morning Mr. Kandt:

Please see attached correspondence. Thank you.

Melanie



Melanie L. Thomas
Attorney
MelanieL.Thomas@lewisbrisbois.com

T: 702.693.1718 F: 702.366.9563

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EXHIBIT C



CENTER FOR DRUG EVALUATION AND RESEARCH

OUTSOURCING FACILITY INFORMATION



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I. INTRODUCTION

In the Drug Quality and Security Act of 2013, Congress created a new category of compounders known as outsourcing facilities. In contrast to "traditional" compounders, outsourcing facilities can, subject to satisfying relevant legal requirements, compound and distribute drugs without receiving prescriptions for individually identified patients, and without limitation on the quantity of drugs that they ship interstate. Drugs compounded by outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements, FDA inspections on a risk-based schedule, and other important conditions that provide greater assurances of the quality of their compounded drugs.

The following information is intended to assist outsourcing facilities in locating provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA policy and procedures that are relevant to their operations, and to assist compounders in deciding whether to register with FDA as outsourcing facilities.

A. Statutory Framework

Section 503B(d)(4)(A) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that:

- Is engaged in the compounding of sterile drugs;
- Has elected to register as an outsourcing facility; and
- Complies with all of the requirements of section 503B.

An outsourcing facility is not required to be a licensed pharmacy, and it may or may not receive prescriptions for identified individual patients. Sections 503B(d)(4)(B) and (C) of the FD&C Act.

A human drug product compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from requirements under three sections of the FD&C Act:

- Labeling with adequate directions for use (section 502(f)(1));
- New drug approval requirements (section 505); and
- Drug supply chain security requirements (section 582).

Drugs compounded by outsourcing facilities remain subject to CGMP requirements established under section 501(a)(2)(B) of the FD&C Act, and other applicable requirements in the Act.

B. Profile of Outsourcing Facilities

Outsourcing facilities vary in terms of size and drug products produced. Some were formerly conventional manufacturing facilities and engage in large-scale production and distribution of compounded drugs. Others were or are state-licensed pharmacies that compound small batches of drug products, often pursuant to prescriptions for identified individual patients. Many compound both sterile and non-sterile drugs for both humans and animals. In addition, some outsourcing facilities, in addition to compounding sterile drugs for human use, engage in conventional manufacturing of FDA-approved drugs; mixing, diluting, and repackaging of biological products; and repackaging drugs.

Of the 59 outsourcing facilities that FDA has inspected as of August 2017:

- 25 engage in both sterile and non-sterile compounding
- 24 engage in both patient-specific and non-patient specific compounding
- 22 compound a portion of their drugs in small batches (10 units or fewer)
- 45 compound drugs from bulk drug substances
- Outsourcing facilities are located in 25 states
- 51 ship compounded drugs in interstate commerce

In addition, in a six-month period, outsourcing facilities that submitted drug product reports to FDA compounded 12,305,873 units of drugs.

II. OUTSOURCING FACILITY OPERATIONS

To meet the definition of an outsourcing facility, the facility must be engaged in the compounding of sterile human drugs (section 503B(d)(4)(A)(i)). Entities that do not compound sterile human drugs should not register as outsourcing facilities.

In addition to compounding human sterile drugs, an outsourcing facility may also compound non-sterile drugs. Drugs in either category that are compounded in accordance with the conditions of section 503B of the Act will qualify for the exemptions.

FDA has issued draft or final guidance regarding the conduct of other activities within an outsourcing facility:

- Repackage drugs as described in FDA's <u>guidance</u>, Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.
- Mix, dilute, or repackage biological products as described in FDA's <u>guidance</u>, <u>Mixing</u>, <u>Diluting</u>, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.
- Compound animal drugs. FDA has issued a draft guidance, Compounding Animal Drugs from Bulk Drug Substances.
- Engage in conventional manufacturing of approved drug products. See FDA's <u>draft guidance</u>, Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

For more information, see the <u>guidance</u>, For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

III. IMPLICATIONS OF BECOMING AN OUTSOURCING FACILITY

When deciding whether to register as an outsourcing facility, compounders should carefully consider the implications, including responsibilities of outsourcing facilities under the FD&C Act.

A. Advantages to Compounders of 503B Registration

FDA understands that many compounders have elected to register as outsourcing facilities for two main reasons:

 Outsourcing facilities can distribute compounded drugs for "office use" without receiving prescriptions for identified individual patients.

Compounders that have not registered as outsourcing facilities, who seek to operate under section 503A of the FD&C Act, can only distribute compounded drugs based on the receipt of valid prescriptions for identified individual patients. Section 503A(a). In contrast, section 503B states that outsourcing facilities "may or may not receive prescriptions for identified individual patients." Section 503B(d)(4)(C). In other words, only outsourcing facilities may distribute compounded drugs to healthcare facilities and practitioners without first receiving a patient-specific prescription.

ii. Purchasers often seek compounded drugs with a greater assurance of quality.

Because the FD&C Act subjects outsourcing facilities to CGMP requirements and Federal oversight, including inspections on a risk-based schedule, specific adverse event reporting requirements, and other conditions, healthcare practitioners who purchase compounded drugs for their patients often source such drugs from outsourcing facilities.

B. Requirements under the FD&C Act

Outsourcing facilities must comply with all applicable requirements of the FD&C Act, including, but not limited to, CGMP requirements and the conditions of section 503B.

i. Compliance with applicable quality standards

Outsourcing facilities are required to comply with CGMP requirements under section 501(a)(2)(B) of the FD&C Act. Under section 501(a)(2)(B), a drug is deemed to be adulterated if it is not produced in accordance with CGMP requirements. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a draft guidance, Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, that, once final, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

The draft guidance reflects FDA's intent to recognize the differences between compounding outsourcing facilities and conventional drug manufacturers, and to tailor CGMP requirements to the nature of the specific compounding operations conducted by outsourcing facilities while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard compounded drug products.

Outsourcing facilities are also subject to other adulteration provisions of the FD&C Act, including the prohibition on preparing, packing, or holding drugs under insanitary conditions whereby they may become adulterated with filth or rendered injurious to health. Section 501(a)(2)(A). Outsourcing facilities also may not produce drugs that are contaminated with filth or super- or sub-potent. Sections 501(a)(1), 501(b), 501(c), 502(a), and 502(j).

ii. Compliance with the conditions of section 503B of the FD&C Act

To meet the statutory definition of an outsourcing facility, and for the compounder's drugs to qualify for the exemptions in section 503B, it must produce all of its compounded drugs in accordance with all of the conditions of section 503B. Section 503B(d)(4)(A)(iii), 503B(a)(11). Examples of conditions in section 503B include, but are not limited to:

- Limitations on bulk drug substances that can be used in compounding (section 503B(a)(2))
- Prohibition on compounding drugs that appear on the list of drugs at 21 CFR 216.24 that have been withdrawn or removed from the market because the drugs or components of the drugs have been found to be unsafe or not effective (section 503B(a)(4))
- Prohibition on compounding drugs that are essentially a copy of one or more approved drugs (section 503B(a)(5))
- Labeling requirements (section 503B(a)(10))
- Drug product reporting requirements (sections 503B(a)(1) and 503B(b)(2))
- Adverse event reporting requirements (sections 503B(a)(1) and 503B(b)(5))

iii. Payment of fees required by sections 503B and 744K of the FD&C Act

Upon initial registration and each year that the entity renews its registration, sections 503B and 744K of the FD&C Act require FDA to assess each outsourcing facility an establishment registration fee of \$15,000, or \$5,000 for small businesses, adjusted each year for inflation. In addition, FDA must assess a fee of \$15,000, adjusted for inflation, for each reinspection that it conducts. A reinspection is an inspection conducted after an inspection in which FDA identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the FDA's satisfaction.

See the <u>guidance</u>, Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act for more information about relevant fees, including how to apply for the small business reduction.

IV. RESOURCES AVAILABLE TO OUTSOURCING FACILITIES

A. Meetings with FDA and Pre-Operational Reviews

In general, FDA is unable to grant most requests for meetings from stakeholders regarding implementation of the compounding provisions of the FD&C Act because of limited resources. However, to facilitate compliance in this new industry, FDA entertains, as resources permit, requests from outsourcing facilities and compounders considering registering as outsourcing facilities to meet with the agency regarding questions about compliance with CGMP requirements and the conditions of section 503B.

In addition, as resources permit, FDA conducts, upon request, preoperational site evaluations of outsourcing facilities to assess facility design, standard operating procedures, and other conditions that are critical to producing sterile drug products before the outsourcing facility initiates production for distribution.

B. Guidance Documents and Regulations

FDA has issued or intends to issue guidance documents that can assist outsourcing facilities in complying with section 503B of the FD&C Act, as well as certain relevant regulations.

FD&C Act Citation	Text of Section 503B	Applicable FDA Draft or Final Policy Documents
Section 503B(a)	Compounding must be by or under the direct supervision of a licensed pharmacist.	FDA intends to issue a policy document on this provision in the future.
Sections 503B(a)(1), 503B(b) and 301(ccc)(3)	The outsourcing facility is in compliance with the registration and reporting requirements of section 503B(b). This includes submitting twice yearly reports regarding the drugs compounded by the outsourcing	Establishment Registration See the final guidance, Registration of Human Drug Compounding Under Section 503B of the FD&C Act.
	facility and submitting adverse event reports in accordance with section 503B(b)(5).	This guidance describes the process for electronic submission of establishment registration information for outsourcing facilities.
		Drug Product Reporting See the final guidance, Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.
		This guidance describes who must report and what information they must provide and explains that drug compounding reports must be submitted in structured product labeling (SPL) format using FDA's electronic submissions system.
		Adverse Event Reporting See the final guidance, Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

		Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA "in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations)." This guidance explains FDA's current thinking on adverse event reporting for outsourcing facilities
Section 503B(a)(2)	If the outsourcing facility compounds drugs using bulk drug substances, the substances are either used to compound drugs on FDA's drug shortage list, or they appear on a list developed by FDA of bulk drug substances that can be used in compounding under section 503B ("bulks list").	See the final guidance, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act. This guidance describes FDA's policy for outsourcing facilities compounding from bulk drug substances that are not used to compound drugs on FDA's drug shortage list,
	In addition, the bulk drug substances are accompanied by a valid certificate of analysis and were manufactured by FDA-registered establishments.	while the bulks list is in development. Interested parties can nominate bulk drug substances for use in compounding at regulations.gov, docket FDA-2015-N-3469.
Section 503B(a)(3)	If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the FDA for purposes of this paragraph if any.	N/A
Section 503B(a)(4)	The outsourcing facility does not compound drugs that appear on a list published by FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective.	The list of drugs that have been withdrawn or removed from the market because the drugs or components of the drugs have found to be unsafe or ineffective appears at 21 CFR 216.24.
Sections 503B(a)(5), 503B(d)(2)	The outsourcing facility does not compound drugs that are essentially a copy of one or more approved drugs.	See the draft guidance, Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act. This guidance describes policies concerning the "essentially a copy" provision of section 503B, including policies concerning the definition of this term.
Section 503B(a)(6)	The outsourcing facility does not compound drugs that appear on a list published by FDA of drugs or categories of drugs that present demonstrable difficulties for compounding.	FDA has not yet developed this list. Interested parties can nominate substances for this list at www.regulations.gov, docket FDA-2017-N-2562.
Section 503B(a)(7)	If the outsourcing facility compounds a drug that is the subject of a risk evaluation and mitigation strategy (REMS) approved with elements to assure safe use pursuant to section 505-1, or from a bulk drug substance that is a component of such drug, the outsourcing facility must demonstrate to FDA before beginning to compound that it will use controls comparable to the controls applicable under the REMS.	FDA intends to issue guidance explaining the process and content of submissions to the agency.

Section 503B(a)(8)	The outsourcing facility's compounded drugs will not be sold or transferred by an entity other than that outsourcing facility.	FDA intends to issue a policy document on this provision in the future.
Sections 503B(a)(9), 744J, 744K	The outsourcing facility has paid all applicable establishment and reinspection fees owed under section 744K.	See FDA's final guidance, Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.
		This guidance describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees
Section 503B(a)(10)	Outsourcing facilities must label their drugs and containers with certain information.	FDA intends to issue a policy document on this provision in the future.
Section 503B(a)(11)	All of the human drugs compounded within an outsourcing facility must be compounded only in accordance with section 503B.	See FDA's final guidance, For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.
		This guidance explains, among other things, that drugs compounded within an outsourcing facility cannot qualify for the exemptions in section 503A.
		See also, FDA's draft guidance, Facility Definition under Section 503B of the Federal Food, Drug, and Cosmetic Act.
		This guidance explains FDA's interpretation of the term "facility at one geographic location or address" in section 503B's definition of an outsourcing facility.

FDA has also issued the following guidance documents regarding drug production operations other than compounding of human drugs by outsourcing facilities.

Drug Production Activity	Applicable FDA Draft or Final Policy Documents
Drug Production Activity epackaging drugs	See FDA's final guidance, Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.
	FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaged drug products are not eligible for exemptions under section 503B of the FD&C Act, but are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Accordingly, this guidance describes, among other things, the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), and 582 when an outsourcing facility repackages drug products.

Mixing, diluting, or repackaging biological products	See FDA's draft guidance, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.
	Biological products are not eligible for exemptions under section 503B of the FD&C Act, and are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. This guidance, if finalized, will describe conditions under which FDA does not intend to take action when certain biological products are mixed, diluted, or repackaged by an outsourcing facility in a manner not described in their approved labeling.
Compounding animal drugs from bulk drug substances	See FDA's draft guidance, Compounding Animal Drugs from Bulk Drug Substances.
	Animal drugs are not eligible for exemptions under section 503B of the FD&C Act and are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Accordingly, when finalized, this guidance will generally describe, among other things, the conditions under which FDA does not intend to take action for violations of sections 501(a)(5) and 502(f)(1) of the FD&C Act when an outsourcing facility compounds animal drugs from bulk drug substances.

C. Contacting the Agency

Outsourcing facilities and compounders considering registering as outsourcing facilities can submit questions, meeting requests, and other messages to the Compounding Team in FDA's Center for Drug Evaluation and Research at compounding@fda.hhs.gov.

Correspondence related to inspections and regulatory actions should be sent to the contact in FDA's Office of Regulatory Affairs listed on your Form FDA-482 or regulatory letter.

V. HOW TO REGISTER AS AN OUTSOURING FACILITY AND SUBMIT DRUG PRODUCT REPORTS

A. Establishment Registration

To register as an outsourcing facility, a compounder must use the electronic registration system (go to CDER Direct) (unless FDA grants a waiver) to provide the following information: name; place of business; unique facility identifier; point of contact email address; an indication of whether the facility intends to compound products on FDA's drug shortage list; an indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile drugs from bulk drug substances.

Once FDA receives the electronic registration submission, it sends the registrant an invoice for the establishment registration fee that must be paid at the time of registration. The amount of this fee and directions for paying the fee are published in the *Federal Register*, which appears on FDA.gov under Regulatory Policy Information.

Provided the registrant pays the required fee within 15 days of receiving the invoice, FDA sends the entity a confirmation that it is registered as an outsourcing facility. FDA then updates the list of outsourcing facilities on its website to reflect the new registrant during the next weekly update.

An outsourcing facility must re-register and pay a fee for each year that it wishes to remain registered as an outsourcing facility. The annual registration period is from October 1-December 31. An entity that registers during this timeframe will remain registered through December 31 of the following year. (See above description of fees.)

See FDA's final guidance, Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act for more information.

B. Drug Product Reporting

Outsourcing facilities must submit a product report upon initial registration under section 503B and twice each year thereafter, once in June and once in December, for products produced during the previous six month period.

- Drug product reports submitted between June 1 and June 30 of each year must report products produced from December 1 through May 31.
- Drug product reports submitted between December 1 and December 30 of each year must report products produced from June1 through November 30.

Each semiannual report must identify all sterile and non-sterile drugs compounded at the outsourcing facility during the previous six-month period and provide all of the following information for each compounded drug:

- The active ingredient and strength of active ingredient per unit
- The source of the active ingredient
- The 10-digit National Drug Code (NDC) number of the source drug or bulk active ingredient, if available
- The dosage form and route of administration
- The package description
- The number of individual units produced
- The 10 digit NDC number of the final product, if assigned

Outsourcing facilities must submit their drug product reporting information electronically in structured product labeling (SPL) format (unless FDA grants a waiver). FDA has created a new <u>SPL</u> document type category for outsourcing facilities' drug product report submissions. Outsourcing facilities may create these files using <u>CDER Direct</u> or any SPL authoring tool to create and submit product report files.

Although each compounded product could be reported in a separate SPL submission, outsourcing facilities can use techniques to simplify and combine the submissions for products with identical active ingredients and different packaging presentations. Multiple strengths, package sizes, and source NDC numbers can be reflected in a single SPL submission, which will reduce the number of SPL submissions that a facility will need to submit to FDA.

See the <u>guidance</u> Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food Drug and Cosmetic Act for more information about drug product reporting, including an example of how outsourcing facilities can combine data into a single product submission.

