

January 2024 Board Meeting Handouts

- 5L. Care Direct Rx, LLC**
- 5M. Efrain Armenta**
- 5N. Juliana Izevbigie**
- 5O. Odette Erian**
- 5P. Poncia Reed**
- 5T. Matthew Okeke**
- 18A. Workshop - RN**
- 18B. Workshop - Compounding**
- 18B. Compounding Public Comment**
- 10A. LifeScience Logistics - DR and MDEG Applications**
- 14. Facility for Treatment with Narcotics Application**
- 15. J.T. Simonsen - 2nd Application**
- 20A. Financial Report**

5L

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CARE DIRECT RX, LLC,
License No. PH03043,

Respondent.

CASE NO. 22-165-PH-O

STIPULATION AND ORDER

Gustaf Vanderdonck, Assistant General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Care Direct Rx, LLC, License No. PH03043, by and through counsel, Amanda E. Rosenthal, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.
2. On or about November 17, 2023, 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.
3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as both parties pursued settlement negotiations.
4. Respondent 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 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 them 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 has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives their rights to

a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them 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. In order to resolve the Accusation in this matter; specifically, Count One for Unprofessional Conduct by a Pharmacy, alleging that Respondent failed to accurately respond to the question on their October 7, 2020 Business Renewal Application that asked, "since your last renewal or recent licensure has any owner, shareholder, partners with any interest, or corporation been the subject of a board citation or an administrative action whether completed or pending in any state," Respondent acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the alleged violation of NAC 639.945(1)(i).

8. In order to resolve the Accusation in this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding their duties and responsibilities to disclose board citations and administrative actions under Chapter 639;

B. Respondent shall pay a fine of One Thousand Dollars and Zero Cents (\$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, within thirty (30) of the effective date of this Order;

C. Respondent shall pay Five Hundred Dollars and Zero Cents (\$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;

D. Any remaining claims of the Accusation, and any other claims arising from the Board's investigation in this matter, shall be dismissed with prejudice.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 22-165-PH-O. However, 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 that Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. The Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639.

10. 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 January 17, 2024. Respondent will appear at the meeting or through counsel 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.

11. 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.

12. 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 agreement herein may not be used or referred to in a full hearing on the merits of this matter.

13. This matter will be reported to the National Practitioner Data Bank as required by 45 C.F.R. §§ 60.3; 60.5; and 60.9.

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

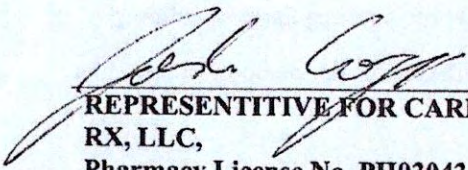
set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

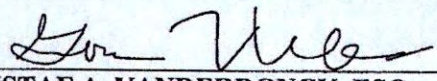
Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 7th day of January, 2024

Signed this 5th day of January, 2024


REPRESENTATIVE FOR CARE DIRECT
RX, LLC,
Pharmacy License No. PH03043


GUSTAF A. VANDERDONCK, ESQ.
Assistant General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 8th day of January, 2024


AMANDA E. ROSENTHAL, ESQ.
COLLINSON, DAEHNKE, INLOW &
GRECO
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Care Direct Rx, LLC, Pharmacy License No. PH03043, in Case No. 22-165-PH-O and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ____ day of January, 2024.

Helen Park, President
Nevada State Board of Pharmacy

5M



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case No. 23-187-RPH-S

Petitioner,

v.

ORDER TO SHOW CAUSE

EFRAIN ARMENTA, RPH,
Certificate of Registration No. 19224,

Respondent.

The Nevada State Board of Pharmacy ("Board") HEREBY ORDERS Respondent Efrain Armenta, ("Respondent"), Certificate of Registration No. 19224, pursuant to NAC 639.965 – NAC 639.978, to appear before the Board on January 17, 2024, at 9:00 a.m. and show cause, if any, why Certificate of Registration No. 19224 should not be revoked.

1. On June 30, 2023, the Board issued a Citation and Fine Order ("Order") to Respondent in Case No. 23-187-RPH-S.

2. The Order directed Respondent to satisfy the following conditions no later than September 1, 2023:

A. Pay an administrative fine of \$500; and

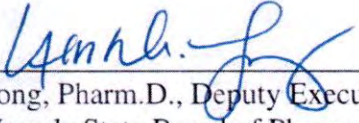
B. Submit proof of completion of thirty (30) continuing education units, one (1) of which must be a Nevada law based continuing education unit.

3. Respondent has failed to comply with the terms of the Order because Respondent failed to: a) pay an administrative fine of \$500; and b) complete and/or show proof of completion of thirty (30) continuing education units, including one (1) Nevada law based continuing education unit.

4. Additionally, Respondent has failed to timely appeal the Order by submitting a written request for a hearing within thirty (30) days of receipt of the Order. Accordingly, the Order became a final decision of the Board as provided by NRS 639.100, NRS 639.2895, and the Adopted Regulation of the Nevada State Board of Pharmacy, 070-19 Nev. Reg. Admin. Regs (Feb. 7, 2020).

THEREFORE, IT IS HEREBY ORDERED that Respondent Efrain Armenta, RPH, Certificate of Registration No. 19224, shall appear before the Board and show cause, if any, why Certificate of Registration No. 19224 should not be revoked.

ENTERED this 24th day of November 2023.



Yen H. Long, Pharm.D., Deputy Executive Secretary
of the Nevada State Board of Pharmacy, for and on
behalf of J. David Wuest, R.Ph., Executive Secretary
of the 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); NAC 639.968.

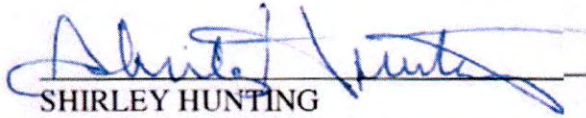
The Board has scheduled your hearing on this matter for Wednesday, January 17, 2024, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn located at 7830 S. Las Vegas Blvd, Las Vegas, Nevada 89123.

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.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Efrain Armenta, RPH
[REDACTED] Venadis St.
North Las Vegas, NV 89030


SHIRLEY HUNTING

Efrain Armenta, RPH
[REDACTED] Venadis St.
North Las Vegas, NV 89030
OSC 23-187-RPH-S

9171 9690 0935 0307 6315 15



Standard .63
Certified 8.53

Answer Due:

12/23/23

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350307631515**[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 8:57 am on December 2, 2023 in NORTH LAS VEGAS, NV 89030.