VI. FDA INSPECTIONS OF OUTSOURCING FACILITIES AND SUBSEQUENT ACTIONS

A. When FDA Conducts 503B Inspections

Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect. Outsourcing facilities are inspected according to a risk-based schedule. Depending on the number of outsourcing facility registrants and other inspection priorities, FDA expects to inspect newly registered outsourcing facilities within two months of initial registration, if the facility has not been previously inspected and the facility is operational. FDA inspects outsourcing facilities for compliance with CGMP requirements and the conditions of section 503B, in addition to other requirements of the FD&C Act. FDA does not generally request that an outsourcing facility wait for an FDA inspection before initiating drug production.

Subsequent inspections will depend on the findings from the first inspection and other factors including but not limited to: the compliance history of the outsourcing facility; the record, history, and nature of recalls linked to the outsourcing facility; the inherent risk of the drugs compounded at the outsourcing facility; the inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected within the last two years; and whether the outsourcing facility has registered as an entity that intends to compound drugs in shortage.

B. Inspectional Observations and Subsequent Action

If FDA investigators observe non-compliance related to a requirement of the FD&C Act, they may issue, at the close of the inspection, a <u>Form FDA-483</u> list of inspectional observations. In determining next steps following an inspection, the agency considers any response to the Form FDA-483 received within 15 days of the inspection.

Depending on the observations during the inspection and any subsequent response from the outsourcing facility, FDA may decide to initiate a regulatory action or close the inspection without further action. Examples of regulatory actions are advisory actions such as untitled letters, warning letters, and regulatory meetings; and enforcement actions such as seizures and injunctions. If FDA decides to close the inspection without pursuing regulatory action, it will routinely issue a copy of the final Establishment Inspection Report (EIR) to the most responsible individual at the inspected firm.

C. Post-Inspection and Regulatory Action Correspondence

Forms FDA-483 are issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the FD&C Act and related acts and regulations. If an outsourcing facility has an objection regarding an observation in a Form FDA-483 or violation cited in a warning letter, or if the outsourcing facility has implemented, or plans to implement corrective action in response, it may discuss the objection or action with the FDA investigator or submit the objection or action to FDA. Information submitted to FDA should be sufficient

for the agency to determine whether the observations or violations have been adequately addressed or whether the proposed corrective action is adequate. For example, outsourcing facilities that have corrected deficiencies in standard operating procedures have included in their response to the agency a copy of the revised procedures and indicated the date the changes were implemented and documentation regarding training of staff on the revised procedures (e.g. training material, training records). Similarly, outsourcing facilities that have violated CGMP requirements by failing to conduct smoke studies under dynamic conditions and subsequently corrected that violation have submitted to FDA a good quality video of the smoke studies in their response to the Form FDA-483. If the information submitted is not sufficient, the FDA may issue a Warning Letter or take other regulatory or enforcement action.

Post-Inspection Actions

Documents and Actions	Description
FMD-145	According to Field Management Directive 145, FDA issues a copy of the EIR to the
	compounding firm once the agency has determined that a surveillance inspection is
	closed.
Untitled Letter	An <u>untitled letter</u> cites violations that do not meet the threshold for significance of
	regulatory significance for a warning letter. See Regulatory Procedures Manual
	Chapter 4.
Regulatory Meeting	A regulatory meeting is a meeting requested by FDA to inform responsible individuals
	or compounders about how one or more products, practices, processes, or other
	activities are considered to be in violation of the law. See Regulatory Procedures
	Manual Chapter 10.
Warning Letter	Warning letters are issued for violations of regulatory significance to give
	compounders an opportunity to take voluntary and prompt action to correct violations
	of the law before the agency initiates an enforcement action. A Warning Letter does
	not constitute final agency action. However, FDA is under no legal obligation to warn
	compounders that they or their products are in violation of the law before taking
	enforcement action. In some cases, FDA might pursue an enforcement action to
	protect the public health without first issuing a warning letter. See Regulatory
_	Procedures Manual Chapter 4.
Warning Letter Close-out Letter	FDA issues a warning letter close-out letter if FDA verifies that the compounder has
	adequately addressed the violations in the warning letter, provided that certain
<u> </u>	conditions are met. See Regulatory Procedures Manual Chapter 4.
Injunction	An injunction is a civil judicial process initiated to stop or prevent violation of the law,
	such as to halt the flow of violative products in interstate commerce, and to correct
	the conditions that caused the violation to occur. See Regulatory Procedures Manual
	Chapter 6.





BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case Nos. 19-090-CS-S

Petitioner,

v.

KIARASH L. MIRKIA, M.D., Certificate of Registration No. CS15197,

Respondent.

OPPOSITION TO RESPONDENT'S MOTION TO DISMISS

Nevada State Board of Pharmacy (Board), by and through counsel prosecuting this matter, Brett Kandt, General Counsel, files this opposition to Respondent Kiarash L. Mirkia, M.D.'s Pre-Hearing Motion to Dismiss filed August 14, 2020. This opposition is made pursuant to NRS 622A.360(3) and based upon the following points and authorities and the pleadings on file herein.

MEMORANDUM OF POINTS AND AUTHORITIES

I. PROCEDURAL BACKGROUND

The Notice of Intended Action and Accusation (Accusation) was filed and served in this matter together with the Statement to Respondent and Notice of Hearing on or about June 13, 2019. Respondent filed his Answer and Notice of Defense on or about March 20, 2020. This matter is set for hearing on September 2, 2020.

II. LEGAL STANDARD

Respondent seeks dismissal of the Accusation "for failure to state facts which, if true, would form a sufficient basis for discipline." NRS 622A.360(2(e). Respondent faces a high bar. See Buzz Stew, Ltd. Liab. Co. v. City of N. Las Vegas, 124 Nev. 224, 227-28, 181 P.3d 670, 672 (2008) (standard for a motion to dismiss for failure to state a claim under NRCP 12(b)(5)).

The Accusation "is a written statement of the charges alleged and must set forth in ordinary and concise language the acts or omissions with which the respondent is charged to the end that the respondent will be able to prepare a defense." NRS 639.241(2). The Accusation in

part "must specify the statutes and regulations which the respondent is alleged to have violated." *Id*.

On a motion to dismiss for failure to state a claim, the Board must construe the Accusation liberally and draw every fair inference in favor of the State. See Brown v. Kellar, 97 Nev. 582, 583, 636 P.2d 874, 874 (1981). All factual allegations in the Accusation must be accepted as true. See Hynds Plumbing & Heating Co. v. Clark Cty. Sch. Dist., 94 Nev. 776, 777, 587 P.2d 1331, 1332 (1978). Dismissal may result only if the prosecution can prove no set of facts that support the charges. See Simpson v. Mars Inc., 113 Nev. 188, 190, 929 P.2d 966, 967 (1997).

III. ARGUMENT

Respondent's Motion must be denied since it relies upon matters outside the pleadings and other extrinsic evidence that cannot be considered in a pre-hearing motion, and because the Accusation states facts which, accepted as true, form a sufficient basis for discipline.

A. Respondent's Motion Is Not Permitted Under Nevada Administrative Law

Respondent's Motion relies upon matters outside the pleadings and other extrinsic evidence that is attached to the Motion and/or incorporated by reference in the Motion. In Nevada civil practice, a motion to dismiss for failure to state a claim supported by matters outside the pleadings and other extrinsic evidence must be treated as one for summary judgment under NRCP 56. See NRCP 12(d); Kopicko v. Young, 114 Nev. 1333, 1335-36, 971 P.2d 789, 790 (1998); MacDonald v. Kassel, 97 Nev. 305, 307, 629 P.2d 1200, 1200 (1981).

However, Nevada law governing administrative procedure before the Board makes no provision for summary judgment in a disciplinary proceeding. See NRS 233B.121; NRS 622A.360; NAC 639.120. The Board's powers as an administrative adjudicator are limited to those specifically set forth in statute. See Andrews v. Nevada State Board of Cosmetology, 86 Nev. 207, 208, 467 P.2d 96, 96-97 (2007). "The grant of authority to the agency must be clear." Id. Summary judgment is not permitted under Nevada administrative law and matters outside

the pleadings and other extrinsic evidence in support of Respondent's Motion should be excluded from the record, and the Motion evaluated under the standard for a motion to dismiss.

B. The Accusation States Three Cognizable Causes of Action

The Accusation states three causes of action against Respondent based upon factual allegations set forth in paragraphs II-XV. The First Cause of Action (Paragraph XXIX) and the Second Cause of Action (Paragraph XXXX) are predicated on Respondent permitting his staff unlawful access to and possession of dangerous drugs, including storing them at their homes. No person may possess or administer a dangerous drug in Nevada without specific statutory authority to do so. Practitioners are granted broad authority in NRS 454.213(1)(a); while registered nurses are granted limited authority in NRS 454.213(1)(c). A registered nurse may possess and administer a dangerous drug "at the direction" of a practitioner, usually in a facility setting where the practitioner is located. A registered nurse may also possess and administer a dangerous drug "pursuant to a chart order, for administration to a patient at another location." Chart orders are patient-specific and medication-specific. Registered nurses may not possess a dangerous drug (or an inventory of dangerous drugs) outside these circumstances.

The Third Second Cause of Action (Paragraph XXXI) is predicated on Respondent purchasing sterile compounded dangerous drugs from Fusion IV Pharmaceuticals, Inc., *dba* Axia Pharmaceuticals, in Los Angeles, California, an entity not licensed with the Board as required by NAC 639.6915, thus aiding and abetting numerous violations law.

The factual allegations, takes as true, establish the basis for the First Cause of Action, that Respondent directed Mirkia IV's staff, none of whom were practitioners licensed to possess or prescribe dangerous drugs, to operate Mirkia IV and/or to obtain, access, possess and store dangerous drugs when the Respondent was not on site, before he examined the patient and before

¹ See NRS 454.201 ("Dangerous drug" defined).

² See NRS 454.191 ("Administer" defined).

³ See NRS 454.00958 ("Practitioner" defined).

⁴ See NRS 639.004 ("Chart order" defined).

he wrote a patient-specific order, in violation of NRS 454.213(1), NRS 454.316 and/or NRS 454.356.

The factual allegations, takes as true, establish the basis for the Second Cause of Action, that Respondent engaged, or assisted and abetted his staff to engage, in unprofessional conduct as defined in NAC 639.945(1)(g), (i), and (k).

The factual allegations, takes as true, establish the basis for the Third Cause of Action, that Respondent purchased sterile compounded dangerous drugs from an entity not licensed with the Board, thus aiding and abetting a violation of NRS 639.233, NRS 639.285 and/or NAC 639.6915.

The factual allegations, takes as true, also establish that Respondent has committed acts that would render his Nevada controlled substance registration inconsistent with the public interest pursuant to NRS 453.236(1)(d), as stated in all three Causes of Action.

As a result, the factual allegations, takes as true, establish that Respondent is subject to discipline pursuant to NRS 639.210(4) and (12), NRS 453.236(1)(d), NRS 453.241(1) and/or NRS 639.255.

IV. CONCLUSION

For the foregoing reasons, the prosecution respectfully requests that the Board deny Respondent's Pre-Hearing Motion to Dismiss.

RESPECTFULLY SUBMITTED this 21th day of August, 2020.

By:

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Nevada State Board of Pharmacy
985 Damonte Ranch Parkway – Suite 206
Reno, NV 89509
bkandt@pharmacy.nv.gov

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Melanie L. Thomas, Esq. Lewis Brisbois 6385 South Rainbow Blvd., Suite 600 Las Vegas, NV 89118



5B



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case No. 20-067-CS-S

Petitioner,

VICTORIA K. WALL, MD, Certificate of Registration No. CS15026,

v.

NOTICE OF INTENDED ACTION AND ACCUSATION

Respondent.

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Victoria K. Wall, MD (Wall), held a Nevada controlled substance registration, Certificate of Registration No. CS15026, issued by the Board.

FACTUAL ALLEGATIONS

II.

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

III.

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

IV.

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

V.

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

VI.

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

VII.

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

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

VIII.

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

APPLICABLE LAW

IX.

No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).

X.

A prescription for a controlled substance may be issued only by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1).

XI.

It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1).

XII.

It is unlawful for any person falsely to represent himself or herself as a practitioner entitled to write prescriptions in this State. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.2813(1).

XIII.

It is unlawful for any person to secure registration for himself or herself by making, or causing to be made, any false representation or to fraudulently represent himself or herself as a practitioner entitled to write prescriptions in this State. NRS 639.281(1).

XIV.

It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e).

XV.

Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

XVI.

Willfully making to the Board any false statement which is material to the administration or enforcement of any of the provisions of NRS Chapter 639 is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

XVII.

Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

XVIII.

Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

XIX.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

XX.

The Board may suspend or revoke a registration to prescribe 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).

XXI.

The surrender of a registration to the Drug Enforcement Administration by a practitioner operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2107.

FIRST CAUSE OF ACTION

XXII.

By falsely representing to the Board that she held an active and current Nevada license with the NSBME on each renewal application for her Certificate of Registration No. CS15026 for the years 2010, 2012, 2014, 2016, and 2018, Wall was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

SECOND CAUSE OF ACTION

XXIII.

By falsely representing to the Board that she held an active and current Nevada license with the NSBME on each renewal application for her Certificate of Registration No. CS15026 for the years 2010, 2012, 2014, 2016, and 2018, Wall violated NRS 453.331(1)(e) and NRS 639.281(1) and is subject to discipline pursuant to NRS 639.210(9) and/or (10).

THIRD CAUSE OF ACTION

XXIV.

By writing multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive, Wall violated 21

U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03, and is subject to discipline pursuant to NRS 639.210(11).

FOURTH CAUSE OF ACTION

XXV.

By writing multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive, Wall violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1)(e), NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1), 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03, and is subject to discipline pursuant to NRS 639.210(12).

FIFTH CAUSE OF ACTION

XXVI.

By falsely representing to the Board that she held an active and current Nevada license with the NSBME on each renewal application for her Certificate of Registration No. CS15026 for the years 2010, 2012, 2014, 2016, and 2018, Wall committed an act that would render her controlled substance registration, Certificate of Registration No. CS15026, inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

SIXTH CAUSE OF ACTION

XXVII.

By writing multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive, Wall committed an act that would render her controlled substance registration, Certificate of Registration No. CS15026, inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

SEVENTH CAUSE OF ACTION

XXVIII.

By surrendering her DEA Certificate of Registration No. BW8998025 for cause, Wall has admitted to failing to comply with the Federal requirements pertaining to controlled substances, and committed an act that would render her controlled substance registration, Certificate of Registration No. CS15026, inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

EIGHTH CAUSE OF ACTION

XXIX.

By surrendering her DEA Certificate of Registration No. BW8998025 for cause, the suspension of Wall's Certificate of Registration No. CS15026 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

XXX.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 26th day of June, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 20-067-CS-S

Petitioner,

v.

VICTORIA K. WALL, MD Certificate of Registration No. CS15026,

Respondent.

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26 day of June, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of June, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Victoria Wall 2013 Grouse St. Las Vegas, Nevada 89134

Baron David Harmon Favil David Berns & Associates 30 E. North Ave. Northlake, IL 60164

KRISTOPHER MANGOSING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

BARON DAVID HARMON FAVIL DAVID BERNS & ASSOCIATES, LLC 30 E. NORTH AVENUE NORTHLAKE, IL 60164 TELEPHONE: (708) 369-1076

FAX: (708) 562-1340

EMAIL:

BHARMON@FDBALAW.COM

NEVADA BAR #: 7003

ANSWER AND NOTICE OF DEFENSE

Hearing Requested

Case No. 20-067-CS-S

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

VICTORIA K. WALL, MD, Certificate of Registration No. CS15026,

Respondent.

ANSWER TO AND NOTICE OF DEFENSE TO INTENDED ACTION AND ACCUSATION

Now comes Victoria K. Wall, MD (Wall or Respondent), by and through her attorney Baron Harmon of Favil David Berns and Associates and provides this Answer and Notice of Defense to the Intended Action and Accusation (this "Action") as follows:

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of

Pharmacy, makes the following that will serve as both a notice of intended action under NRS

233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

Answer: Wall neither admits nor denies the allegations in this section.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Victoria K. Wall, MD (Wall), held a Nevada controlled substance registration, Certificate of Registration No. CS 15026, issued by the Board.

Answer: Wall admits the allegations in this Section.

FACTUAL ALLEGATIONS

11.

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

Answer: Wall admits to requesting and receiving inactive NSBME status since May 13, 2009. Wall neither admits nor denies the remaining allegations in this paragraph.

III.

On each renewal application for her Certificate of Registration No. CS 15026 for the years 2010,2012,2014,2016, and 2018, Wall certified to the Board that she held an active and current Nevada license with the NSBME.

Answer: The renewal applications speak for themselves. Ms. Wall affirmatively states that she believed that she thought she was qualified to renew her Certificate of Registration. Her medical license status as "Inactive" is a matter of public record with the state and should not be deemed to be the basis for fraud or misrepresentation after 11 years.

IV.

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

Answer: Dr. Wall had a reasonable belief that she qualified to write prescriptions to her

immediate family without charge. But for a registration fee difference, Dr. Wall would have otherwise qualified to write prescription medications.

V.

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

Answer: Wall admits the allegations in this paragraph and affirmative states that she has fully complied with the Board's order and in doing so surrendered her DEA license.

VI.

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

<u>Answer</u>: Once Dr. Wall realized she made a mistake she immediately sought to rectify it by voluntarily surrendering her DEA Registration No. BW8998025.

VII.

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

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

Answer: The form speaks for itself. It evidences Dr. Wall's good faith desire to correct her mistakes.

VIII.

Wall's surrender of her DEA Certificate of Registration No. BW8998025 for cause operated as an immediate suspension of her Certificate of Registration No. CS 15026 with the Board pursuant to NRS 639.2107.

Answer: Wall admits to the allegations in this section.

APPLICABLE LAW

IX.

No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).

<u>Answer</u>: Wall neither admits nor denies the allegations in this section, but demands strict proof thereof.

X.

A prescription for a controlled substance may be issued only by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a) (2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a) (1).

Answer: Wall neither admits nor denies the allegations in this section, but demands strict proof thereof. Dr. Wall affirmatively states that she held an active license to practice medicine in California until 2018. But for a registration fee difference she could have registered as active in Nevada as she kept current with her continuing medical education credits annually and Nevada. Nevada is a member of the Interstate Medical License Compact. Her Board of Ophthalmology certification is current too.

It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. NRS 453.226(1); NRS 453.32I (1) (a); NRS 639.100(1).

Answer: Wall neither admits nor denies the allegations in this section.

XII.

It is unlawful for any person falsely to represent himself or herself as a practitioner entitled to write prescriptions in this State. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.2813(1).

Answer: Wall neither admits nor denies the allegations in this section.

XIII.

It is unlawful for any person to secure registration for himself or herself by making, or causing to be made, any false representation or to fraudulently represent himself or herself as a practitioner entitled to write prescriptions in this State. NRS 639.281(1).

Answer: Wall neither admits nor denies the allegations in this section

XIV.

It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1) (e).

Answer: Wall neither admits nor denies the allegations in this section.

XV.

Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(I)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS

639.210(4).

Answer: Wall neither admits nor denies the allegations in this section.

XVI.

Willfully making to the Board any false statement which is material to the administration or enforcement of any of the provisions of NRS Chapter 639 is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

Answer: Wall neither admits nor denies the allegations in this section.

XVII.

Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

Answer: Wall neither admits nor denies the allegations in this section.

XVIII.

Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

Answer: Wall neither admits nor denies the allegations in this section.

XIX.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration

issued by the Board. NRS 639.210(12).

Answer: Wall neither admits nor denies the allegations in this section.

XX.

The Board may suspend or revoke a registration to prescribe 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 (l) (d) and NRS 453.241(1).

Answer: Wall admits the allegations in this section.

XXI.

The surrender of a registration to the Drug Enforcement Administration by a practitioner operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2107.

Answer: Wall neither admits nor denies the allegations in this section.

FIRST CAUSE OF ACTION

XXII.

By falsely representing to the Board that she held an active and current Nevada license with the NSBME on each renewal application for her Certificate of Registration No. CS 15026 for the years 2010, 2012, 2014, 2016, and 2018, Wall was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(l) (h), and is subject to discipline pursuant to NRS 639.210(4).

Answer: Dr. Wall denies the allegations in this section. Dr. Wall affirmatively states that she mistakenly believed that the registration she paid every year to the NSBME allowed her to renew her Certificate of Registration. At no time did Dr. Wall intend to deceive the board or the public.

SECOND CAUSE OF ACTION

XXIII

By falsely representing to the Board that she held an active and current Nevada license with the NSBME on each renewal application for her Certificate of Registration No. CSI5026 for the years 2010, 2012, 2014, 2016, and 2018. Wall violated NRS 453.331 (I) (e) and NRS 639.281 (I) and is subject to discipline pursuant to NRS 639.210(9) and/or (10).

Answer: Dr. Wall denies the allegations in this section. Dr. Wall affirmatively states that she mistakenly believed that the registration she paid every year to the NSBME allowed her to renew her Certificate of Registration. At no time did Dr. Wall intend to deceive the board or the public.

THIRD CAUSE OF ACTION

XXIV.

By writing multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive, Wall violated 21 U.S.C. § 822(a) (2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 306.03, and is subject to discipline pursuant to NRS 639.210 (11).

Answer: Dr. Wall denies the allegations in this section.

FOURTH CAUSE OF ACTION

XXV.

By writing multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive, Wall violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.32I(1)(a), NRS 453.33I(I)(e), NRS 639.100(1), NRS 639.235(1), NRS 639.281(1), NRS 639.2813(1),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03, and is subject to discipline pursuant to NRS 639.210(12).

Answer: Dr. Wall denies the allegations in this section.

FIFTH CAUSE OF ACTION

XXVI.

By falsely representing to the Board that she held an active and current Nevada license with the NSBME on each renewal application for her Certificate of Registration No. CS 15026 for the years 2010, 2012, 2014, 2016, and 2018, Wall committed an act that would render her controlled substance registration, Certificate of Registration No. CS 15026, inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1) (d) and NRS 453.241 (1).

<u>Answer</u>: Dr. Wall denies the allegations in this section. Dr. Wall affirmatively states mistakenly believed her application to be accurate. She never intended to provide inaccurate information.

SIXTH CAUSE OF ACTION XXVII.

By writing multiple prescriptions for controlled substances from June 2009 to the present while her NSBME License No. 12154 to practice medicine in Nevada was inactive. Wall committed an act that would render her controlled substance registration, Certificate of Registration No. CS 15026, inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1) (d) and NRS 453.241(1).

Answer: Dr. Wall denies the allegations in this section.

2.

SEVENTH CAUSE OF ACTION

XXVIII.

By surrendering her DEA Certificate of Registration No. BW8998025 for cause, Wall has admitted to failing to comply with the Federal requirements pertaining to controlled substances, and committed an act that would render her controlled substance registration, Certificate of Registration No. CS 15026, inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236 (1) (d) and NRS 453.241 (I).

Answer: Dr. Wall denies the allegations in this section.

EIGHTH CAUSE OF ACTION

XXIX.

By surrendering her DEA Certificate of Registration No. BW8998025 for cause, the suspension of Wall's Certificate of Registration No. CS 15026 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

Answer: Dr. Wall makes no answer to this section.

XXX.

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.

Answer: Dr. Wall makes no answer to this section.

FIRST AFFIRMATIVE DEFENSE –SCRIVNER'S ERROR

The instant matter arose March 2020 as a result of <u>Dr. Wall filling a complaint</u> with the Nevada State Board of Pharmacy ("NBOP") against Walgreens for refusing to honor the prescriptions for antibiotics she wrote for Joe Scala, her husband. There is no complaint of patient harm. Dr. Wall qualifies to receive "Active" status. She has consistently met her continuing medical education requirements. Up until 2018 she held an active license in California as a Physician and Surgeon. (Both California and Nevada registration numbers appear on her prescription pad). But for paying the difference between an active and inactive license, she would have been qualified to treat and prescribe. She needed only to have paid for the more expensive "Active License" and she would have been compliant. She made a mistake in filing out the BOP controlled substance registration. She did not understand that selecting and paying for "Active License" on the web site was a pre-requisite to maintaining her CS Registration.

Dr. Wall is a native Hawaiian woman who through her own frugalities and acumen attended, graduated and paid for medical school at the University of Nevada Medical School in the year 2000. She is a Physician and Surgeon. In 2004 she was licensed in California as a Physician and Surgeon (License No:

A88040). Her mom was a Captain (now Lieutenant Colonel) in the U.S. Army and she wanted to be in California to be closer to her. In 2008 she stopped working to focus on starting a family. February of 2008 was the last time she saw a paying non-family member patient. Prior to May 2008 renewal of her license, she spoke to someone at the Medical Board of Nevada. She explained that she had now planned to focus on her family and not work as before. She was looking to save money on license fees. She understood that person to say that the cheaper "Inactive" license only meant that she was not charging fees and actively seeking patients, but was otherwise the same in all respects. Dr. Wall always planned to return to work. In 2009 she became pregnant. In 2010 she gave birth to her daughter Mia Scala. In 2018 she gave up her California License. 2019 her husband Joe Scala was diagnosed with cancer. She has consistently kept up with her CME (39.5 hours for 2020) and otherwise paid for her licenses. Had she foreseen this issue she would have gladly paid for the full license.

She never stopped being a doctor and a surgeon at heart. She provided care to her family and friend for free. In question are a total of 29 prescriptions written over a 12 year period to 4 people. (Her husband - Joe Scala, his daughter - Veronica, his nephew- Harold Drezner and a close family friend — Eric Sjostrom). She is not alleged to over prescribe or misdiagnose. No patient was harmed. She is enclosing the records requested. She would like the opportunity to change her Nevada license from inactive to active and pay the appropriate licensing fee.

SECOND AFFIRMATIVE DEFENSE – RIPENESS

There is pending an inquiry before the NSBME regarding Dr. Wall. In that case Dr. Wall is seeking the opportunity to correct the status of her license nuc pro tunc. If the NSBME sees fit to grant her relief, then actions complained of at the NBOP would be cured. Dr. Wall is asking the instant matter be delayed until the NSBME issues a final ruling.

THIRD AFFIRMATIVE DEFENSE - SCIRE FACIAS

Dr. Wall's status of "Inactive" is a public record since 2009. It is readily available on the State of Nevada website. All state agencies are deemed to know what is in the public record. The record on its face

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gives notice and cannot serve as a basis for misrepresentation. (Scire Facias). The NBOP has waited 11 years to take disciplinary action? Dr. Wall is entitled to rely on the past course of dealing and course performance with the State of Nevada.

FOURTH AFFIRMATIVE DEFENSE – LATCHES

Dr. Wall's license in Nevada is inactive for 11 years. The NBOP has waived the right to take action for past conduct based on the "Inactive" status of the Nevada medical license.

Signed this 7th day of July, 2020.

BARON DAVID HARMON Attorney for the Respondent



Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521 PHONE (775) 850-1440 • FAX (775) 850-1444 E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

June 5, 2020

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO: vkwall@earthlink.net

Victoria Kawohikukapulani Wall, MD 6401 Centennial Center Blvd Las Vegas, NV 89149

Re: CEASE and DESIST: Unlicensed Prescribing (Case No. 20-067-S)

Dear Dr. Wall:

cc:

The Nevada State Board of Pharmacy (Board) has determined that you have routinely prescribed controlled substances for Nevada patients without holding an active license with the Nevada State Board of Medical Examiners. Your License No. 12154 to practice medicine in Nevada has been inactive since 2009.

This constitutes a violation of federal and state law, including, without limitation, NRS 453.226, NRS 453.321, NRS 639.100, NRS 639.235, NRS 639.2813, NRS 639.310. 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846 and 21 CFR § 1306.03. Falsely representing oneself as a practitioner entitled to write prescriptions in this State is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.2813(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST prescribing controlled substances for Nevada patients.

Please be aware that the forgoing does not preclude the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt General Counsel

Nevada State Board of Pharmacy

Nevada State Board of Medical Examiners

BEFORE THE NEVADA STATE BOARD OF PHARMACY

FILED

AUG 2 0 2020

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

VICTORIA K. WALL, MD, Certificate of Registration No. CS15026,

Respondent.

Case No. 20-067-S

NEVADA STATE BOARD OF PHARMACY

MOTION TO DEEM ALLEGATIONS ADMITTED

BRETT KANDT, General Counsel, prosecuting this matter on behalf of the State, hereby moves that the Nevada State Board of Pharmacy (Board) deem the allegations set forth in the Notice of Intended Action and Accusation as admitted by Respondent Victoria K. Wall, MD (Wall), Certificate of Registration No. CS15026. This Motion is made pursuant to NRS 622A.360 and based upon the following points and authorities and the papers and pleadings on file herein.

MEMORANDUM OF POINTS AND AUTHORITIES

I. FACTUAL AND PROCEDURAL BACKGROUND

The Notice of Intended Action and Accusation (Accusation) was filed and served in this matter together with the Statement to Respondent and Notice of Hearing on or about June 26, 2020. Wall filed her Answer and Notice of Defense on or about July 7, 2020. This matter is set for hearing on September 2, 2020.

II. LEGAL STANDARD

NRS 622A.360 provides that a party may file a written motion to request a ruling on any issue of law or procedure in a case. NRS 639.244(1) provides that the Answer and Notice of Defense responding to an Accusation must "permit the respondent, by completing and signing the notice, to: (a) Object to the accusation as being incomplete and failing to set forth clearly the charges; and (b) Deny or admit, in part or in whole, the violations alleged."

The rules of civil procedure in both federal and state courts establish that a party must answer by admitting, denying, or stating that it lacks sufficient information to form a reasonable belief about

an allegation, which has the effect of a denial. See FRCP 8(b) and NRCP 8(b). Improper denials are deemed admissions. See FRCP 8(b)(6) ("[a]n allegation—other than one relating to the amount of damages—is admitted if a responsive pleading is required and the allegation is not denied.") and NRCP 8(d) ("[a]verments in a pleading to which a responsive pleading is required, other than those as to the amount of damage, are admitted when not denied in the responsive pleading."). See also 2 MOORE'S FEDERAL PRACTICE § 8.07 (3d'ed. 2017); NEVADA CIVIL PRACTICE MANUAL § 9.05 (Sixth ed. 2017).

Additionally, concessions in pleadings are judicial admissions, which are conclusively binding. *See Reyburn Lawn & Landscape Designers, Inc. v. Plaster Dev. Co.*, 127 Nev. 331, 343, 255 P.3d 268, 277 (2011); *Palmer v. Pioneer Inn Assocs., Ltd.*, 118 Nev. 943, 954 n.31,59 P.3d 1237, 1244 n.31 (2002). "Judicial admissions. . . have the effect of withdrawing a fact from issue and dispensing wholly with the need for proof of the fact." 2 McCormick on Evid. § 254 (7th ed.). A judicial admission "relieves an opposing party from having to prove the admitted fact and bars the party who made the admission from disputing it." Judicial Admission, Black's Law Dictionary (10th ed. 2014).

The rules of civil procedure in both federal and state courts further establish the requirements for asserting affirmative defenses. *See* FRCP 8(c) and NRCP 8(c). "[A]llegations must be pleaded as affirmative defenses if they raise 'new facts and arguments that, if true, will defeat the plaintiff's [causes of action], even if all allegations in the complaint are true." *Clark Cty. Sch. Dist. v. Richardson Constr.*, *Inc.*, 123 Nev. 382, 393, 168 P.3d 87, 94 (2007).

III. ARGUMENT

Based upon Wall's responses and judicial admissions as set forth in her Answer and Notice of Defense, there are no material issues of fact and the Board may make findings of fact consistent with the factual allegations in the Accusation. Furthermore, Wall does not challenge the applicable laws that govern her conduct. Finally, Wall has failed to assert any cognizable affirmative defenses to the violations of law stated in the Accusation.

A. There Are No Material Issues of Fact

Based upon Wall's responses to the factual allegations set forth in paragraphs I-VIII of the Accusation, there are no material issues of fact to be tried. Her assertions as to her state of mind - "she believed that she thought she was qualified to renew her Certificate of Registration" (response to paragraph III) and "had a reasonable belief that she qualified to write prescriptions" (response to paragraph IV) – are irrelevant and immaterial. NRS 48.015; NRS 233B.123. "The substantive law controls which factual disputes are material and will preclude summary judgment; other factual disputes are irrelevant." Wood v. Safeway, Inc., 121 Nev. 724, 731, 121 P.3d 1026, 1031 (2005). In her responses to paragraphs I-VIII Wall either admits these factual allegations, fails to deny the allegations which constitutes an admission, and/or makes judicial admissions consistent with the allegations. This includes her admissions in paragraphs VI and VII of executing a DEA Form 104 surrendering her DEA Certificate of Registration No. BW8998025 to the U.S. Drug Enforcement Administration for Cause on June 14, 2020 (Exhibit A hereto). Consequently, there are no material facts in dispute and the Board may make findings of fact consistent with the factual allegations set forth in paragraphs I-VIII of the Accusation and may admit Wall's filed Answer and Notice of Defense and executed DEA Form 104 (see response to paragraph VI) as evidence.

B. There Is No Issue as to the Applicable Law

In response to the recitations of the applicable law in paragraphs IX-XXI of the Accusation, Wall admits to paragraph XX but otherwise "neither admits nor denies the allegations" and for paragraphs IX and X "demands strict proof thereof." Her failure to deny these allegations, including her "strict proof" demands, constitutes an admission that this is the substantive law that governs her conduct:

"[A]lthough the concept of "strict proof," whatever that may mean, is nowhere to be found in the Rules (or to this Court's knowledge in any other set of rules or in any treatise on the subject of pleading), some members of the same coterie of careless defense counsel will also often include an impermissible demand for such proof. In all of these respects, see this Court's earlier published opinions in *Gilbert v. Johnston*, 127 F.R.D.

145, 146 (N.D. III. 1989) and King Vision Pay Per View, Ltd. V. J.C. Dimitri's Restaurant, Inc., 180 F.R.D. 332 (N.D. III. 1998).

State Farm Mut. Auto. Ins. Co. v. Riley, 199 F.R.D. 276, 278 (N.D. Ill. 2001). "[D]emands for "strict proof" in are improper and meaningless and clearly violate Rule 8(b)." Sun Life Assur. Co. v. Great Lakes Bus. Credit LLC, 968 F. Supp. 2d 898, 903-4 (N.D. Ill. 2013); see also United States v. Vehicle 2007 Mack 600 Dump Truck, 680 F.Supp.2d 816, 828 (E.D. Mich. 2010) (answers that neither admit nor deny the allegations, and demand that the Government prove its case, taken as admissions). Consequently, the substantive law governing Wall's conduct as recited in paragraphs IX-XXI of the Accusation is not in dispute and the Board may proceed to make legal conclusions on the basis of the undisputed material facts.