Get More Out of USPS Tracking:**USPS Tracking Plus®**

Delivered

Delivered, Left with Individual

NORTH LAS VEGAS, NV 89030

December 2, 2023, 8:57 am

[See All Tracking History](#)[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)**Text & Email Updates****USPS Tracking Plus®****Product Information****See Less ^**

Track Another Package

Enter tracking or barcode numbers

Feedback

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Efrain Armenta, RPH
 Venadis St.
 North Las Vegas, NV 89030

9171 9690 0935 0307 6315 1516

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X

☐ Agent

☐ Addressee

B. Received by (Printed Name)

C. Date of Delivery

D. Is delivery address different from Item 1? ☐ Yes
 If YES, enter delivery address below: ☐ No

3. Service Type

☐ Adult Signature

☐ Adult Signature Restricted Delivery

☒ Certified Mail®

☐ Certified Mail Restricted Delivery

☐ Collect on Delivery

☐ Delivery Restricted Delivery

☐ Registered Mail™

☐ Registered Mail Restricted Delivery

☐ Priority Mail Express®

☐ Registered Mail™

☐ Registered Mail Restricted Delivery

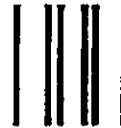
☐ Signature Confirmation™

☐ Signature Confirmation Restricted Delivery

PS Form 3811, July 2020 PSN 7530-02-000-9053

Domestic Return Receipt

USPS TRACKING#
LAS VEGAS NV 890



First-Class Mail
Postage & Fees Paid
USPS
Permit No. G-10

9590 9402 6874 1104 6888 01

United States
Postal Service

• Sender: Please print your name, address, and ZIP+4® in this box•

Shirley Hunting
NV ST Board of Pharmacy
985 Damonte Ranch Pkwy., Ste. 206
Reno, NV 89521-4881



NBOR11

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

June 30, 2023

VIA CERTIFIED U.S. MAIL & ELECTRONIC MAIL

Efrain Armenta, Rph.
Certificate of Registration No. 19224
[REDACTED] Venadis St
North Las Vegas, NV 89030
[\[REDACTED\]@sbeglobal.net](mailto:[REDACTED]@sbeglobal.net)

RE: Notice of Nevada CITATION-and-FINE: Case No. 23-187-RPH-S

Greetings:

The Nevada State Board of Pharmacy ("Board") has determined that you failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2019, and ending on October 31, 2021.

This notice shall serve as a CITATION & FINE pursuant to NRS 639.2895(2) for failing to timely complete your required continuing education. The Board has assessed an administrative fine of five hundred dollars (\$500.00) pursuant to NRS 639.2895(3). This administrative fine must be paid within 30 days of receipt of this citation. Payment must be by *personal, business, cashier's, certified check, or money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521. Please include a copy of this notice with payment.

In addition, you are hereby ordered to complete the required thirty (30) continuing education units, one (1) of which shall be a Nevada law based continuing education unit. You are ordered to submit a single email, attaching proof of your completed continuing education, to teambc@pharmacy.nv.gov, not later than Friday, September 1, 2023. Include the following information in the subject line of your email: (1) your full name; (2) your Nevada pharmacist registration number; and (3) the words "Proof of CE Compliance 2021." Please be aware that any continuing education credits submitted for your 2019-2021 biennial registration cannot be used toward your 2021-2023 biennial registration.

You have the right to appeal this citation by submitting a written or email request for an appeal hearing to the Board at the Board's Reno Office or teambc@pharmacy.nv.gov no later than 30 days after receipt of this notice. See NRS 639.2895(2).

Sincerely,

Nevada State Board of Pharmacy

9171 9690 0935 0307 2043 13

Tele: 775-850-1440 • Fax: 775-850-1444 • Web: bop.nv.gov
• E-mail: pharmacy@pharmacy.nv.gov



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

December 14, 2023

Efrain Armenta

██████ Venadis St

North Las Vegas, NV 89030

Re: Efrain Armenta, and Case No. 23-187-RPH-S

Dear Efrain Armenta,

The hearing for case number **23-187-RPH-S** has been scheduled for Wednesday, 1/17/2024 at 9:00:00 AM PST or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

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.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Darlene Nases

Assistant Board Coordinator

9171 9690 0935 0307 6318 98

NBOP15

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350307631898**[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 12:35 pm on December 18, 2023 in NORTH LAS VEGAS, NV 89030.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Delivered, Left with Individual

NORTH LAS VEGAS, NV 89030

December 18, 2023, 12:35 pm

In Transit to Next Facility

December 17, 2023

Departed USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 16, 2023, 8:05 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 16, 2023, 6:02 am

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER

December 14, 2023, 9:55 pm

Accepted at USPS Origin Facility

Feedback

NBOP16

RENO, NV 89521
December 14, 2023, 8:40 pm

Pre-Shipment, USPS Awaiting Item
December 14, 2023

Hide Tracking History

[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates



USPS Tracking Plus®



Product Information



See Less ^

Track Another Package

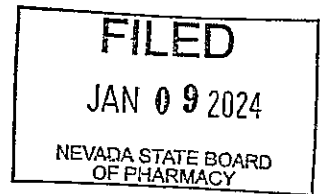
Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

BEFORE THE NEVADA STATE BOARD OF PHARMACY



NEVADA STATE BOARD OF PHARMACY,

Case Nos. 23-187-RPH-S

Petitioner,

v.

**MEMORANDUM OF
COSTS AND FEES**

**EFRAIN ARMENTA,
Certificate of Registration No. 19224,**

Respondents.

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigation Time (Deputy Director YenH Long)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
11/2023	Investigation	3.0	\$83.50	\$250.54
Subtotal (Investigation):				\$250.54

Attorney Time (Gustaf Vanderdonck)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
11/2023	Discussion, Review Report, Review Statutes and Regulations, Draft Order to Show Cause	5.0	\$49.52	\$247.60
Subtotal (Attorney Time)				\$247.60

Administrative Costs

<u>Date(s)</u>	<u>Description</u>	<u>Amount</u>
11/30/2023	Postage	\$8.53
Subtotal (Administrative Costs)		\$8.53

Total Costs and Fees:

\$506.67

I, Gustaf Vanderdonck, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of costs and reasonable attorney's fees incurred by the Board in the above-entitled action.