C. There Are No Valid Affirmative Defenses

Wall asserts four affirmative defenses, none of which defeats or mitigates the legal consequences of her unlawful conduct. Wall first pleads "scrivner's error" [sic], an archaic term that only appears in a single, unpublished Nevada Supreme Court opinion. *See Pankey v. Wells Fargo Home Mortg.*, No. 57059, 2012 Nev. Unpub. LEXIS 423 (Mar. 21, 2012). Scrivener's errors are clerical errors "resulting from a minor mistake or inadvertence" . . . however, "[a]n error that is the deliberate or conscious result of the exercise of judicial or professional judgment, or a misapprehension of the law or the facts, will not qualify as a scrivener's error." *Handelsman v. Handelsman*, 366 Ill.App.3d 1122, 1135, 852 N.E.2d 862, 872-73 (Ill. App. Ct. 2006) (citations omitted); *see also* Scrivener's Error, The Wolters Kluwer Bouvier Law Dictionary (Desk ed. 2012). Wall admits that her actions were deliberate and conscious and a misapprehension of the law: she "mistakenly believed that the registration she paid every year to the NSBME allowed her to renew her Certificate of Registration" with the Board (response to paragraph XXII), and thus she cannot avail herself of this defense.

Wall pleads "ripeness" as her second affirmative defense and alleges that the reinstatement of her license to practice medicine is pending before the Nevada State Board of Medical Examiners.

This will not justify or excuse her past violations of law or overcome her lack of a DEA registration. 21 CFR § 1306.03. A case is ripe when the degree to which the harm alleged is sufficiently concrete, rather than remote or hypothetical, and yields a justiciable controversy. *Cote H. v. Eighth Judicial Dist. Court*, 124 Nev. 36, 38 n.1, 175 P.3d 906, 907 n.1 (2008). NRS 630.255 expressly prohibits an inactive licensee from practicing medicine in Nevada. Furthermore, NRS 453.577 provides:

The authority of the Board [of Pharmacy] to take disciplinary action to enforce the provisions of this chapter is not limited by the authority of any other regulatory body that may be authorized or required to take disciplinary action for the same conduct with respect to any license, registration, certificate or other professional designation issued and regulated by that regulatory body.

Wall admits that she has practiced medicine and written prescriptions in Nevada without the required licensure (response to paragraph IV). These violations of law cannot be cured by any action of the NSBME. This matter is ripe for adjudication by the Board and thus Wall cannot avail herself of this defense.

Wall invokes another esoteric legal concept by pleading "scire facias" as her third affirmative defense, and asserts that since the fact that she has not held an active to license to practice medicine in Nevada since 2009 was a matter of public record this somehow precludes the Board from taking action. Enacted into English law in 1285, scire facias was a writ founded upon some matter of record requiring the person against whom it was brought to show cause why the party bringing the writ should not be able to cite that record in his own interest. Scire facias, BLACK'S LAW DICTIONARY (10th ed. 2014). This common-law writ has been abolished under federal law and is essentially unknown in modern practice and thus does not constitute a valid defense. FRCP 81(b); *Kapp v. Seventh Judicial Dist. Court*, 32 Nev. 264, 267, 107 P. 95, 95 (1910). Moreover, Wall admits that she certified on each renewal application for her Certificate of Registration No. CS15026 for the years 2010, 2012, 2014, 2016, and 2018, that she held an active and current Nevada license with the NSBME (response to paragraph III). Her repeated misrepresentations to the Board are not annulled by the fact that her status with the NSBME was a public record.

Finally, Wall pleads "latches" [sic] as her forth affirmative defense and alleges that the Board has somehow waived the right to take action against her due to the length of time her license has been inactive. This argument disregards the fact that she does not qualify to hold a controlled substance registration in the first place. Moreover, while it is debatable whether the equitable doctrine of laches applies to the Board's enforcement authority, Wall cannot show that any delay in holding her accountable has worked to her disadvantage. *See State v. Rosenthal*, 107 Nev. 772, 777-78, 819 P.2d 1296, 1298 (1991). Absent such a showing Wall cannot avail herself of this defense.

None of Wall's asserted affirmative defenses limit or excuse her culpability and she should be held to account for her violations of law.

IV. CONCLUSION

For the foregoing reasons, the prosecution respectfully submits that the Board should deem all allegations set forth in the Accusation as admitted by Respondent, should admit Wall's filed Answer and Notice of Defense and executed DEA Form 104 into the record as evidence, and should proceed to judgment as a matter of law.

RESPECTFULLY SUBMITTED this 20th day of August, 2020.

By:

BRETT KANDT, Esq. General Counsel

Nevada State Board of Pharmacy 985 Damonte Ranch Parkway – Suite 206

Reno, NV 89509

bkandt@pharmacy.nv.gov

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

DEA USE ONLY

File No.

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

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

ADDRESS OF REGISTRANT

Victoria Wall	2013 Grouse St. Las vojas, NV 89134
DEA REGISTRATION NO. BW 8998025	2003 1 901 - 71 - 9
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE
Wall strategy as	6/14/2020
WITNESSES TO REGISTRANT'S SIGNATURE	
Beverly a for 6/14/2020	
NAME AND DATE GIA/2020	mle

PRIVACY ACT

AUTHORITY: PURPOSE: ROUTINE USES:

Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).

Permit surrender for cause of DEA Certificate of Registration.

The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory egencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory egencies for law enforcement and regulatory purposes.

C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of oustomers and practitioners.

Submission of this Information is voluntary. There is no effect on the Individual If not provided.

EFFECT:

NAME OF REGISTRANT (Print)

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

BARON DAVID HARMON FAVIL DAVID BERNS & ASSOCIATES 30 E. NORTH AVE. NORTHLAKE, IL 60164

BRETT KANDT

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

FEB 1 3 2020

NEVADA STATE BOARD

OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

 $\mathbf{v}_{\boldsymbol{\cdot}}$

JOSHUA AIGHOBAHI, RPH, Certificate of Registration No. 18747,

KATHERINE KUEHL, RPH, Certificate of Registration No. 11172,

FELICIA AIGHOBAHI, PT, Certificate of Registration No. PT17660, and

DIVINE TOUCH SERVICES PHARMACY, Pharmacy License No. PH03411,

Respondents.

Case Nos. 19-035-RPH-A-S 19-035-RPH-B-S 19-035-PT-S 19-035-PH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Joshua Aighobahi, R.Ph., Certificate of Registration No. 18747, and Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172 (Kuehl), were pharmacists registered by the Board, Respondent Felicia Aighobahi, Certificate of Registration No. PT17660, was a pharmaceutical technician registered by the Board, and Respondent Divine Touch Services Pharmacy, License No. PH03411 (Divine Touch), was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

II.

Joshua Aighobahi owns and operates Divine Touch; he was the managing pharmacist of Divine Touch and the only registered pharmacist employed in the pharmacy until approximately October 31, 2019.

III.

Felicia Aighobahi is Joshua Aighobahi's wife and employed as a pharmaceutical technician by Divine Touch.

IV.

Throughout 2019, Felicia Aighobahi performed functions that are limited by law to a registered pharmacist and attributed the performance of those functions to Joshua Aighobahi.

V.

During annual inspections of Divine Touch on or about September 7, 2017, September 8, 2018, and September 23, 2019, Board staff observed that Joshua Aighobahi failed to conduct a proper biennial inventory of the pharmacy.

VI.

During the September 23, 2019, annual inspection Board staff observed that Joshua Aighobahi exhibited behavior that rendered him incapable of safely and competently practicing pharmacy, that he failed to a maintain an accurate perpetual inventory of schedule II-controlled substances, and that he failed to maintain DEA 222 forms.

VII.

On or about October 10, 2019, Board staff conducted a joint inspection of Divine Touch with the Drug Enforcement Administration (DEA). During the DEA audit of controlled substances at Divine Touch, both Board staff and DEA investigators observed that Joshua

Aighobahi exhibited behavior that rendered him incapable of complying with the audit and/or of safely and competently practicing pharmacy.

VIII.

On or about October 21, 2019, Joshua Aighobahi represented to Board staff that he would voluntarily cease operation of Divine Touch until he either successfully completed an evaluation of his competence to practice pharmacy pursuant to NRS 639.2445 or, alternatively, placed a managing pharmacist approved by Board staff in charge of the pharmacy pursuant to NRS 639.220(1).

IX.

On or about October 31, 2019, Joshua Aighobahi represented to Board staff through his legal counsel that he had employed Kuehl as the managing pharmacist for Divine Touch and had ceased practicing pharmacy.

X.

On or about January 9, 2020, Board staff conducted an inspection of Divine Touch and observed that Joshua Aighobahi continued to practice pharmacy even as his behavior continued to render him incapable of safely and competently practicing pharmacy, that Kuehl as the new managing pharmacist failed to properly conduct an initial inventory of the pharmacy, and that prescription labels did not include the expiration date for the medication.

XI.

During the inspections of Divine Touch on or about September 23, 2019, October 10, 2019, and January 9, 2020, Board staff observed that the pharmacy had possession of expired controlled substances and dangerous drugs for dispensing that were not properly segregated.

XII.

On or about January 21, 2020, Kuehl represented to Board staff that Joshua Aighobahi continued to practice pharmacy and perform certain functions reserved for a managing pharmacist.

APPLICABLE LAW

XIII.

NRS 453.246 Recordkeeping and inventory requirements for registrants. Persons registered to dispense controlled substances pursuant to the provisions of NRS 453.011 to 453.552, inclusive, shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law and with any additional regulations the Board issues.

XIV.

NRS 453.251 Order forms. Controlled substances listed in schedules I and II may be distributed by a registrant or licensed pharmacy to another registrant or licensed pharmacy only pursuant to an order form and may be received by a registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed in compliance with this section.

XV.

NRS 453.326 Unlawful acts relating to recordkeeping, inspections and knowingly keeping or maintaining a place where controlled substances are unlawfully used, kept or sold; penalty.

- 1. It is unlawful for a person:
- (a) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under the provisions of NRS 453.011 to 453.552, inclusive;

XVI.

NRS 453.236 Suspension, revocation of registration; seizure, placement under seal of controlled substance owned or possessed by registrant; notification of Drug Enforcement Administration and Division concerning suspension, revocation or forfeiture; registrant prohibited from employing person whose pharmacist's certificate was suspended or revoked.

- 1. The Board may suspend or revoke a registration pursuant to NRS 453.231 to dispense a controlled substance upon a finding that the registrant has:
- (d) Committed an act that would render registration under NRS 453.231 inconsistent with the public interest as determined pursuant to that section.

XVII.

NRS 639.100(1)(a) states in relevant part: "It is unlawful for any person to sell or dispense, or permit to be . . . sold or dispensed, any drug, . . . unless the person . . . [i]s a registered pharmacist. See also 21 U.S.C. § 841(a).

XVIII.

NRS 639.210 Grounds for suspension or revocation of certificate, license, registration or permit or denial of application. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant:

- 1. Is not of good moral character;
- 4. Is guilty of unprofessional conduct or conduct contrary to the public interest;
- 9. Has willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of this chapter;
- 11. Has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs;

12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit;

. . . .

15. Has, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of this chapter or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision;

. . . .

17. Has failed to maintain and make available to a state or federal officer any records in accordance with the provisions of this chapter or chapter 453 or 454 of NRS;

XIX.

NRS 639.2445 Physical or mental examination of holder of certificate believed to be incompetent; competency hearing; probation for use of alcohol or drugs.

- 1. Whenever the Board believes that a holder of a certificate is or has become incompetent to practice pharmacy by reason of any physical or mental injury, illness or disability or by reason of chronic or excessive use of alcohol or drugs, the Board may order that the holder of the certificate submit to a physical or psychiatric examination, or both, at the expense of the Board.
- 2. The Board shall designate a physician or a psychiatrist or both, as the case may be, to conduct the examination or examinations of the holder of the certificate and furnish the Board and the holder of the certificate with a report of the findings. If the holder of the certificate is dissatisfied with the findings, the holder of the certificate may obtain an independent examination and report at his or her own expense, not later than 10 days following receipt of the initial report.
- 3. Upon receipt of the findings the Board shall conduct a hearing to determine whether the holder of the certificate is competent to practice pharmacy. Except as provided in subsection 4, if the Board finds that the holder of the certificate is not competent to practice pharmacy, it shall order an immediate suspension of his

or her right to practice pharmacy, and the suspension remains in effect until the Board determines that a certificate may be reinstated.

4. The Board may place on probation a holder of a certificate who is not competent to practice pharmacy by reason of chronic or excessive use of alcohol or drugs if the holder of the certificate voluntarily enters and completes a program of treatment approved by the Board and complies with any other conditions imposed by the Board.

XX.

NRS 639.282 Unlawful possession or sale of certain pharmaceutical preparations, drugs or chemicals; destruction.

- 1. Except as otherwise provided . . . it is unlawful for any person to have in his or her possession, or under his or her control, for the purpose of resale, or to sell or offer to sell or dispense or give away, any pharmaceutical preparation, drug or chemical which:
- (d) Is no longer safe or effective for use, as indicated by the expiration date appearing on its label; or

XXI.

NAC 453.475 Initial and biennial inventory of controlled substances by new managing pharmacist.

- 1. A pharmacist who is hired or promoted to manage a pharmacy pursuant to the provisions of NRS 639.220 shall:
- (a) Within 48 hours after first reporting for duty as the managing pharmacist, conduct an inventory of the controlled substances of the pharmacy with the pharmacist who preceded him or her as the managing pharmacist. The pharmacists shall sign the inventory.
- (b) After the date on which the inventory required pursuant to paragraph (a) was taken, conduct an inventory of the controlled substances of the pharmacy at least once every 2 years during the course of his or her employment as managing pharmacist at the pharmacy. The managing pharmacist may conduct the biennial inventory on any date which is within 2 years of the date on which the previous biennial inventory was conducted.
 - 2. An inventory required by subsection 1 must be:
- (a) Conducted according to the method prescribed by the provisions of 21 C.F.R. Part 1304; and
- (b) Placed in the records of the controlled substances of the pharmacy.

XXII.

NAC 639.050 Storage and destruction of certain controlled substances.

. . . .

2. Each practitioner or pharmacy shall physically separate each controlled substance which is outdated, damaged, deteriorated, misbranded or adulterated from the balance of its stock medications.

XXIII.

NAC 639.473 Procurement and storage of drugs.

- 1. The managing pharmacist of a pharmacy is responsible for the procurement and storage of drugs in that pharmacy.
- 3. Outdated drugs must be removed from stock and identified and maintained separately from other stock until disposal.

XXIV.

NAC 639.482 Maintenance and availability of records.

- 1. Each record required to be kept pursuant to NAC 639.483 to 639.489, inclusive, must be kept by a pharmacy for at least 2 years after the date of the record.
- 2. Records maintained by a pharmacy must be made available for inspection and copying upon the request of the Board, its representatives, or another authorized local, state or federal law enforcement agency.

XXV.

NAC 639.485 Maintenance of records for controlled substances.

- 1. A pharmacy shall maintain records for controlled substances:
 - (a) In a readily retrievable manner.
- (b) In a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy.
- 2. A pharmacy shall maintain a perpetual inventory of any controlled substance listed in schedule II.
- 3. Records of the distribution of controlled substances listed in schedule II, schedule III or schedule IV must include:
 - (a) The name of the drug, dosage form and strength.
- (b) The name of the pharmacist distributing or authorizing the distribution of the controlled substance.

- (c) The name of the authorized person receiving the controlled substance. This information may be included on the record of administration.
- (d) The location to which the controlled substance is being distributed.
 - (e) Controlled substances returned to the pharmacy.
- (f) A record of any waste of any prepared or partially administered dose of a controlled substance, which must be witnessed and cosigned by another person who is licensed to provide medical care.

XXVI.

NAC 639.487 Maintenance of additional records.

In addition to any other requirements for keeping records, a pharmacy shall maintain the following records:

- 1. Copy 3 of the order form of the Drug Enforcement Administration (DEA 222C), properly dated, initialed and filed, copies of each unaccepted or defective order form, and any attached statements or other documents.
- 2. Suppliers' invoices of controlled substances and dangerous drugs. The pharmacist or other personnel of the pharmacy shall clearly record on each invoice the actual date on which the controlled substance or dangerous drug was received.
- 3. Suppliers' credit memos for controlled substances and dangerous drugs.
- 4. The biennial inventory of controlled substances required by the Drug Enforcement Administration.
- 5. Any reports of theft or significant loss of controlled substances submitted to the Drug Enforcement Administration.
- 6. Reports of the surrender or destruction of controlled substances or dangerous drugs, or both, to an appropriate state or federal agency.
- 7. A register book for nonprescription drugs listed in schedule V.

XXVII.

NAC 639.510 Maintenance and storage of pharmaceutical stock.

2. The managing pharmacist of a pharmacy:

- (a) Is responsible for, and must have knowledge and control of, the acquisition and disposition by the pharmacy of the stock of the pharmacy; and
- (b) Shall ensure that the records relating to the acquisition or disposition of the stock of the pharmacy are maintained as required by law.
- 3. The dangerous drugs, controlled substances, chemicals, biologicals and devices kept in the stock of a pharmacy must meet all of such standards of purity and strength as established by current official compendia or as established on the appropriate labels, and must be properly stored. Any preparation which varies from such standards of purity and strength or becomes unfit for use from deterioration or other cause must not be carried in stock and must be destroyed in a manner provided by law when so ordered by an agent of the Board.

XXVIII.

NAC 639.512 Class A and B packaging: Label; expiration date; log.

2. Each unit dose of a controlled substance or dangerous drug packaged or repackaged by a pharmacy must contain a label which specifies:

(c) The expiration date; and

. . . .

XXIX.

NAC 639.523 Physical address for delivery of drugs.

3. A pharmacist employed by a pharmacy shall acknowledge on every invoice that the drugs listed in the invoice were physically received by the pharmacy at the physical address to which the Board has issued the license of the pharmacy.

XXX.

NAC 639.601 Prescription drugs: Separation and disposal of certain drugs.

1. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier.

. . .

XXXI.

NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.

1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

(h) Performing or in any way being a party to any fraudulent

or deceitful practice or transaction.

- (i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.
- (j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.
- (k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.

. . . .

(m) Failing to provide any document, data or information that is required to be made and maintained pursuant to chapters 453, 454, 585 and 639 of NRS and chapters 453, 454, 585 and 639 of NAC to a member of the Board or a member of the staff of the Board upon his or her request.

. . . .

2. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ.

XXXII.

NAC 639.955 Imposition of fines; authority to take disciplinary action.

1. Except as otherwise provided in this section, the Board may impose a fine against a pharmacist or pharmacy pursuant to paragraph (f) of subsection 1 of NRS 639.255 according to the following schedule:

. . . .

(h) For failing to make or maintain a biennial inventory of controlled substances......\$1,000.00

. . . .

2. The Board may impose a fine for a violation listed in subsection 1 that is less than or greater than the amount set forth in that subsection for that violation after giving consideration to any aggravating and mitigating factors that relate to the violator's role in and responsibility for the conduct for which the fine is being imposed, and the unique circumstances of each case.

. . . .

- 5. The Board may, as it deems appropriate, impose a fine for a violation not listed in subsection 1 that is commensurate with the severity of the violation.
 - 6. No fine imposed by the Board will exceed \$10,000.

. . . .

8. This section will be construed and applied so as to preserve the discretion of the Board to take any disciplinary action authorized by NRS 639.255.

XXXIII.

21 C.F.R. § 1304.11 Inventory requirements.

. . . .

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

XXXIV.

21 C.F.R. § 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to §1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mailback package, except that no registrant shall be required to maintain a perpetual inventory.

XXXV.

21 U.S.C. § 842(a)(5) states in relevant part: "It shall be unlawful for any person . . . to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration,

order or order form, statement, invoice, or information required under this subchapter or subchapter II[.]"

FIRST CAUSE OF ACTION

Failure to Maintain Perpetual Inventories of Controlled Substances (Respondents Joshua Aighobahi and Divine Touch)

XXXVI.

By failing to maintain at least two years' worth of perpetual inventories of schedule II-controlled substances in a readily retrievable manner, Joshua Aighobahi and Divine Touch violated NRS 453.246, NAC 639.485(1) and (2), and NAC 639.482(a) and (b), engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4), (12) and (17).

SECOND CAUSE OF ACTION

Failure to Maintain Accurate Biennial Inventories of Controlled Substances (Respondents Joshua Aighobahi and Divine Touch)

XXXVII.

By failing to maintain at least two years' worth of biennial inventories of its controlled substances in a readily retrievable manner, Joshua Aighobahi and Divine Touch violated NRS 453.246, NAC 453.475(1)(b) and (2), NAC 639.482(a) and (b), NAC 639.487(4), NAC 639.510, 21 U.S.C. § 842(a)(5) and 21 CFR § 1304.11, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and are subject to discipline pursuant to NRS 453.236(1), NRS 639.210(4), (12) and (17).

THIRD CAUSE OF ACTION

Failure to Maintain Records of Controlled Substance Purchases (Respondents Joshua Aighobahi and Divine Touch)

XXXVIII.

By failing to maintain accurate and complete invoices for the controlled substances

Divine Touch purchased and received, Joshua Aighobahi and Divine Touch violated NRS

453.246, NRS 453.251, NRS 453.326(1)(a), NAC 639.510, NAC 639.523(3), 21 U.S.C. §

842(a)(5) and 21 CFR § 1304.21, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and are subject to discipline pursuant to NRS 453.236(1), NRS 639.210(4), (11), (12) and (17).

FOURTH CAUSE OF ACTION

Fraudulent or Deceitful Practice/Practicing as a Registered Pharmacist Without Registration

(Respondent Felicia Aighobahi)

XXXIX.

By performing functions that are limited by law to a registered pharmacist and attributing the performance of those functions to Joshua Aighobahi, Felicia Aighobahi was party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct as defined in NAC 639.945(1)(h) and (k), and is subject to discipline pursuant to NRS 639.210(4).

FIFTH CAUSE OF ACTION

Fraudulent or Deceitful Practice / Aiding or Abetting a Person Not Licensed to Practice Pharmacy

(Respondent Joshua Aighobahi)

XL.

By permitting Felicia Aighobahi to perform duties that are limited by law to a registered pharmacist, Joshua Aighobahi was party to a fraudulent or deceitful practice or transaction, aided or abetted a person not licensed to practice pharmacy in the State of Nevada, engaged in unprofessional conduct as defined in NAC 639.945(1)(h) and (j), and is subject to discipline pursuant to NRS 639.210(4).

SIXTH CAUSE OF ACTION

Unlawful Dispensing and Sales (Respondents Joshua Aighobahi and Felicia Aighobahi)

XLI.

By permitting Felicia Aighobahi to perform functions that are limited by law to a registered pharmacist and attributing the performance of those functions to Joshua Aighobahi, Joshua Aighobahi and Felicia Aighobahi violated, attempted to violate, assisted or abetted in the

violation of or conspired to violate NRS 453.331(1)(c), NRS 453.381(8), NRS 453.401(1)(a), NRS 639.100(1)(a), NRS 639.284 and/or 21 U.S.C. § 841(a), and are subject to discipline pursuant to NRS 639.210(9), (11) and (12).

SEVENTH CAUSE OF ACTION Failure to Conduct Initial Inventory of Controlled Substances (Respondent Kuehl)

XLII.

By failing to properly conduct an initial inventory of the pharmacy as the new managing pharmacist, Kuehl violated NRS 453.246, NAC 453.475(1)(a) and (2) and NAC 639.510, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and is subject to discipline pursuant to NRS 639.210(4), (15) and (17).

EIGHTH CAUSE OF ACTION

Failure to Properly Store Expired Drugs (Respondents Joshua Aighobahi, Kuehl and Divine Touch)

XLIII.

By failing to segregate expired drugs from unexpired drugs and secure those expired drugs in an area where they could not be used to administer or fill prescriptions, Joshua Aighobahi, Kuehl and Divine Touch violated NRS 639.282(1)(d), NAC 639.050(2), NAC 639.473(1) and (3), NAC 639.510(3) and NAC 639.601(1), engaged in unprofessional conduct as defined in NAC 639.945(i), and are subject to discipline pursuant to NRS 639.210(4), (12) and (15).

NINTH CAUSE OF ACTION

Failure to Properly Label Prescription Drugs (Respondents Joshua Aighobahi, Kuehl and Divine Touch)

XLIV.

By failing to include the expiration date for medication on prescription labels, Joshua Aighobahi, Kuehl and Divine Touch violated NAC 639.512(2)(c), engaged in unprofessional

conduct as defined in NAC 639.945(i), and are subject to discipline pursuant to NRS 639.210(4), (12) and (15).

TENTH CAUSE OF ACTION

Incompetent, Unskillful and Negligent Practice of Pharmacy (Respondent Joshua Aighobahi)

XLV.

By continuing to practice pharmacy even as his behavior rendered him incapable of safely and competently practicing pharmacy, Joshua Aighobahi performing his duties as a registered pharmacist and as the owner of Divine Touch in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct as defined in NAC 639.945(1)(i), is subject to discipline pursuant to NRS 639.210(4), and should be required to submit to a physical or psychiatric examination, or both, pursuant to NRS 639.2445.

ELVENTH CAUSE OF ACTION

Managing Pharmacist Responsibilities (Respondents Joshua Aighobahi and Kuehl)

XLVI.

As the managing pharmacists of Divine Touch at the time of the violations alleged herein, either Joshua Aighobahi and Kuehl are responsible for those violations, including those of the pharmacy's employees, pursuant to NRS 639.220(1), NAC 639.473, NAC 639.510 and NAC 639.702, and are subject to discipline pursuant to NRS 639.210(15).

TWELVTH CAUSE OF ACTION

Pharmacy/Pharmacy Owner Responsibility (Respondent Joshua Aighobahi)

XLVII.

As the owner of Divine Touch at the time of each of the violations alleged herein, Joshua Aighobahi is responsible for the violations, including those of his employees, pursuant to NRS 639.230(5) and NAC 639.945(2), and is subject to discipline pursuant to NRS 639.210(1), (4), (9) (11), (12), (15) and (17).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and/or licenses of these respondents.

DATED this 13 Hday of February, 2020.

David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-035-RPH-B-S

Petitioner,

v.

KATHERINE KUEHL, RPH, Certificate of Registration No. 11172,

Respondent.

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, March 18, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 13^{11} day of February, 2020.

David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-035-RPH-B-S

Petitioner,

v.

KATHERINE KUEHL, RPH Certificate of Registration No. 11172,

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies
and alleges as follows:
I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and
all facts therein stated, are true and correct to the best of my knowledge.
DATED this day of February 2020.
KATHERINE KUEHL, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of February, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Joshua Aighobahi, R.Ph. 9504 Empire Rock Street Las Vegas, NV 89143

Katherine L. Kuehl, R.Ph. 700 North Las Vegas Blvd. Las Vegas, NV 89101

Felicia Aighobahi, PT 2208 E. Charleston Blvd., #B Las Vegas, NV 89104

Divine Touch Services Pharmacy 2208 E. Charleston Blvd., #B Las Vegas, NV 89104

Persi J. Mishel, Esq. 10161 Park Run Drive, Ste. 150 Las Vegas, NV 89145

SHIRLEY HUNTING

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of March, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Katherine L. Kuehl, RPH 2000 Paradise Rd., #1205 Las Vegas, NV 89104

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JOSHUA AIGHOBAHI, RPH, Certificate of Registration No. 18747,

KATHERINE KUEHL, RPH, Certificate of Registration No. 11172,

FELICIA AIGHOBAHI, PT, Certificate of Registration No. PT17660, and

DIVINE TOUCH SERVICES PHARMACY, Pharmacy License No. PH03411,

Respondents.

Case Nos. 19-035-RPH-A-S 19-035-RPH-B-S 19-035-PT-S 19-035-PH-S

STIPULATION AND ORDER (Respondent Katherine Kuehl)

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172 (Kuehl), HEREBY STIPULATE AND AGREE THAT:

- 1. On or about March 19, 2020, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.
- 2. Respondent is fully aware of her right to seek the advice of counsel in this matter prior to entering into this Stipulation.
- 3. Respondent is aware of her right to a hearing on the matters alleged in the Accusation, her right to reconsideration, her right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

- 4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of Paragraph 7 below, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).
- 5. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*, that:
- A. By failing to properly conduct an initial inventory of the pharmacy as the new managing pharmacist, Kuehl violated NRS 453.246, NAC 453.475(1)(a) and (2) and NAC 639.510, engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (m), and is subject to discipline pursuant to NRS 639.210(4), (15) and (17);
- B. By failing to segregate expired drugs from unexpired drugs and secure those expired drugs in an area where they could not be used to administer or fill prescriptions, Kuehl violated NRS 639.282(1)(d), NAC 639.050(2), NAC 639.473(1) and (3), NAC 639.510(3) and NAC 639.601(1), engaged in unprofessional conduct as defined in NAC 639.945(i), and is subject to discipline pursuant to NRS 639.210(4), (12) and (15);
- C. By failing to include the expiration date for medication on prescription labels, Kuehl violated NAC 639.512(2)(c), engaged in unprofessional conduct as defined in NAC 639.945(i), and is subject to discipline pursuant to NRS 639.210(4), (12) and (15); and
- D. As the managing pharmacist of Divine Touch at the time of the violations herein, Kuehl is responsible for those violations, including permitting Joshua Aighobahi to continue to practice pharmacy even as his behavior continued rendered him incapable of safely

and competently practicing pharmacy, pursuant to NRS 639.220(1), NAC 639.473, NAC 639.510 and NAC 639.702, and Kuehl is therefore subject to discipline pursuant to NRS 639.210(15).

- 6. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 639.210 and NRS 639.255.
- 7. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172, stipulate to the following penalties:
- A. Kuehl shall receive a letter of reprimand from Board Staff regarding her duties and responsibilities as a managing pharmacist.
- B. Kuehl may not be designated as and shall not work as managing pharmacist in any facility licensed by the Board for a period of one (1) year;
- C. Kuehl shall complete two (2) extra hours of continuing education (CE) on pharmacy management, in addition to the CE hours she must otherwise complete to maintain her licensure;
- D. Kuehl shall pay a fine of One-Thousand Dollars (\$1000.00) for the alleged violations, payable by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, in monthly installments of \$250.00 for four (4) months and due on the first date of each month commencing September 1, 2020; and
- E. Kuehl shall pay Five-Hundred Dollars (\$500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte

Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

- 8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.
- 9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 15, 2020, in Las Vegas. Respondent will appear at the meeting to answer questions from the Board members and/or staff. The Board members may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.
- 10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board it shall be a public record pursuant to NRS 622.330.
- 11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.
- 12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:	
Signed this day of July, 2020	Signed this day of July, 2020
KATHERINE KUEHL, RPH, Certificate of Registration No. 11172	BRETT KANDT, ESQ. General Counsel Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Katherine Kuehl, R.Ph., Certificate of Registration No. 11172, in Case No. 19-035-RPH-B-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ____ day of July, 2020.

Helen Park, President
Nevada State Board of Pharmacy

5D



NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

GLORY K. REMLEY, R.PH, Certificate of Registration No. 10562,

JESSICA L. HUEY, R.PH. Certificate of Registration No. 18577, and

WALMART PHARMACY #10-3728 Certificate of Registration No. PH02226

Respondents.

Case Nos. 18-096-RPH-A-S 18-096-RPH-B-S 18-096-PH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Glory K. Remley, R.Ph. (Remley), Certificate of Registration No. 10562, and Jessica L. Huey, R.Ph. (Huey), Certificate of Registration No. 18577, were pharmacists registered with the Board, and Walmart Pharmacy #10-3728 (Walmart) License No. PH02226, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

II.

Remley and Huey were employed by Walmart at the time of the events alleged herein.

III.

On August 3, 2018, A.L. was examined by a nurse practitioner and received a prescription for Tramadol 50 mg. with instructions to take one tablet every six hours as needed. The prescription allowed for a quantity of 12 tablets for a three day supply and "0" (zero) refills.

IV.

A.L. tendered the prescription to Walmart where pharmaceutical technician John Castro (Castro) performed data entry in Walmart's computer system. The computer system designated the prescription as No. 4466273.

V.

During data entry, Castro erroneously entered the days' supply of "3" in the refill field rather than the "0" refills written on the prescription by the prescriber.

VI.

Remley is on record as the verifying pharmacist for the four point data entry check for Prescription No. 4466273. She failed to detect the error in the number of refills when she verified data entry as accurate.

VII.

Huey performed the final visual check and failed to identify the refill error during the final product review.

VIII.

The initial fill of Prescription No. 4466273 was dispensed to A.L. on August 9, 2018.

IX.

Prescription No. 4466273 was subsequently refilled and dispensed on August 16, 2018, and again on August 26, 2018.

X.

The refill error was discovered when A.L.'s nurse practitioner reported unauthorized refills to the Prescription Monitoring Program.

FIRST CAUSE OF ACTION

Unprofessional Conduct, Failure to Verify Dispensed Medication (Respondent Remley)

XI.

Unprofessional conduct includes the failure by a licensee to follow strictly the instructions of a practitioner when labeling and dispensing a prescription. *See* NAC 639.945(1)(d). It also includes a licensee performing his duties in an "incompetent, unskillful or negligent manner". *See* NAC 639.945(1)(i).

Additionally, NAC 639.252 states in relevant part:

If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, *the pharmacist supervising the pharmaceutical technician* is responsible for the filled prescription, including, but not limited to, verifying:

- (a) The selection and strength of the drug;
- (b) The dosage form; and
- (c) The labeling of the prescription.

NAC 639.252(2) (emphasis added.)

Remley violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when she verified as accurate the data entry of Prescription No. 4466273, in which a technician's erroneous data entry error resulted in Walmart dispensing two unauthorized refills of Prescription No. 4466273. Remley is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

SECOND CAUSE OF ACTION

Unprofessional Conduct, Failure to Verify Dispensed Medication (Respondent Jessica Huey)

XII.