DATED this 9th day of January 2024.

/s/ Gustaf A. Vanderdonck
Assistant General Counsel
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY



NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

EFRAIN ARMENTA, RPH,
Certificate of Registration No. 19224,

Respondent.

Case No. 23-187-RPH-S

DECLARATION OF DARLENE NASES

I, Darlene Nases, hereby state the following:

1. Pursuant to NRS 53.045, I have made this declaration at the request of Gustaf A. Vanderdonck, Assistant General Counsel, for use in the above-entitled administrative action. I make this declaration for the purpose of authenticating Exhibit 4, attached hereto.
2. I am employed by the Nevada State Board of Pharmacy ("Board") as the supervisor of its Board Coordination team. In that capacity, I provide administrative support to the Board and the Board's staff, and I also serve as the Board's custodian of records.
3. I am knowledgeable about the Board's business processes and information systems as they pertain to the licensure and/or registration of persons who are subject to the Board's regulatory jurisdiction. I am also familiar with the use and operation of the Board's data management system and its processes for serving and filing accusations, notices of hearing, and related legal documents.
4. The Board maintains a searchable data management system that contains licensing information and records, including contact information, for the Board's licensees and registrants. Information and records are entered into the system in the regular course of the Board's business at or near the time by, or from information transmitted by persons with knowledge of such information and/or the contents of such records.
5. The Board also maintains an on-line portal through which the Board's licensees and registrants may obtain, renew, and/or update their licenses and/or registrations. This IT system generates a searchable record of all on-line transactions and stores it in the database. I am familiar with

the operation of this system and the way in which the Board's registrants and licensees may access the system's portal to conduct business with the Board.

6. In addition to using the on-line portal, the Board's licensees and registrants may use email or regular mail to update their contact information on file with the Board.

7. I have searched the Board's database for information concerning Efrain Armenta, RPH, who holds Certificate of Registration No. 19224. As of December 14, 2023, the contact information in the database lists Mr. Armenta's last-known address as 3527 Venadis Street, North Las Vegas, NV 89030.

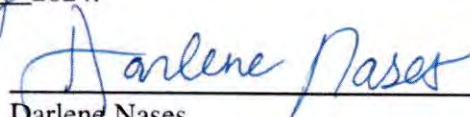
8. As of December 14, 2023, I have been unable to locate any notes or transactional records in the Board's IT system to indicate that Mr. Armenta attempted to update their contact information via the Board's on-line portal, via email, or through other means of communication.

9. Exhibit 2 is a true and correct copy of the twenty-one-day letter sent to Respondent in this case.

10. The address on Exhibit 2 accurately reflects that on December 14, 2023, I mailed copies of the associated accusation and notice of hearing to Efrain Armenta, RPH, to their last-known address on file with the Board. I mailed one copy to Mr. Armenta via Certified U.S. Mail. USPS records show that the letter was delivered on December 18, 2023.

I, Darlene Nases, declare under penalty of perjury that the foregoing is true and correct.

Executed this 8th day of January 2024.



Darlene Nases
Assistant Board Coordinator
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

FILED

JAN 09 2024

NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case No. 23-187-RPH-S

Petitioner,

v.

EFRAIN ARMENTA, RPH,
Certificate of Registration No. 19224,

Respondent.

DECLARATION OF SHIRLEY
HUNTING

I, Shirley Hunting, hereby state the following:

1. Pursuant to NRS 53.045, I have made this declaration at the request of Gustaf A. Vanderdonck, Assistant General Counsel, for use in the above-entitled administrative action. I make this declaration for the purpose of authenticating Exhibits 1-3, attached hereto.

2. I am employed by the Nevada State Board of Pharmacy ("Board") as the supervisor of its Board Coordination team. In that capacity, I provide administrative support to the Board and the Board's staff, and I also serve as the Board's custodian of records.

3. I am knowledgeable about the Board's business processes and information systems as they pertain to the licensure and/or registration of persons who are subject to the Board's regulatory jurisdiction. I am also familiar with the use and operation of the Board's data management system and its processes for serving and filing accusations, citations and fines, notices of hearing, and related legal documents.

4. The Board maintains a searchable data management system that contains licensing information and records, including contact information, for the Board's licensees and registrants. Information and records are entered into the system in the regular course of the Board's business at or near the time by, or from information transmitted by persons with knowledge of such information and/or the contents of such records.

5. The Board also maintains an on-line portal through which the Board's licensees and registrants may obtain, renew, and/or update their licenses and/or registrations. This IT system

generates a searchable record of all on-line transactions and stores it in the database. I am familiar with the operation of this system and the way in which the Board's registrants and licensees may access the system's portal to conduct business with the Board.

6. In addition to using the on-line portal, the Board's licensees and registrants may use email or regular mail to update their contact information on file with the Board.

7. I have searched the Board's database for information concerning Efrain Armenta, RPH, who holds Certificate of Registration No. 19224. As of November 30, 2023, the contact information in the database lists Mr. Armenta's last-known address as 3527 Venadis Street, North Las Vegas, NV 89030.

8. As of November 30, 2023, I have been unable to locate any notes or transactional records in the Board's IT system to indicate that Efrain Armenta, RPH, attempted to update their contact information via the Board's on-line portal, via email, or through other means of communication.

9. Exhibit 1 is a true and correct copy of the Order to Show Cause and notice of hearing for this case. Page 4 of Exhibit 1 is a certificate of service that bears my signature.

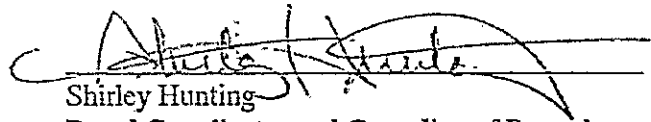
10. The certificate of service on Exhibit 1 accurately reflects that on November 30, 2023, I mailed copies of the associated Order to Show Cause and notice of hearing to Efrain Armenta, RPH, at their last-known address on file with the Board. I mailed two copies to Mr. Armenta, one via Certified U.S. Mail and another via Standard U.S. Mail. Both copies were received.