Respondent Huey violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when she verified as accurate, the final product on Prescription No. 4466273, in which a technician's erroneous data entry error resulted in Walmart dispensing two unauthorized refills of Prescription No. 4466273. Huey is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

THIRD CAUSE OF ACTION

(Pharmacy/Pharmacy Owner Responsibility) (Respondent Walmart Pharmacy #10-3728)

XIII.

NRS 639.230(5) provides: "Any violation of any of the provisions of this chapter [NRS Chapter 639] by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for the suspension or revocation of the license of the pharmacy by the Board."

Additionally, "[t]he owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission." NAC 639.702.

Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walmart #10-3728 is responsible for each of the violations alleged herein pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

Signed this 11 day of June, 2020.

J. David Wuest, Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY.

CASE NO. 18-096-PH-S

Petitioner,

 \mathbf{v}_{ullet}

WALMART PHARMACY #10-3728
Certificate of Registration No. PH02226,

Respondent.

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 15, 2020, 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this May of June, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 15th day of June, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Glory Remley, R.Ph. 7 Lois Ct. Attleboro, MA 02703

Jessica Huey, R.Ph. 9270 Keystone Ridge Ave. Las Vegas, NV 89148

Walmart Pharmacy #10-3728 3950 W. Lake Mead Blvd. North Las Vegas, NV 89032

SHIRLEY HUNTING

JUL 21 2020

NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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HAL TAYLOR, ESQ. 223 Marsh Avenue RENO, NV 89609 TEL. (775)825-2223, FAX (775) 329-1113

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NEVADA STATE BOARD OF PHARMACY, Case Nos. 18-096-RPH-A-S
Petitioner, 18-096-RPH-B-S

18-096-PH-S

v.

GLORY K. REMLEY, R.PH.
Certificate of Registration No. 10562

JESSICA L. HUEY, R.PH.
Certificate of Registration No. 18577, and

WALMART PHARMACY #10-3728
Certificate of Registration No. PH02226

Respondents

AND NOTICE OF DEFENSE

Respondent Walmart Pharmacy #10-3728 ("Respondent Walmart"), in answer to the Notice of Intended Action and Accusation ("Accusation") in the above matter, admits, denies and alleges as follows:

Jurisdiction

1.

Admitted.

Factual Allegations

11.

Admitted

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III.

Admitted that A.L. was prescribed Tramadol 50 mg. with instructions to take one tablet every six hours as needed. The prescription allowed for a quantity of 12 tablets for a three-day supply and "0(Zero)" refills. ("Prescription") Admitted that the Prescription was dated August 3, 2018. Respondent Walmart has no direct knowledge of A.L.'s medical examination that let to the Prescription being written.

IV.

Admitted that on August 9, 2018, A.L. tendered the Prescription to Walmart, and that pharmaceutical technician John Castro ("Castro") performed the initial data entry into Walmart's pharmaceutical computer system. Admitted that the computer system designated the Prescription as Prescription No. 4466273.

V.

Admitted that during the data entry, Castro mistakenly entered the days' supply of "3" into the computer system's refill field rather than the "0" refills written in the Prescription.

VI.

Admitted. Further answering, an image of the original Prescription was available on the computer screen for verification purposes during the four-point data entry check on the Prescription. Therefore, the process put in place by Walmart for confirming that the refill information for this Prescription had been properly transferred to the computer was sufficient to have detected the error.

VII.

Admitted that Respondent Huey performed the Visual Verification on the medication. Per the applicable Walmart Standards of Practice, the pharmacist performing the Visual Verification has no responsibility for confirming that the refill information has been properly transferred from the subject prescription to the computer. Respondent Walmart denies that Respondent Huey violated any statute or regulation by not identifying any refill error for this Prescription.

HAL TAYLOR, ESQ. 223 Harsh Avenus RENO, NV 89609 IEL. (775)826-2223, FAX (775) 329-1113 1

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VIII.

Admitted that the initial fill of the Prescription was dispensed to A.L. on August 9, 2018.

IX.

Admitted that Walmart's records reflect that the Prescription was subsequently refilled and dispensed on August 16, 2018, and again on August 26, 2018.

X.

Respondent Walmart has no personal knowledge of the allegation in this paragraph.

FIRST CAUSE OF ACTION

(Respondent Remley)

This Cause of Action does not require a response by Respondent Walmart.

SECOND CAUSE OF ACTION

Unprofessional Conduct, Failure to Verify Dispensed Medication

(Respondent Huey)

This Cause of Action does not require a response by Respondent Walmart..

THIRD CAUSE OF ACTION

(Respondent Walmart Pharmacy #10-3728)

Respondent Walmart admits that it owned and operated the pharmacy in which the refill error alleged in the Accusation occurred.

Respondent Walmart denies that the mere ownership and operation of this pharmacy makes it subject to suspension or revocation for any violations of NRS 639 by any managing pharmacist or other pharmacy personnel in violation of NRS 639.230(5)

Respondent Walmart denies that the mere ownership and operation of this pharmacy makes it subject to discipline under NAC 639.702 for errors committed by pharmaceutical technicians or other personnel who are not pharmacists as alleged in this Accusation, because Respondent Walmart did not know, nor should it have known

Respondent Walmart denies that the mere ownership and operation of this pharmacy makes it subject to discipline under NAC 639.945(2) for the acts of all personnel in Walmart's employ.

Respondent Walmart denies that the mere ownership and operation of this pharmacy makes it strictly responsible and subject to discipline for the acts and omissions of any licensed or non-licensed personnel it employed absent any act or omission by Respondent Walmart that contributed to the errors alleged in the Accusation.

AFFIRMATIVE DEFENSE

Had Respondent Walmart's policies and procedures been properly followed, the errors alleged in the Accusation would not have occurred, therefore Respondent Walmart should not be held responsible for any violations alleged in the Accusation.

WHEREFORE, Respondent Walmart #10-3728 prays for dismissal of ail accusations against it.

Dated: July ____, 2020.

Walmart #10-3728

By: Shelley Tustison, Director
U. S. Health and Wellness
Practice Compliance

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

Date: July <u>A</u>, 2020.

HAL TAYLOR, ESQ.

223 Marsh Ave.

Reno, Nevada 89509

(775) 825-2223

Email haltaylorlawyer@gbls.com

Hai Taylor, Esq.

HAL TAYLOR, ESQ. 223 Marsh Avenue RENO, NV 89609 TEL. (775)825-2223, FAX (775) 329-1113

CERTIFICATE OF SERVICE

On this date, the undersigned, an employee of Hal Taylor, Esq., delivered by email a copy of the attached Answer and Notice of Defense upon the following:

Brett Kandt General Counsel Nevada Board of Pharmacy bkandt@pharamcy.nv.gov

Date: July 21, 2020.

Hal Taylor

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner.

v.

Case Nos. 18-096-RPH-A-S 18-096-RPH-B-S

18-096-PH-S

ORDER

GLORY K. REMLEY, R.PH, Certificate of Registration No. 10562,

JESSICA L. HUEY, R.PH., Certificate of Registration No. 18577, and

WALMART PHARMACY #10-3728. Certificate of Registration No. PH02226,

Respondents.

- J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), hereby orders as follows:
- On or about July 22,2020, Respondent Glory K. Remley, R.Ph. (Remley), 1. Certificate of Registration No. 10562, filed an Answer and Notice of Defense to the Notice of Intended Action and Accusation on file in this matter. The First Cause of Action (Paragraph XI) against Remley is hereby dismissed. Remley shall subject to a CITATION pursuant to NRS 639.2895(2) for violating NAC 639.252(2) and shall be assessed an administrative fine of one thousand dollars (\$1,000.00) pursuant to NRS 639.2895(3). The administrative fine shall be paid by cashier's check or certified check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway - Suite 206, Reno, Nevada 89521, within thirty (30) days of the entry of this Order. Remley has the right to appeal this citation and fine by submitting a written request for a hearing to the Board at the Board's Reno office within thirty (30) days of the entry of this Order. See NRS 639.2895(2).

2. On or about July 21,2020, Respondent Jessica L. Huey, R.Ph., Certificate of Registration No. 18577, filed an Answer and Notice of Defense to the Notice of Intended Action and Accusation on file in this matter. The Second Cause of Action (Paragraph XII) against Huey is hereby dismissed.

IT IS SO ORDERED.

Entered this 27⁴ day of July, 2020.

J. David Wuest, Executive Secretary Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Glory Remley, R.Ph. 7 Lois Ct. Attleboro, MA 02703

Jessica Huey, R.Ph. 9270 Keystone Ridge Ave. Las Vegas, NV 89148

Walmart Pharmacy #10-3728 3950 W. Lake Mead Blvd. North Las Vegas, NV 89032

Hal Taylor, Esq. 223 Marsh Avenue Reno, NV 89509

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

GLORY K. REMLEY, R.PH, Certificate of Registration No. 10562,

JESSICA L. HUEY, R.PH., Certificate of Registration No. 18577, and

WALMART PHARMACY #10-3728, Certificate of Registration No. PH02226,

Respondents.

Case Nos. 18-096-RPH-A-S 18-096-RPH-B-S 18-096-PH-S

STIPULATION AND ORDER (Respondent Walmart Pharmacy #10-3728 Only)

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Walmart Pharmacy #10-3728, Pharmacy License No. PH02226, by and through counsel, Hal Taylor, Esq., **HEREBY STIPULATE AND AGREE THAT**:

- 1. The Board has jurisdiction over Respondents and this matter.
- 2. On or about June 11, 2020, Board Staff properly served Respondent Walmart Pharmacy #10-3728 with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.
- 3. On or about July 29 ,2020, Respondent Walmart Pharmacy #10-3728 filed an Answer and Notice of Defense to the Accusation.
- 4. Respondent Walmart Pharmacy #10-3728 is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.
- 5. Respondent Walmart Pharmacy #10-3728 is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to Respondent pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

- 6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent Walmart Pharmacy #10-3728 has failed to comply with the provisions of Paragraph 9 below, Respondent hereby freely and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).
- 7. Respondent Walmart Pharmacy #10-3728 admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*, that:
- A. Respondent Glory K. Remley, R.Ph., Certificate of Registration No. 10562, violated NAC 639.252(2) when she verified as accurate the data entry of Prescription No. 4466273 for Tramadol 50 mg., in which a technician's erroneous data entry error resulted in Walmart dispensing two unauthorized refills; and
- B. As the pharmacy/pharmacy owner at which the alleged violation of law occurred, Walmart Pharmacy #10-3728 is responsible for the violation pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).
- 8. The violation is plead with particularity in the Accusation, and grounds for action pursuant to NRS 639.210 and NRS 639.255.
- 9. Based upon the Accusation and the foregoing admissions, the Board and Respondent Walmart Pharmacy #10-3728 stipulate to the following penalties. Respondent Walmart Pharmacy #10-3728, Pharmacy License No. PH02226, shall:
- A. Pay a fine of One-Thousand Dollars (\$1,000.00) for the alleged violation, by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order; and

- B. Pay One-Thousand Dollars (\$1,000.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, by cashier's check or certified check or money order made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.
- 10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.
- 11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 2, 2020. Respondent and/or its authorized representative(s) may appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.
- 12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board it shall be a public record pursuant to NRS 622.330.
- 13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.
- 14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

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Signed this 1 day of September, 2020

Signed this ___ day of September, 2020

WALMART PHARMACY #10-3728
Certificate of Registration No. PH02226

BRETT KANDT, ESQ. General Counsel Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Walmart Pharmacy #10-3728, Pharmacy License No. PH02226, in Case No. 18-096, and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ____ day of September, 2020.

Helen Park, President Nevada State Board of Pharmacy **5E**

NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-066-RPH-S

AND ACCUSATION

NOTICE OF INTENDED ACTION

v.

Petitioner,

PAUL LUKE, RPH Certificate of Registration No. 15314,

Respondent.

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Paul Luke ("Luke"), Certificate of Registration No. 15314, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

- 2. Luke was employed by St. Rose Dominican Hospital San Martin Campus ("St. Rose"), located on 8280 West Warms Springs Road, Las Vegas, Nevada 89113, until April 2019.
- 3. On or about April 5, 2019, Pharmacist Jason Glick, Director of Pharmacy for St. Rose, reported Luke to the Board alleging concealment of drugs and pharmacy supply items in a bag from St. Rose with intent to divert.

- 4. A subsequent investigation by St. Rose's staff identified a total of at least twenty (20) tablets diverted by Luke:
 - 20 Minocycline 50mg tablets
 - 1 box of Tylenol
 - 1 bottle of Peridex
- 5. During the investigation, Luke admitted to the unlawful diversion activity, and submitted a statement regarding same.
 - 6. St. Rose terminated Luke on April 5, 2019.

FIRST CAUSE OF ACTION

Unprofessional Conduct - Diversion

- 7. "Supplying or diverting drugs . . . which are legally sold in pharmacies . . . so that unqualified persons can circumvent any law pertaining to the legal sale of such articles" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(g). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).
- 8. By diverting a dangerous drug, and other pharmacy supplies as alleged herein, Luke engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

SECOND CAUSE OF ACTION Unprofessional Conduct - Deceitful Practice

9. "Performing or in any way being a party to any fraudulent or deceitful practice or transaction" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(h). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).

10. By diverting a dangerous drug, and converting other items as alleged herein, Luke was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is subject to discipline pursuant to NRS 639.210(4).

THIRD CAUSE OF ACTION

Statutory Violations- Unlawful Possession and Dispensing of a Dangerous Drug

- 11. Violating any law or regulation relating to drugs is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(12).
- 12. By possessing and diverting a dangerous drug as alleged herein, Luke violated or attempted to violate, NRS 454.213, NRS 454.215, NRS 454.221, NRS 454.311, NRS 454.321, NRS 639.100(1) and NRS 639.284(2) and is subject to discipline pursuant to NRS 639.210(12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 3. h day of July, 2020.

J. David Wuest, Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-066-RPH-S

Petitioner,

 \mathbf{v}_{\bullet}

PAUL LUKE, RPH Certificate of Registration No. 15314, STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

- 1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.
- 2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. *See* NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. *See* NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this this Statement and Notice, and of the Notice of Intended Action and Accusation served within. *See* NRS 639.320; NRS 639.243.
- 3. The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

- 4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.
- 5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. See NRS 622A.350.

DATED this 301 day of July, 2020.

J. David Wuest, R.Ph., Executive Secretary Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-066-RPH-S

Petitioner,

 \mathbf{v} .

PAUL LUKE, RPH Certificate of Registration No. 15314, ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

DATED this day of	, 2020.
all facts therein stated, are true and correct to the	best of my knowledge.
I hereby declare, under penalty of perjury, that th	ne foregoing Answer and Notice of Defense, and
	ē.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Paul Luke, RPH 1401 Via Merano Street Henderson, NV 89052

HIRLEY HUNTING

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NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-079-IN-S

Petitioner,

v.

THEODORE HERRERA, Certificate of Registration No. IN04741,

Respondent.

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Theodore Herrera ("Herrera"), Certificate of Registration No. IN04741, was a pharmacy intern registered with the Board.

FACTUAL ALLEGATIONS

- 2. Respondent Herrera was employed by Walgreens Pharmacy #5311, located on 1180 East Flamingo Road, Las Vegas, Nevada 89119, from approximately June 2018 to April 2019.
- 3. On or about April 19, 2019, Walgreens' Asset Protection Manager ("APM") Michael Lisi ("Lisi") was contacted by APM Serge Ahmad concerning a customer who reported a prescription for Oxycodone 15 mg was missing two (2) tablets, filled on April 18, 2019.

- 4. A subsequent investigation by Walgreens' loss prevention staff identified a total of at least sixty-six (66) tablets sold and diverted between June 2018 and April 2019 by Respondent Herrera. The valid prescriptions to other patients, from which Herrera diverted a portion, consisted of the following controlled substances:
 - 20 Alprazolam 1mg tablets
 - 10 Alprazolam 2mg tablets
 - 6 Oxycodone 10mg tablets
 - 10 Oxycodone 15mg tablets
 - 20 Oxycodone 30mg tablets
 - 5. During the investigation, Herrera admitted to the unlawful diversion activity.
 - 6. Walgreens terminated Herrera on April 23, 2019.

FIRST CAUSE OF ACTION Unlawful Acquisition of Controlled Substances

- 7. NRS 453.331(1)(d) states, in relevant part, that "[i]t is unlawful for a person knowingly or intentionally to . . . [a]cquire or obtain . . . possession of a controlled substance . . . by misrepresentation, fraud, forgery, deception, subterfuge or alteration." Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. See NRS 639.210(12).
- 8. By diverting controlled substances as alleged herein, Respondent Herrera violated, or attempted to violate, NRS 453.331(1)(d) and is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION Unlawful Possession of Controlled Substances

9. NRS 453.336(1) states, in relevant part, that "a person shall not knowingly or intentionally possess a controlled substance, unless the substance was obtained directly from, or pursuant to, a [lawful] prescription or order of a [practitioner]". Violating, attempting to violate,

assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. *See* NRS 639.210(12).

10. By diverting controlled substances as alleged herein, Respondent Herrera violated, or attempted to violate, NRS 453.336(1) and is subject to discipline pursuant to NRS 639.210(12).