11. Exhibit 2 is a true and correct copy of USPS tracking information, and Certified Mail delivery slip.

12. Exhibit 3 is a true and correct copy of the citation and fine order that was sent to Mr. Armenta by Board Coordination via Certified Mail and email in case no. 23-187-RPH-S.

I, Shirley Hunting, declare under penalty of perjury that the foregoing is true and correct.

Executed this 9th day of January 2024.



Shirley Hunting
Board Coordinator and Custodian of Records
Nevada State Board of Pharmacy

5N



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JULIANA IZEBIGIE, RPH,
Certificate of Registration No. 09672,

Respondent.

Case No. 23-193-RPH-S

ORDER TO SHOW CAUSE

The Nevada State Board of Pharmacy ("Board") HEREBY ORDERS Respondent Juliana Izevbigie, RPH, ("Respondent"), Certificate of Registration No. 09672, pursuant to NAC 639.965 – NAC 639.978, to appear before the Board on January 17, 2024, at 9:00 a.m. and show cause, if any, why Certificate of Registration No. 09672 should not be revoked.

1. On June 30, 2023, the Board issued a Citation and Fine Order ("Order") to Respondent in Case No. 23-193-RPH-S.

2. The Order directed Respondent to satisfy the following conditions no later than September 1, 2023:

A. Pay an administrative fine of \$500; and

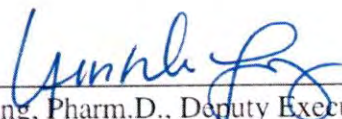
B. Submit proof of completion of thirty (30) continuing education units, one (1) of which must be a Nevada law based continuing education unit.

3. Respondent has failed to comply with the terms of the Order because Respondent failed to: a) pay an administrative fine of \$500; and b) complete and/or show proof of completion of thirty (30) continuing education units, including one (1) Nevada law based continuing education unit.

4. Additionally, Respondent has failed to timely appeal the Order by submitting a written request for a hearing within thirty (30) days of receipt of the Order. Accordingly, the Order became a final decision of the Board as provided by NRS 639.100, NRS 639.2895, and the Adopted Regulation of the Nevada State Board of Pharmacy, 070-19 Nev. Reg. Admin. Regs (Feb. 7, 2020).

THEREFORE, IT IS HEREBY ORDERED that Respondent Juliana Izevbigio, RPH, Certificate of Registration No. 09672, shall appear before the Board and show cause, if any, why Certificate of Registration No. 09672 should not be revoked.

ENTERED this 29th day of November 2023.



Yen H. Long, Pharm.D., Deputy Executive Secretary
of the Nevada State Board of Pharmacy, for and on
behalf of J. David Wuest, R.Ph., Executive Secretary
of the 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); NAC 639.968.

The Board has scheduled your hearing on this matter for Wednesday, January 17, 2024, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn located at 7830 S. Las Vegas Blvd, Las Vegas, Nevada 89123.

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.

CERTIFICATE OF SERVICE

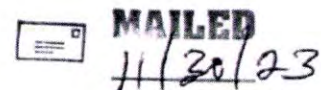
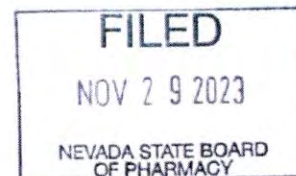
I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Juliana Izevbigie, RPH
[REDACTED] Copper Falls Ave.
Las Vegas, NV 89129


SHIRLEY HUNTING

Juliana Izevbigie, RPH
[REDACTED] Copper Falls Ave.
Las Vegas, NV 89129
OSC 23-193-RPH-S

9171 9690 0935 0307 6315 39



Standard 63
Certified 8.53

Answer Due:

12/25/23

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
☒ Complete Items 1, 2, and 3. ☒ Print your name and address on the reverse so that we can return the card to you. ☒ Attach this card to the back of the mailpiece, or on the front if space permits.	A. Signature X  ☐ Agent ☐ Addressee B. Received by (Printed Name) C. Date of Delivery 
1. Article Addressed to: Juliana Izevbigie, RPH  Copper Falls Ave. Las Vegas, NV 89129	D. Is delivery address different from Item 1? ☐ Yes If YES, enter delivery address below: ☐ No
2. 	3. Service Type ☐ Adult Signature ☐ Priority Mail Express® ☐ Adult Signature Restricted Delivery ☐ Registered Mail™ ☐ Certified Mail® ☐ Registered Mail Restricted Delivery ☐ Certified Mail Restricted Delivery ☐ Signature Confirmation™ ☐ Collect on Delivery ☐ Signature Confirmation Restricted Delivery
PS Form 3811, July 2020 PSN 7530-02-000-9053 Domestic Return Receipt	

9171 9690 0935 0307 6315 39

USPS TRACKING #



LAS VEGAS NV 890

4 DEC 2023 PM 4 L



First-Class Mail
Postage & Fees Paid
USPS
Permit No. G-10

9590 9402 6874 1104 6887 88

**United States
Postal Service**

• Sender: Please print your name, address, and ZIP+4® in this box •

Shirley Hunting
NV ST Board of Pharmacy
985 Damonte Ranch Pkwy., Ste. 206
Reno, NV 89521-4881



USPS Tracking®

[FAQs >](#)

Tracking Number:

Remove X

9171969009350307631539[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 2:23 pm on December 4, 2023 in LAS VEGAS, NV 89129.

[Get More Out of USPS Tracking:](#)[USPS Tracking Plus®](#)

Delivered

Delivered, Left with Individual

LAS VEGAS, NV 89129

December 4, 2023, 2:23 pm

[See All Tracking History](#)

Feedback

[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)[Text & Email Updates](#)[USPS Tracking Plus®](#)[Product Information](#)[See Less ^](#)[Track Another Package](#)

NBOP10

Need More Help?

Contact USPS Tracking support for further assistance.

[FAQs](#)

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

June 30, 2023

VIA CERTIFIED U.S. MAIL & ELECTRONIC MAIL

Juliana Izevbigie, RPh.
Certificate of Registration No. 09672
[REDACTED] Copper Falls Ave
Las Vegas, NV 89129
[REDACTED]

RE: Notice of Nevada CITATION-and-FINE: Case No. 23-193-RPH-S

Greetings:

The Nevada State Board of Pharmacy ("Board") has determined that you failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2019, and ending on October 31, 2021.

This notice shall serve as a CITATION & FINE pursuant to NRS 639.2895(2) for failing to timely complete your required continuing education. The Board has assessed an administrative fine of five hundred dollars (\$500.00) pursuant to NRS 639.2895(3). This administrative fine must be paid within 30 days of receipt of this citation. Payment must be by *personal, business, cashier's, certified check, or money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521. Please include a copy of this notice with payment.

In addition, you are hereby ordered to complete the required thirty (30) continuing education units, one (1) of which shall be a Nevada law based continuing education unit. You are ordered to submit a single email, attaching proof of your completed continuing education, to teambc@pharmacy.nv.gov, not later than Friday, September 1, 2023. Include the following information in the subject line of your email: (1) your full name; (2) your Nevada pharmacist registration number; and (3) the words "Proof of CE Compliance 2021." Please be aware that any continuing education credits submitted for your 2019-2021 biennial registration cannot be used toward your 2021-2023 biennial registration.

You have the right to appeal this citation by submitting a written or email request for an appeal hearing to the Board at the Board's Reno Office or teambc@pharmacy.nv.gov no later than 30 days after receipt of this notice. See NRS 639.2895(2).

Sincerely,

Nevada State Board of Pharmacy

9171 9690 0935 0307 2043 75

Tele: 775-850-1440 • Fax: 775-850-1444 • Web: bop.nv.gov
• E-mail: pharmacy@pharmacy.nv.gov



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

December 14, 2023

Juliana Izevbigie
[REDACTED] Copper Falls Ave
Las Vegas, NV 89129

Re: Juliana Izevbigie, and Case No. 23-193-RPH-S

Dear Juliana Izevbigie,

The hearing for case number **23-193-RPH-S** has been scheduled for Wednesday, 1/17/2024 at 9:00:00 AM PST or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

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.

If you have any questions, please feel free to contact the board staff.

Sincerely,
Darlene Nases
Assistant Board Coordinator

9171 9690 0935 0307 6319 04

NBOP15

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350307631904**[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 1:08 pm on December 18, 2023 in LAS VEGAS, NV 89129.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Delivered, Left with Individual

LAS VEGAS, NV 89129

December 18, 2023, 1:08 pm

In Transit to Next Facility

December 17, 2023

Departed USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 16, 2023, 8:05 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 16, 2023, 6:02 am

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER

December 14, 2023, 9:55 pm

Accepted at USPS Origin Facility

[Feedback](#)

NBOP16

RENO, NV 89521

December 14, 2023, 8:40 pm

Pre-Shipment, USPS Awaiting Item

December 14, 2023

Hide Tracking History**What Do USPS Tracking Statuses Mean?** (<https://faq.usps.com/s/article/Where-is-my-package>)**Text & Email Updates****USPS Tracking Plus®****Product Information****See Less**

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

BEFORE THE NEVADA STATE BOARD OF PHARMACY

FILED

JAN 10 2024

NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JULIANA IZEBIGIE, RPH,
Certificate of Registration No. 09672,

Respondent.

Case No. 23-193-RPH-S

DECLARATION OF SHIRLEY
HUNTING

I, Shirley Hunting, hereby state the following:

1. Pursuant to NRS 53.045, I have made this declaration at the request of Gustaf A. Vanderdonck, Assistant General Counsel, for use in the above-entitled administrative action. I make this declaration for the purpose of authenticating Exhibits 1-3, attached hereto.
2. I am employed by the Nevada State Board of Pharmacy ("Board") as the supervisor of its Board Coordination team. In that capacity, I provide administrative support to the Board and the Board's staff, and I also serve as the Board's custodian of records.
3. I am knowledgeable about the Board's business processes and information systems as they pertain to the licensure and/or registration of persons who are subject to the Board's regulatory jurisdiction. I am also familiar with the use and operation of the Board's data management system and its processes for serving and filing accusations, notices of hearing, and related legal documents.
4. The Board maintains a searchable data management system that contains licensing information and records, including contact information, for the Board's licensees and registrants. Information and records are entered into the system in the regular course of the Board's business at or near the time by, or from information transmitted by persons with knowledge of such information and/or the contents of such records.
5. The Board also maintains an on-line portal through which the Board's licensees and registrants may obtain, renew, and/or update their licenses and/or registrations. This IT system generates a searchable record of all on-line transactions and stores it in the database. I am familiar with

the operation of this system and the way in which the Board's registrants and licensees may access the system's portal to conduct business with the Board.

6. In addition to using the on-line portal, the Board's licensees and registrants may use email or regular mail to update their contact information on file with the Board.

7. I have searched the Board's database for information concerning Juliana Izevbigie, RPH, who holds Certificate of Registration No. 09672. As of November 30, 2023, the contact information in the database lists Ms. Izevbigie's last-known address as 8608 Copper Falls Avenue, Las Vegas, NV 89129.

8. As of November 30, 2023, I have been unable to locate any notes or transactional records in the Board's IT system to indicate that Ms. Izevbigie attempted to update her contact information via the Board's on-line portal, via email, or through other means of communication.

9. Exhibit 1 is a true and correct copy of the Order to Show Cause and notice of hearing for this case. Page 4 of Exhibit 1 is a certificate of service that bears my signature.

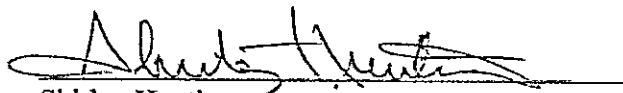
10. The certificate of service on Exhibit 1 accurately reflects that on November 30, 2023, I mailed copies of the Order to Show Cause and notice of hearing to Juliana Izevbigie, RPH, at her last-known address on file with the Board. I mailed two copies to Ms. Izevbigie, one via Certified U.S. Mail and another via Standard U.S. Mail. Both copies were delivered.

11. Exhibit 2 is a true and accurate copy of the Certified Mail envelope and USPS tracking information for the letter sent via standard mail. Both mailing attempts are shown to have been delivered.

12. Exhibit 3 is a true and accurate copy of the citation and fine sent to Ms. Izevbigie on June 30, 2023.

I, Shirley Hunting, declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of January 2024.

A handwritten signature in cursive script, appearing to read "Shirley Hunting", is written over a horizontal line.

Shirley Hunting
Board Coordinator and Custodian of Records
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

FILED

JAN 10 2024

NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JULIANA IZEVBIGIE, RPH,
Certificate of Registration No. 09672,

Respondent.