THIRD CAUSE OF ACTION Unprofessional Conduct - Diversion

- 11. "Supplying or diverting drugs . . . which are legally sold in pharmacies . . . so that unqualified persons can circumvent any law pertaining to the legal sale of such articles" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(g). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).
- 12. By diverting controlled substances as alleged herein, Respondent Herrera engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

FOURTH CAUSE OF ACTION Unprofessional Conduct - Deceitful Practice

- 13. "Performing or in any way being a party to any fraudulent or deceitful practice or transaction" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(h). Conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board. *See* NRS 639.210(4).
- 14. By diverting controlled substances as alleged herein, Respondent Herrera was a party to any fraudulent or deceitful practice or transaction, engaged in unprofessional conduct

and conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is subject to discipline pursuant to NRS 639.210(4).

FIFTH CAUSE OF ACTION

Violations of Federal Law

- Violating any provision of the Federal Food, Drug and Cosmetic Act or any other 15. federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. See NRS 639.210(11).
- By diverting controlled substances as alleged herein, Respondent Herrera violated, 16. or attempted to violate, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), and 21 U.S. Code § 844, and is subject to discipline pursuant to NRS 639.210(11).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 23^{nf)} day of July, 2020.

J. David Wuest, Executive Secretary

Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-079-IN-S

Petitioner,

 \mathbf{v}_{\bullet}

THEODORE HERRERA, Certificate of Registration No. IN04741,

Respondent.

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

- 1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.
- 2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. *See* NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. *See* NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this this Statement and Notice, and of the Notice of Intended Action and Accusation served within. *See* NRS 639.320; NRS 639.243.
- 3. The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

- 4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.
- 5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. See NRS 622A.350.

DATED this 25° day of July, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-079-IN-S

Petitioner,

v.

THEODORE HERRERA, Certificate of Registration No. IN04741, ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of In	ntended Action and Accusation, he admits, denies
and alleges as follows:	
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all facts therein stated, are true and correct to	at the foregoing Answer and Notice of Defense, and
an racis therein stated, are true and correct to	the best of my knowledge.
DATED this day of July, 2020.	
	THEODORE HERRERA
	9

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Theodore Herrera 2362 N. Green Valley Pkwy #P-236 Henderson, NV 89014

SHIRLEY HUNTING

5G



NEVADA STATE BOARD

NEVADA STATE BOARD OF PHARMACY,

CASE NOS. 19-061-RPH-S 19-061-PH-S

Petitioner,

v.

JERALD CLYDE, RPH, Certificate of Registration No. 10310, and

SMITH'S PHARMACY #366, License No. PH01771,

Respondents.

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Jerald Clyde (Clyde), Certificate of Registration No. 10310, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #366, License No. PH01771, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

- 2. Clyde was employed by Smith's #366 at the time of the events alleged herein.
- 3. On June 21, 2018, L.V.'s physician electronically transmitted a prescription to Smith's Pharmacy #348 for Dexilantⁱ 60 mg. delayed release capsule, quantity 90, for a 90-day supply. The prescription allowed for three (3) refills.
- 4. Smith's Pharmacy #348 computer system designated the prescription as no. 6759964.
- 5. Smith's Pharmacy #348 dispensed the initial fill of 30 Dexilant 60 mg. capsules on June 22, 2018, and dispensed a refill on July 30, 2018.

Dexilant is a proton pump inhibitor used to treat heartburn and gastroesophageal reflux disease (GERD).

- 6. On September 28, 2018, Smith's Pharmacy #348 electronically transferred prescription no. 6759964 to Smith's Pharmacy #366.
- 7. Smith's Pharmacy #366 computer system designated the transferred prescription as no. 6027081.
- 8. Smith's Pharmacy #3,66 refilled and dispensed 30 capsules of Dexilant 60 mg. on September 28, 2018, and again on October 31, 2018.
- 9. On November 30, 2018, pharmaceutical technician Daniel Saucedo processed a refill of prescription no. 6027081.
- 10. Clyde filled the prescription. During the filling process, Clyde inadvertently selected a bottle of *Duloxetine*ⁱⁱ 60 mg. capsules rather than the *Dexilant* 60 mg. capsules as prescribed.
- 11. Clyde is on record as the verifying pharmacist for prescription no. 6027081. He failed to detect the medication error when he performed the final product review.
- 12. L.V. experienced headaches and ophthalmological issues after ingesting seven (7) doses of the mis-filled medication over a three-day period. L.V. checked the medication bottle and discovered the error.

FIRST CAUSE OF ACTION

(Respondent Clyde)

13. Unprofessional conduct includes the failure by a licensee to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). It also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). Additionally, NAC 639.252 states in relevant part:

If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, *the pharmacist supervising the pharmaceutical technician* is responsible for the filled prescription, including, but not limited to, verifying:

- (a) The selection and strength of the drug:
- (b) The dosage form; and
- (c) The labeling of the prescription.

Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor antidepressant used to treat major depressive disorder.

NAC 639.252(2) (emphasis added.)

14. Respondent Clyde violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when he verified the scanned data and final product on prescription no. 6027081 as accurate when it was not, which resulted in Smith's dispensing *Duloxetine* 60 mg. capsules rather than the *Dexilant* 60 mg. capsules as prescribed. Clyde is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

SECOND CAUSE OF ACTION

(Respondent Smith's Pharmacy #366)

- [NRS Chapter 639] by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for the suspension or revocation of the license of the pharmacy by the Board." Additionally, "[t]he owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission." NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).
- 16. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Smith's Pharmacy #366 is responsible for any violations of law by Clyde pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

Signed this day of July, 2020.

J. David Wuest, Executive Secretary Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

NEVADA STATE BOARD OF PHARMACY,

CASE NOS. 19-061-RPH-S

Petitioner,

v.

JERALD CLYDE, RPH Certificate of Registration No. 10310,

Respondent.

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30 day of July, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-061-RPH-S

Petitioner,

 \mathbf{v}_{\bullet}

JERALD CLYDE, RPH Certificate of Registration No. 10310,

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of	of Intended Action and Accusation, he admits, denies
and alleges as follows:	
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	, that the foregoing Answer and Notice of Defense, and
all facts therein stated, are true and correct	t to the best of my knowledge.
DATED this day of	. 2020
	JERALD CLYDE, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jerald Clyde, R.Ph. 2378 Goldfire Circle Henderson, NV 89052

Smith's Pharmacy #366 55 South Valle Verde Drive Henderson, NV 89012

SHIRLEY HUNTING

5H

NEVADA STATE BOARD OF PHARMACY,

CASE NOS. 19-061-PH-S

Petitioner,

v.

SMITH'S PHARMACY #366 License No. PH01771,

Respondent.

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30 day of July, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-061-PH-S

Petitioner,

 \mathbf{v}_{\bullet}

SMITH'S PHARMACY #366 License No. PH01771.

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

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acts therein stated, are					of Defense
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DATED this	lay of	<u> </u>	, 2020).	
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CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jerald Clyde, R.Ph. 2378 Goldfire Circle Henderson, NV 89052

> Smith's Pharmacy #366 55 South Valle Verde Drive Henderson, NV 89012

> > SHIRLEY HUNTING



NEVADA STATE BOARD OF PHARMACY,

Petitioner,

V.

ABDEL M. KHALEK, MD, Certificate of Registration Nos. CS19745 and PD00722,

ROBERT CHANCELLOR, MD, Certificate of Registration Nos. CS22616 and PD27416, and

LINDSAY HOFFMAN, PA-C, Certificate of Registration Nos. CS18262 and PD00177, NOTICE OF INTENDED ACTION

AND ACCUSATION

19-003-CS-A-S 19-003-CS-B-S

19-003-CS-C-S

Case Nos.

Respondents.

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Abdel M. Khalek, MD (Khalek), held a controlled substance registration, Certificate of Registration No. CS19745, and dispensing practitioner registration, Certificate of Registration No. PD00722; Respondent Robert Chancellor, MD (Chancellor), held a controlled substance registration, Certificate of Registration No. CS22616, and dispensing practitioner registration, Certificate of Registration No. PD27416; and Lindsay Hoffman, PA-C (Hoffman), held a controlled substance registration, Certificate of Registration No. CS18262, and dispensing practitioner registration, Certificate of Registration No. PD00177, all issued by the Board.

FACTUAL ALLEGATIONS

- 2. Vinay Kumar Bararia, MD (Bararia) was not registered with the Board at the time of the events alleged herein.
- 3. Bararia voluntarily surrendered his license to practice medicine, License No. 11355, to the Nevada State Board of Medical Examiners (NSBME) on March 8, 2013, and was sentenced in federal court for distribution of controlled substances in September 2014.
- 4. Bararia has owned and operated Nevada Health Services, LLC aka Trimcare (Trimcare), located at 5375 South Fort Apache Road, Suites 102 and 103, in Las Vegas, since August 2018.
- 5. Khalek co-owned and/or was employed at Trimcare from October 2018 to April 2019.
- 6. Chancellor co-owned and/or was employed by Trimcare from November 2018 to the present.
 - 7. Hoffman was employed by Trimcare from August 2018 to present.
- 8. Ageless Aesthetics (Ageless Aesthetics), an unnamed third party, is a medical spa that operates at 5375 South Fort Apache Road, Suite 101, Las Vegas, Nevada 89148, next door to Trimcare, for which Khalek was the medical director from approximately October 2018 to April 2019.
- 9. Investigators from the Board, the Nevada State Board of Medical Examiners (BME) and the Drug Enforcement Administration (DEA) conducted a joint investigation of Trimcare and found evidence of misconduct and violations involving the unlawful possession, administration, prescribing and dispensing of controlled substances and/or dangerous drugs.
- 10. Khalek, Chancellor and Hoffman permitted Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another

practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state.

- 11. Khalek unlawfully prescribed controlled substances and/or dangerous drugs, including, without limitation, Testosterone, Phentermine, Phendimetrazine, Topamax, Botox, and Juvederm, for at least two-hundred ninety-eight (298) patients with whom he did not have a bona fide therapeutic relationship from September 2018 to April 2019 by pre-signing prescriptions, providing his log-on information to e-scribing systems to Bararia, and/or failing to secure his secondary authenticator for e-scribing CII medications.
- 12. Chancellor unlawfully prescribed controlled substances and/or dangerous drugs, including, without limitation, Adderall, Phentermine, and Topamax, for at least ten (10) patients with whom he did not have a bona fide therapeutic relationship from November 2018 to present by pre-signing prescriptions, his log-on information to e-scribing systems to Bararia, and/or failing to secure his secondary authenticator for e-scribing CII medications.
- 13. Hoffman unlawfully prescribed controlled substances/dangerous drugs, including, but not limited to, Phentermine, and Topamax for at least two (2) patients with whom she did not have a bona fide therapeutic relationship in April 2019 by pre-signing prescriptions.
- 14. Khalek, Chancellor and Hoffman permitted access of their inventory of controlled substances and dangerous drugs to unlicensed employees of Trimcare and/or Ageless Aesthetics.
- 15. Khalek, Chancellor and Hoffman failed to issue a written prescription for each medication dispensed, failed to verify medications for accuracy prior to dispensing, failed to maintain complete, accurate and readily retrievable records of all controlled substances and dangerous drugs purchased and dispensed, failed to inventory controlled substances at least once every two (2) years, failed to properly store and maintain the inventory, failed to maintain the

security of the inventory from unauthorized access, and failed to segregate and/or dispose of adulterated and/or expired dangerous drugs.

- 16. Chancellor and Hoffman had possession of pre-drawn, unlabeled syringes containing an unidentified dangerous drug.
- 17. On or about July 7, 2020, Board staff served Bararia with an order pursuant to NRS 639.2895(1) to immediately cease and desist possessing, administering, prescribing and/or dispensing controlled substances and dangerous drugs for Nevada patients from Trimcare.

APPLICABLE LAW

- 18. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).
- 19. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.381(1).
- 20. It is unlawful for a practitioner to prescribe or dispense a controlled substance or dangerous drug except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS 454.215; NRS 454.301, NRS 639.100(1); NRS 639.23505; NAC 453.410; NAC 639.742; NAC 639.745.
- 21. It is unlawful for a person to purchase, possess, administer or furnish a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321 and/or NRS 454.356.
- 22. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(c), (d), (f), (h) and (i).

- 23. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.281(1); NRS 639.2813(1).
- 24. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).
- A dispensing practitioner must issue a written prescription for each medication dispensed, verify medications for accuracy prior to dispensing, maintain complete, accurate and readily retrievable records of all controlled substances and dangerous drugs purchased and dispensed, inventory controlled substances at least once every two (2) years, properly store and maintain the inventory, maintain the security of the inventory from unauthorized access, and segregate and/or dispose of adulterated and/or expired dangerous drugs. NRS 453.246; NRS 585.370; NRS 585.420; NRS 639.282; NAC 453.400; NAC 453.410; NAC 453.475; NAC 454.040; NAC 639.475; NAC 639.476; NAC 639.510; NAC 639.601; NAC 639.742, NAC 639.743; NAC 639.745; 21 U.S.C. § 842(a)(5); 21 CFR 1304.11; 21 CFR 1304.21.
- 26. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).
- 27. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).
- 28. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to

NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

- 29. Dispensing a drug as a dispensing practitioner or prescribing a drug as a prescribing practitioner to a patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).
- 30. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).
- 31. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).
- 32. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

FIRST CAUSE OF ACTION

Unprofessional Conduct - Party to a Fraudulent/Deceitful Practice/Transaction

33. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including pre-

signing prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

SECOND CAUSE OF ACTION

Unprofessional Conduct - Incompetent, Unskillful or Negligent Performance of Duties

34. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including presigning prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman performed their duties as the holders of controlled substance registrations and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

THIRD CAUSE OF ACTION Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

35. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the

practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including presigning prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman aided or abetted a person not licensed to practice pharmacy in the State of Nevada and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(j), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH CAUSE OF ACTION Unprofessional Conduct – Prescribing/Dispensing Without Bona Fide Therapeutic Relationship

36. By unlawfully prescribing and dispensing controlled substances to patients with whom they did not have a bonda fide therapeutic relationship, Khalek, Chancellor and Hoffman engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(n) and (o), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FIFTH CAUSE OF ACTION Violations of Federal Controlled Substances Act

37. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including presigning prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and

Hoffman violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846 and 21 CFR §§ 1306.03–1306.05, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11).

SIXTH CAUSE OF ACTION Violations of State Law for Unlicensed Practice

38. By permitting Bararia, who was not a licensed practitioner, in the course of operating Trimcare to purchase, access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including presigning prescriptions, providing log-on information to e-scribing systems to Bararia, and failing to secure secondary authenticator for e-scribing CII medications, Khalek, Chancellor and Hoffman violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of NRS 453.226, NRS 453.316, NRS 453.321(1)(a), NRS 453.331 (1)(c)(d)(f)&(i), NRS 453.381(1), NRS 453.401(l)(a), NRS 454.213, NRS 454.215, NRS 454.221, NRS 454.311, NRS 454.316, NRS 454.321, NRS 639.100(1), NRS 639.235, NRS 639.23505, NRS 639.281, NRS 639.2813 and NRS 639.310, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

SEVENTH CAUSE OF ACTION Security of Controlled Substances on December 19

Failure to Maintain Security of Controlled Substances or Dangerous Drugs

39. By failing to maintain proper locked security of their inventory of controlled substances and dangerous drugs and/or permitting unauthorized access to their inventory by Bararia and/or other unlicensed employees of Trimcare and/or Ageless Aesthetics, Khalek,

Chancellor and Hoffman violated NAC 453.400, NAC 453.410(1)(d), NAC 454.040, NAC 639.742(3)(c), NAC 639.742(3)(a)(b)(c)&(e), and NAC 639.745(1)(c), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

Failure to Maintain Records for Controlled Substances Dispensed

40. By failing to keep complete, accurate, and readily retrievable records of all controlled substances dispensed, including failing to issue a written prescription for each medication dispensed and failing to inform the patient that he or she may request a written prescription to have it filled at another location of their choice, Khalek, Chancellor, and Hoffman violated NRS 453.246, NAC 453.410(1)(a)(B) and (2), NAC 639.745(2) and (3)(b)(2), 21 U.S.C. § 842(a)(5), 21 CFR 1304.11 and 21 CFR § 1304.21, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11), (12) and (17).

NINTH CAUSE OF ACTION Failure to Verify Dispensed Medications for Accuracy

41. By failing to verify medications for accuracy prior to dispensing, Khalek, Chancellor, and Hoffman violated NAC 639.743(2)(a) and (b), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

TENTH CAUSE OF ACTION Failure to Inventory Controlled Substances Every Two Years

42. By failing to inventory controlled substances at least once every two (2) years, Khalek, Chancellor, and Hoffman violated NRS 453.246, NAC 453.475(1)(b), 21 U.S.C. § 842(a)(5), 21 CFR 1304.11 and 21 CFR § 1304.21 and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11), (12) and (17).