Case No. 23-193-RPH-S

DECLARATION OF DARLENE NASES

I, Darlene Nases, hereby state the following:

1. Pursuant to NRS 53.045, I have made this declaration at the request of Gustaf A. Vanderdonck, Assistant General Counsel, for use in the above-entitled administrative action. I make this declaration for the purpose of authenticating Exhibit 2, attached hereto.
2. I am employed by the Nevada State Board of Pharmacy ("Board") as the supervisor of its Board Coordination team. In that capacity, I provide administrative support to the Board and the Board's staff, and I also serve as the Board's custodian of records.
3. I am knowledgeable about the Board's business processes and information systems as they pertain to the licensure and/or registration of persons who are subject to the Board's regulatory jurisdiction. I am also familiar with the use and operation of the Board's data management system and its processes for serving and filing accusations, notices of hearing, and related legal documents.
4. The Board maintains a searchable data management system that contains licensing information and records, including contact information, for the Board's licensees and registrants. Information and records are entered into the system in the regular course of the Board's business at or near the time by, or from information transmitted by persons with knowledge of such information and/or the contents of such records.
5. The Board also maintains an on-line portal through which the Board's licensees and registrants may obtain, renew, and/or update their licenses and/or registrations. This IT system generates a searchable record of all on-line transactions and stores it in the database. I am familiar with

the operation of this system and the way in which the Board's registrants and licensees may access the system's portal to conduct business with the Board.

6. In addition to using the on-line portal, the Board's licensees and registrants may use email or regular mail to update their contact information on file with the Board.

7. I have searched the Board's database for information concerning Juliana Izevbigie, RPH., who holds Certificate of Registration No. 09672. As of December 14, 2023, the contact information in the database lists Ms. Izevbigie's last-known address as 8608 Copper Falls Avenue, Las Vegas, NV 89129.

8. As of December 14, 2023, I have been unable to locate any notes or transactional records in the Board's IT system to indicate that Ms. Izevbigie attempted to update her contact information via the Board's on-line portal, via email, or through other means of communication.

9. Exhibit 4 is a true and correct copy of the twenty-one-day letter sent to Respondent in this case.

10. The address on Exhibit 2 accurately reflects that on December 14, 2023, I mailed a copy of the associated twenty-one-day letter to Odette Erian, RPH, to her last-known address on file with the Board. I mailed one copy to Ms. Erian via Certified U.S. Mail. USPS records show that it was delivered.

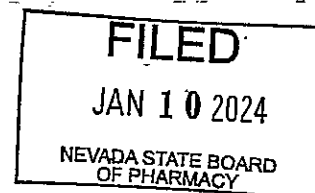
I, Darlene Nases, declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of January 2024.



Darlene Nases
Assistant Board Coordinator
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY



NEVADA STATE BOARD OF PHARMACY,

Case No. 23-193-RPH-S

Petitioner,

v.

**MEMORANDUM OF
COSTS AND FEES**

JULIANA IZEVBIGIE, RPH,
Certificate of Registration No. 09672,

Respondents.

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigation Time (Deputy Director Yen Long)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
11/2023	Investigation	3.0	\$83.50	\$250.54
Subtotal (Investigation):				\$250.54

Attorney Time (Gustaf Vanderdonck)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
11/2023	Discussion, Review Report, Review Statutes and Regulations, Draft Order to Show Cause	5.0	\$49.52	\$247.60
Subtotal (Attorney Time)				\$247.60

Administrative Costs

<u>Date(s)</u>	<u>Description</u>	<u>Amount</u>
11/30/2023	Postage	\$8.53

Subtotal (Administrative Costs)

\$8.53

Total Costs and Fees:

\$506.67

I, Gustaf Vanderdonck, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of costs and reasonable attorney's fees incurred by the Board in the above-entitled action.

DATED this 10th day of January 2024.

/s/ Gustaf A. Vanderdonck
Assistant General Counsel
Nevada State Board of Pharm

50

Exhibit 1



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case No. 23-196-RPH-S

Petitioner,

v.

ORDER TO SHOW CAUSE

ODETTE ERIAN, RPH,
Certificate of Registration No. 16558,

Respondent.

The Nevada State Board of Pharmacy ("Board") HEREBY ORDERS Respondent Odette Erian, RPH, ("Respondent"), Certificate of Registration No. 16558, pursuant to NAC 639.965 – NAC 639.978, to appear before the Board on January 17, 2024, at 9:00 a.m. and show cause, if any, why Certificate of Registration No. 16558 should not be revoked.

1. On June 30, 2023, the Board issued a Citation and Fine Order ("Order") to Respondent in Case No. 23-196-RPH-S.

2. The Order directed Respondent to satisfy the following conditions no later than September 1, 2023:

A. Pay an administrative fine of \$500; and

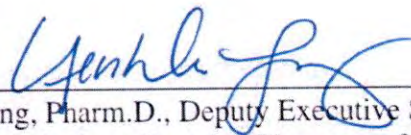
B. Submit proof of completion of thirty (30) continuing education units, one (1) of which must be a Nevada law based continuing education unit.

3. Respondent has failed to comply with the terms of the Order because Respondent failed to: a) pay an administrative fine of \$500; and b) complete and/or show proof of completion of thirty (30) continuing education units, including one (1) Nevada law based continuing education unit.

4. Additionally, Respondent has failed to timely appeal the Order by submitting a written request for a hearing within thirty (30) days of receipt of the Order. Accordingly, the Order became a final decision of the Board as provided by NRS 639.100, NRS 639.2895, and the Adopted Regulation of the Nevada State Board of Pharmacy, 070-19 Nev. Reg. Admin. Regs (Feb. 7, 2020).

THEREFORE, IT IS HEREBY ORDERED that Respondent Odette Erian, RPH, Certificate of Registration No. 16558, shall appear before the Board and show cause, if any, why Certificate of Registration No. 16558 should not be revoked.

ENTERED this 29th day of November 2023.

A handwritten signature in blue ink, appearing to read 'Yen Long', is written over a horizontal line.

Yen Long, Pharm.D., Deputy Executive Secretary
of the Nevada State Board of Pharmacy, for and on
behalf of J. David Wuest, R.Ph., Executive Secretary
of the 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); NAC 639.968.

The Board has scheduled your hearing on this matter for Wednesday, January 17, 2024, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn located at 7830 S. Las Vegas Blvd, Las Vegas, Nevada 89123.

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.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Odette Erian, RPH
[REDACTED] Elmstone Pl.
Las Vegas, NV 89138

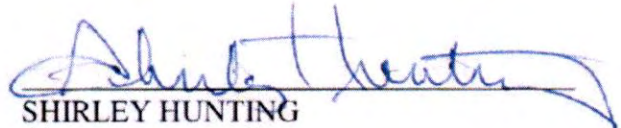

SHIRLEY HUNTING

Exhibit 2

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 • Reno, Nevada 89521

ADDRESS SERVICE REQUESTED



CERTIFIED MAIL



9171 9690 0935 0307 6315 22

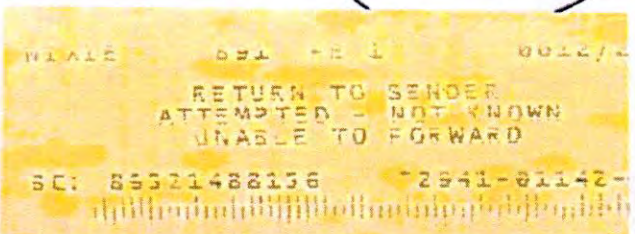
NOV 20 2020
PM 2 L



DEC 26 2023

Odette Erian, RPH
Elmstone Pl.
Las Vegas, NV 89138

W
12/2



ANK
9171 9690 0935 0307 6315 22

PS Form 3811, July 2020 PSN 7530-02-000-9053

9171 9690 0935 0307 6315 22

2. Article

Las Vegas, NV 89138
Elmstone Pl.
Odette Erian, RPH

1. Article Addressed to:
■ Attach this card to the back of the mailpiece, or on the front if space permits.
■ Print your name and address on the reverse so that we can return the card to you.
■ Complete items 1, 2, and 3.

SENDER: COMPLETE THIS SECTION

COMPLETE THIS SECTION ON DELIVERY

A. Signature ☒ X

B. Received by (Printed Name) _____

C. Date of Delivery _____

D. Is delivery address different from item 1? ☐ Yes ☐ No
If YES, enter delivery address below:

3. Service Type

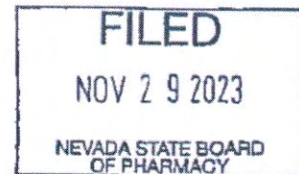
☐ Priority Mail Express®	☐ Registered Mail™
☐ Registered Mail Restricted Delivery	☐ Delivery
☐ Signature Confirmation™	☐ Signature Confirmation™
☐ Restricted Delivery	☐ Restricted Delivery

Domestic Return Receipt

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT OF THE RETURN ADDRESS. FOLD AT DOTTED LINE

Odette Brian, RPH
Elmstone Pl.
Las Vegas, NV 89138
OSC 23-196-RPH-S

9171 9690 0935 0307 6315 22



MAILED

11/30/23

Standard .63
Certified 8.53

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350307631522**[Copy](#)[Schedule a Redelivery \(https://tools.usps.com/redelivery.htm\)](https://tools.usps.com/redelivery.htm)

Latest Update

This is a reminder to arrange for redelivery of your item before December 16, 2023 or your item will be returned on December 17, 2023. You may arrange redelivery by using the Schedule a Redelivery feature on this page or may pick up the item at the Post Office indicated on the notice.

Get More Out of USPS Tracking:**USPS Tracking Plus®**

Feedback

Delivery Attempt: Action Needed

Reminder to Schedule Redelivery of your item before December 16, 2023

December 7, 2023

Notice Left (No Authorized Recipient Available)

LAS VEGAS, NV 89138

December 2, 2023, 1:14 pm

[See All Tracking History](#)[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)[Text & Email Updates](#)[Schedule Redelivery](#)[USPS Tracking Plus®](#)

NBOP9

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350307631522**[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

This is a reminder to arrange for redelivery of your item or your item will be returned to sender.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivery Attempt

Reminder to Schedule Redelivery of your item

December 7, 2023

Notice Left (No Authorized Recipient Available)

LAS VEGAS, NV 89138

December 2, 2023, 1:14 pm

[See All Tracking History](#)

Feedback

[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)[Text & Email Updates](#)[USPS Tracking Plus®](#)[Product Information](#)[See Less ^](#)

NBOP10

December 2, 2023, 8:26 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 1, 2023, 4:02 pm

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER

November 30, 2023, 11:08 pm

USPS picked up item

RENO, NV 89521

November 30, 2023, 12:09 pm

Hide Tracking History

What Do USPS Tracking Statuses Mean? (<https://faq.usps.com/s/article/Where-is-my-package>)

Text & Email Updates



USPS Tracking Plus®



Product Information



See Less ^

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

December 2, 2023, 8:26 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 1, 2023, 4:02 pm

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER

November 30, 2023, 11:08 pm

USPS picked up item

RENO, NV 89521

November 30, 2023, 12:09 pm

Hide Tracking History

What Do USPS Tracking Statuses Mean? (<https://faq.usps.com/s/article/Where-is-my-package>)

Text & Email Updates



USPS Tracking Plus®



Product Information



See Less ^

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

From: [Gus Vanderdonck](#)
To: [REDACTED]
Cc: [Shirley Hunting](#); [Darlene Nases](#); [Erin Miller](#)
Subject: Case No. 23-196-RPH-S
Date: Tuesday, December 26, 2023 9:47:51 AM
Attachments: [23-196-RPH-S.OSC.Erian.pdf](#)

Greetings Ms. Erian,

I am emailing you regarding Nevada State Board of Pharmacy Case No. 23-196-RPH-S. The Board has been trying to reach you at your last known address, but it does not appear that you have kept it updated. While we only need to send an accusation or order to show cause to your last known address, as a courtesy, I am also sending a copy to you via email. Please reach out to me ASAP regarding this case.

Best Regards,

Gustaf Vanderdonck
Assistant General Counsel
Nevada State Board of Pharmacy
(775)-850-1440 Ext. 132
gvanderdonck@pharmacy.nv.gov



NOTICE: This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not establish an attorney-client relationship. This information does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

Exhibit 3

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

June 30, 2023

VIA CERTIFIED U.S. MAIL & ELECTRONIC MAIL

Odette Erian, RPh.
Certificate of Registration No. 16558
[REDACTED] Elmstone Pl
Las Vegas, NV 89138
[REDACTED]

RE: Notice of Nevada CITATION-and-FINE: Case No. 23-196-RPH-S

Greetings:

The Nevada State Board of Pharmacy ("Board") has determined that you failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2019, and ending on October 31, 2021.