ELEVENTH CAUSE OF ACTION

Failure to Properly Segregate/Dispose Adulterated/Expired Drugs

43. By failing to properly segregate and/or dispose of adulterated and/or expired dangerous drugs for administration, Khalek, Chancellor, and Hoffman violated NRS 585.370(1), NRS 639.282(1)(d), NAC 639.050(2), NAC 639.473(1) and (3), NAC 639.510(3) and NAC 639.601(1), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

TWELFTH CAUSE OF ACTION Failure to Properly Label Pre-Filled Syringes Against

44. By pre-filling syringes without proper labels and/or temperature control, Chancellor and Hoffman violated NRS 585.420, NRS 639.282 (1)(e), NAC 639.476 and NAC 639.510, and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210 (12).

THIRTEENTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

45. By their actions as set forth herein, Khalek, Chancellor and Hoffman have committed acts that render their registrations to prescribe or otherwise dispense a controlled substance inconsistent with the public interest pursuant to NRS 453.231, and are subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

DATED this 24 day of July, 2020.

David West, R.Ph., Executive Secretary

Neyada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-A-S

Petitioner,

v.

ABDEL M. KHALEK, MD, Certificate of Registration Nos. CS19745 and PD00722,

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of July, 2020.

L. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-A-S

Petitioner,

v.

ABDEL M. KHALEK, MD, Certificate of Registration Nos. CS19745 and PD00722,

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Inte	ended Action and Ac	cusation, he admits	s, denies
nd alleges as follows:			
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*I		(#) Q	
peraby declare under nonalty of nations, that	41 C	131 (C
nereby declare, under penalty of perjury, that			etense, ar
l facts therein stated, are true and correct to the	ne best of my knowle	edge.	
DATED this day of	, 2020		
		-	
\overline{Al}	BDEL M. KHALE	K. MD	

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Abdel M. Khalek, MD 8600 Starboard Avenue Las Vegas, NV 89117

Shirley Hunting

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Abdel Khalek, MD 5375 S Ft Apache Rd #102-103 Las Vegas, NV 89148

Robert Chancellor, MD 7975 W Sahara Ave #104 Las Vegas, NV 89117

Lindsay Hoffman, PA-C 5375 S FT Apache Rd #102-103 Las Vegas, NV 89148

Jill Chase, Esq. Lewis Brisbois 6385 S. Rainbow Blvd., Ste. 600 Las Vegas, NV 89118

E. Brent Bryson, Esq. 7730 W. Sahara Ave., Ste. 109 Las Vegas, NV 89117

SHIRLEY HUNTING

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-B-S

Petitioner,

v.

ROBERT CHANCELLOR, MD, Certificate of Registration Nos. CS22616 and PD27416, STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July, 2020.

J. David Waest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy



NEVADA STATE BOARD OF PHARMACY,	.)	Case No.: 19-003-CS-B-S
Petitioner,)	
ROBERT CHANCELLOR, MD, Certificate of Registration No. CS22616 and PD27416,)	ANSWER AND NOTICE OF DEFENSE
Respondent.) _)	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

- 1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: None.
- 2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

Respondent Denies the allegations contained in the Notice of Intended Action and Accusation, Case No. 19-003-CS-B-S.

I hereby, declare under penalty or perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

Date this May of August, 2020.

Robert Chancellor my ROBERT CHANCELLOR, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Abdel Khalek, MD 5375 S Ft Apache Rd #102-103 Las Vegas, NV 89148

Robert Chancellor, MD 7975 W Sahara Ave #104 Las Vegas, NV 89117

Lindsay Hoffman, PA-C 5375 S FT Apache Rd #102-103 Las Vegas, NV 89148

Jill Chase, Esq. Lewis Brisbois 6385 S. Rainbow Blvd., Ste. 600 Las Vegas, NV 89118

E. Brent Bryson, Esq. 7730 W. Sahara Ave., Ste. 109 Las Vegas, NV 89117

HIRLEY HUNTING

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NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-003-CS-C-S

Petitioner,

v.

LINDSAY HOFFMAN, PA-C, Certificate of Registration Nos. CS18262 and PD00177,

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of July, 2020.

J. David Wuest, R.Ph., Executive Secretary

Nevada State Board of Pharmacy



NEVADA STATE BOARD OF PHARMACY,) Case No.: 19-003-CS-C-S
Petitioner,)
vs.) ANSWER AND NOTICE OF) DEFENSE
LINDSAY HOFFMAN, P-AC,)
Certificate of Registration No. CS18262 and	í
PD00177,)
Respondent.)
)
)

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

- 1. That her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against her, is hereby interposed on the following grounds: None.
- 2. That, in answer to the Notice of Intended Action and Accusation, she admits, denies and alleges as follows:

Respondent Denies the allegations contained in the Notice of Intended Action and Accusation, Case No. 19-003-CS-C-S.

I hereby, declare under penalty or perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

Date this day of August, 2020.

LINDSAY HOFFMAN, PA-C

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Abdel Khalek, MD 5375 S Ft Apache Rd #102-103 Las Vegas, NV 89148

Robert Chancellor, MD 7975 W Sahara Ave #104 Las Vegas, NV 89117

Lindsay Hoffman, PA-C 5375 S FT Apache Rd #102-103 Las Vegas, NV 89148

Jill Chase, Esq. Lewis Brisbois 6385 S. Rainbow Blvd., Ste. 600 Las Vegas, NV 89118

E. Brent Bryson, Esq. 7730 W. Sahara Ave., Ste. 109 Las Vegas, NV 89117

SHIRLEY HUNTING

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NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

BERNARD KOFI ADDO-QUAYE, MD, Certificate of Registration No. CS10103,

MUKWEL AIYUK, APRN, Certificate of Registration No. CS25545, and

SOLOMON JOSHUA, APRN, Certificate of Registration No. CS27011,

Respondents.

Case Nos. 19-242-CS-A-S 19-242-CS-B-S 19-242-CS-C-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Bernard Addo-Quaye, MD ("Addo-Quaye"), held a controlled substance registration, Certificate of Registration No. CS10103; Respondent Mukwel Aiyuk, APRN ("Aiyuk"), held a controlled substance registration, Certificate of Registration No. CS25545; and Solomon Joshua, APRN ("Joshua"), held a controlled substance registration, Certificate of Registration No. CS27011, all issued by the Board.

FACTUAL ALLEGATIONS

- 2. Victor R. Bruce, MD ("Bruce") was not registered with the Board at the time of the events alleged herein.
- 3. On December 31, 2014, the Nevada State Board of Medical Examiners ("NSBME") revoked Bruce's license to practice medicine, as a result of a federal court criminal judgment entered against Bruce for distribution of a controlled substance.
- 4. Respondent Bernard Addo-Quaye, MD ("Addo-Quaye") owns and operates
 Bernard Addo-Quaye, MD PC dba TruCare Medical Center ("TruCare") from November 14,
 2000 to present. TruCare is located at 2290 McDaniel Street, Suite 2A, North Las Vegas,
 Nevada.
- 5. Addo-Quaye was out of the country during certain relevant timeframes in 2018 and 2019.
- 6. Bruce received a reinstated license to practice medicine from the NSBME, with a restriction from prescribing controlled substances, in September 2018.
- 7. Addo-Quaye served as Bruce's preceptor from September 2018 to approximately September 2019.
 - 8. Bruce was employed by TruCare from September 2018 to present.
- 9. Aiyuk was an independent contractor and/or employed by TruCare during the relevant timeframes in question.
- 10. Joshua was an independent contractor and/or employed by TruCare during the relevant timeframes in question.
- 11. Investigators from the Board, the Nevada State Board of Medical Examiners ("NSBME") conducted an investigation of TruCare and found evidence of misconduct and violations involving the unlawful possession, administration, and prescribing of controlled substances and/or dangerous drugs.

- 12. Addo-Quaye permitted Bruce, who was restricted from prescribing controlled substances, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe controlled substances and/or dangerous drugs under Addo-Quaye's name and credentials, and/or otherwise falsely represent himself as a practitioner entitled to write or escribe controlled substance prescriptions in this state.
- 13. Addo-Quaye unlawfully prescribed controlled substances and/or dangerous drugs, including, without limitation, Citalopram, Estradiol, Cyanocobalamin, Fluticasone Propionate, Androgel, Focalin, and Lisinopril, for at least four (4) patients with whom he did not have a bona fide therapeutic relationship from September 1, 2019 to September 20, 2019 by providing his blank prescription pads, providing his log-on information to e-scribing systems to Bruce, Aiyuk and/or Joshua and/or failing to secure his secondary authenticator for e-scribing controlled substance and dangerous medications.
- 14. Aiyuk unlawfully prescribed controlled substances/dangerous drugs under Addo-Quaye's name and credentials, including, but not limited to Norco, Valium, Flexeril, Morphine Sulfate ER, Percocet, Ambien, Hydromorphone, and Clonazepam, for at least three (3) patients from July 8, 2019 to July 10, 2019.
- Joshua unlawfully prescribed controlled substances/dangerous drugs under Addo-Quaye's name and credentials, including, but not limited to Tramadol, Sumatriptan, Gabapentin, Clonazepam, Ambien, Methadone, Norco, and Narcan, for at least three (3) patients from October 30, 2018 to December 19, 2018.
- 16. On or about July 21, 2020, Board staff served Bruce with an order pursuant to NRS 639.2895(1) to immediately cease and desist possessing, administering, prescribing and/or dispensing controlled substances and/or dangerous drugs under another practitioner's credentials for Nevada patients from TruCare.

APPLICABLE LAW

- 17. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).
- 18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.381(1).
- 19. It is unlawful for a practitioner to prescribe a controlled substance or dangerous drug except as authorized by law. NRS 453.226(1); NRS 453.321(1)(a); NRS 454.215; NRS 454.301, NRS 639.100(1); NRS 639.23505; NAC 453.410; NAC 639.742; NAC 639.745.
- 20. It is unlawful for a person to possess, administer or furnish a dangerous drug except as authorized by law. NRS 454.213(1); NRS 454.221; NRS 454.311; NRS 454.316; NRS 454.321 and/or NRS 454.356.
- 21. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(c), (d), (f), (h) and (i).
- 22. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 639.281(1); NRS 639.2813(1).
- 23. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).
- 24. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

- 25. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).
- 26. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).
- 27. Prescribing a drug as a prescribing practitioner to a patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and (o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).
- 28. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).
- 29. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).
- 30. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

FIRST CAUSE OF ACTION Unprofessional Conduct – Party to a Fraudulent/Deceitful Practice/Transaction

31. By permitting Bruce, who had a restricted license excluding prescription of controlled substances, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye was a party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

SECOND CAUSE OF ACTION

Unprofessional Conduct - Incompetent, Unskillful or Negligent Performance of Duties

32. By permitting Bruce, who had a restricted license excluding controlled substance prescriptions, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient, and/or otherwise falsely represent himself as a practitioner entitled to write controlled substance prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged

in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

- 33. By permitting Aiyuk to treat patients and to utilize Addo-Quaye's name and credentials by providing log-on information to e-scribing systems, and/or failing to secure the secondary authenticator for e-scribing controlled substance medications, Addo-Quaye and Aiyuk performed their duties as holders of controlled substance registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).
- 34. By permitting Joshua to treat patients, and to utilize Addo-Quaye's name and credentials by providing log-on information to e-scribing systems, and/or failing to secure the secondary authenticator for e-scribing controlled substance medications, Addo-Quaye and Joshua performed their duties as holders of controlled substance registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

THIRD CAUSE OF ACTION Unprofessional Conduct – Aiding and Abetting Unlicensed Practice

35. By permitting Bruce, who had a restricted license excluding prescriptions of controlled substances, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient, and/or otherwise falsely represent himself as a practitioner entitled to write controlled substance prescriptions in this state, including providing blank prescription pads,

providing log-on information to e-scribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye aided or abetted a person not fully licensed to practice pharmacy in the State of Nevada and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(j), and issubject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH CAUSE OF ACTION Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship

36. By unlawfully prescribing controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Addo-Quaye engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(n) and (o), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FIFTH CAUSE OF ACTION Violations of Federal Controlled Substances Act

37. By permitting Bruce, who had a restricted license excluding controlled substance prescriptions, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write prescriptions in this state, including providing blank prescription pads, providing log-on information to e-scribing systems to Bruce, and/or failing to secure the secondary authenticator for e-scribing controlled substance medications, Addo-Quaye violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. §

842(a), 21 U.S.C. § 846 and 21 CFR §§ 1306.03–1306.05, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11).

SIXTH CAUSE OF ACTION Violations of State Law for Unlicensed Practice

By permitting Bruce, who had a restricted license excluding controlled substance 38. prescriptions, in the course of operating TruCare to access, store, possess, administer, furnish, prescribe and/or dispense controlled substances and dangerous drugs under another practitioner's name, without that practitioner having a bona fide therapeutic relationship with any such patient or the practitioner being present at the time the prescription was dispensed, and/or otherwise falsely represent himself as a practitioner entitled to write controlled substance prescriptions in this state, including providing blank prescription pads, providing log-on information to escribing systems to Bruce, and/or failing to secure secondary authenticator for e-scribing controlled substance medications, Addo-Quaye violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of NRS 453.226, NRS 453.316, NRS 453.321(1)(a), NRS 453.331 (1)(c)(d)(f)&(i), NRS 453.381(1), NRS 453.401(l)(a), NRS 454.213, NRS 454.215, NRS 454.221, NRS 454.311, NRS 454.316, NRS 454.321, NRS 639.100(1), NRS 639.235, NRS 639.23505, NRS 639.281, NRS 639.2813 and NRS 639.310, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

SEVENTH CAUSE OF ACTION Commission of Acts that Render Registration Inconsistent with the Public Interest

39. By their actions as set forth herein, Addo-Quaye, Aiyuk, and Bruce have committed acts that render their registrations to prescribe controlled substances inconsistent with

the public interest pursuant to NRS 453.231, and are subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these Respondents.

DATED this 3/ day of August, 2020.

J. David Wuest, R.Ph., 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. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-A-S

Petitioner,

v.

BERNARD KOFI ADDO-QUAYE, MD, Certificate of Registration No. CS10103,

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3th day of August, 2020.

J David Wuest, R.Ph., Executive Secretary

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-A-S

Petitioner,

v.

BERNARD KOFI ADDO-QUAYE, MD Certificate of Registration No. CS10103,

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

101 Tal. 1	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 Defe			
	all facts therein stated, are true and correct to the best of my knowledge.		
	DATED this day of August, 2020.		
	Differ this day of August, 2020.		
	BERNARD KOFI ADDO-QUAYE, MD		

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

BERNARD KOFI ADDO-QUAYE, MD 2290 MCDANIEL ST #2A N. LAS VEGAS, NV 89030

MUKWEL AIYUK, APRN 2021 S JONES BLVD LAS VEGAS, NV 89146

MUKWEL AIYUK, APRN 304 S JONES BLVD LAS VEGAS, NV 89107

SOLOMON JOSHUA, APRN 2290 MCDANIEL ST #2A N. LAS VEGAS, NV 89030

SOLOMON JOSHUA, A.P.R.N. 3305 EAST ROME BLVD #2068 NORTH LAS VEGAS, NV 89086

JOHN A. HUNT, ESQ. CLARK HILL PLC 3800 HOWARD HUGHES PARKWAY LAS VEGAS, NV 89169

SHIRLEY HUNTING

5M

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-B-S

Petitioner,

v.

MUKWEL AIYUK, APRN, Certificate of Registration No. CS25545,

Respondent.

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this ³ day of August, 2020.

J. David Wuest, R.Ph., Executive Secretary

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-B-S

Petitioner,

v.

MUKWEL AIYUK, APRN, Certificate of Registration No. CS25545,

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of	f Intended Action and A	ccusation, he admits, denies			
and alleges as follows:					
*					
I hereby declare under penalty of periury	that the foregoine Ange	ton and Nation of D. C			
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 knowl	edge.			
DATED this day of August, 20	20				
day of reagable, 20	.20.				
MUKWEL AIYUK, APRN					

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

BERNARD KOFI ADDO-QUAYE, MD 2290 MCDANIEL ST #2A N. LAS VEGAS, NV 89030

MUKWEL AIYUK, APRN 2021 S JONES BLVD LAS VEGAS, NV 89146

MUKWEL AIYUK, APRN 304 S JONES BLVD LAS VEGAS, NV 89107

SOLOMON JOSHUA, APRN 2290 MCDANIEL ST #2A N. LAS VEGAS, NV 89030

SOLOMON JOSHUA, A.P.R.N. 3305 EAST ROME BLVD #2068 NORTH LAS VEGAS, NV 89086

JOHN A. HUNT, ESQ. CLARK HILL PLC 3800 HOWARD HUGHES PARKWAY LAS VEGAS, NV 89169

SHIRLEY HUNTING

5N

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-C-S

Petitioner,

v.

SOLOMON JOSHUA, APRN, Certificate of Registration No. CS27011,

STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

Respondent.

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 2, 2020, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3ⁿ day of August, 2020.

J. David Wuest, R.Ph., Executive Secretary

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-242-CS-C-S

Petitioner,

v.

SOLOMON JOSHUA, APRN, Certificate of Registration No. CS27011,

ANSWER AND NOTICE OF DEFENSE

Respondent.

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

and alleges as follows:				
	4 7			
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 August, 2020.				
$\overline{\mathbf{sc}}$	DLOMON JOSHUA, APRN			

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 4th day of August, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

BERNARD KOFI ADDO-QUAYE, MD 2290 MCDANIEL ST #2A N. LAS VEGAS, NV 89030

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