This notice shall serve as a CITATION & FINE pursuant to NRS 639.2895(2) for failing to timely complete your required continuing education. The Board has assessed an administrative fine of five hundred dollars (\$500.00) pursuant to NRS 639.2895(3). This administrative fine must be paid within 30 days of receipt of this citation. Payment must be by *personal, business, cashier's, certified check, or money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521. Please include a copy of this notice with payment.

In addition, you are hereby ordered to complete the required thirty (30) continuing education units, one (1) of which shall be a Nevada law based continuing education unit. You are ordered to submit a single email, attaching proof of your completed continuing education, to teambc@pharmacy.nv.gov, not later than Friday, September 1, 2023. Include the following information in the subject line of your email: (1) your full name; (2) your Nevada pharmacist registration number; and (3) the words "Proof of CE Compliance 2021." Please be aware that any continuing education credits submitted for your 2019-2021 biennial registration cannot be used toward your 2021-2023 biennial registration.

You have the right to appeal this citation by submitting a written or email request for an appeal hearing to the Board at the Board's Reno Office or teambc@pharmacy.nv.gov no later than 30 days after receipt of this notice. See NRS 639.2895(2).

Sincerely,

Nevada State Board of Pharmacy

9171 9690 0935 0307 2044 05

Tele: 775-850-1440 • Fax: 775-850-1444 • Web: bop.nv.gov
• E-mail: pharmacy@pharmacy.nv.gov

Exhibit 4



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

December 14, 2023

Odette Erian
[REDACTED] Elmstone Pl
Las Vegas, NV 89138

Re: Odette Erian, and Case No. 23-196-RPH-S

Dear Odette Erian,

The hearing for case number **23-196-RPH-S** has been scheduled for Wednesday, 1/17/2024 at 9:00:00 AM PST or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

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.

If you have any questions, please feel free to contact the board staff.

Sincerely,
Darlene Nases
Assistant Board Coordinator

9171 9690 0935 0307 6319 11

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)

9171969009350307631911

[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item could not be delivered on January 8, 2024 at 10:00 am in LAS VEGAS, NV 89134. It was held for the required number of days and is being returned to the sender.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Alert

Unclaimed/Being Returned to Sender

LAS VEGAS, NV 89134

January 8, 2024, 10:00 am

Reminder to Schedule Redelivery of your item

December 23, 2023

Notice Left (No Authorized Recipient Available)

LAS VEGAS, NV 89138

December 18, 2023, 10:43 am

Departed USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 16, 2023, 8:05 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER

December 16, 2023, 6:02 am

In Transit to Next Facility

Feedback

NBOP18

December 15, 2023

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER

December 14, 2023, 9:54 pm

Accepted at USPS Origin Facility

RENO, NV 89521

December 14, 2023, 8:39 pm

Pre-Shipment, USPS Awaiting Item

December 14, 2023

Hide Tracking History

[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates



USPS Tracking Plus®



Product Information



See Less

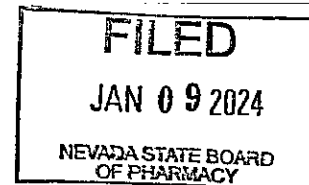
Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ODETTE ERIAN, RPH,
Certificate of Registration No. 16558,

Respondents.

Case Nos. 23-196-RPH-S

MEMORANDUM OF
COSTS AND FEES

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigation Time (Deputy Director Yen Long)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
11/2023	Investigation	3.0	\$83.50	\$250.54
Subtotal (Investigation):				\$250.54

Attorney Time (Gustaf Vanderdonck)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
11/2023	Discussion, Review Report, Review Statutes and Regulations, Draft Order to Show Cause	5.0	\$49.52	\$247.60
Subtotal (Attorney Time)				\$247.60

Administrative Costs

<u>Date(s)</u>	<u>Description</u>	<u>Amount</u>
11/30/2023	Postage	\$8.53
Subtotal (Administrative Costs)		\$8.53

Total Costs and Fees:

\$506.67

I, Gustaf Vanderdonck, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of costs and reasonable attorney's fees incurred by the Board in the above-entitled action.

DATED this 9th day of January 2024.

/s/ Gustaf A. Vanderdonck
Assistant General Counsel
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

FILED

JAN 10 2024

NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ODETTE ERIAN, RPH,
Certificate of Registration No. 16558,

Respondent.

Case No. 23-196-RPH-S

DECLARATION OF DARLENE NASES

I, Darlene Nases, hereby state the following:

1. Pursuant to NRS 53.045, I have made this declaration at the request of Gustaf A. Vanderdonck, Assistant General Counsel, for use in the above-entitled administrative action. I make this declaration for the purpose of authenticating Exhibit 2, attached hereto.

2. I am employed by the Nevada State Board of Pharmacy ("Board") as the supervisor of its Board Coordination team. In that capacity, I provide administrative support to the Board and the Board's staff, and I also serve as the Board's custodian of records.

3. I am knowledgeable about the Board's business processes and information systems as they pertain to the licensure and/or registration of persons who are subject to the Board's regulatory jurisdiction. I am also familiar with the use and operation of the Board's data management system and its processes for serving and filing accusations, notices of hearing, and related legal documents.

4. The Board maintains a searchable data management system that contains licensing information and records, including contact information, for the Board's licensees and registrants. Information and records are entered into the system in the regular course of the Board's business at or near the time by, or from information transmitted by persons with knowledge of such information and/or the contents of such records.

5. The Board also maintains an on-line portal through which the Board's licensees and registrants may obtain, renew, and/or update their licenses and/or registrations. This IT system generates a searchable record of all on-line transactions and stores it in the database. I am familiar with

the operation of this system and the way in which the Board's registrants and licensees may access the system's portal to conduct business with the Board.

6. In addition to using the on-line portal, the Board's licensees and registrants may use email or regular mail to update their contact information on file with the Board.

7. I have searched the Board's database for information concerning Odette Erian, RPH., who holds Certificate of Registration No. 16558. As of December 14, 2023, the contact information in the database lists Ms. Erian's last-known address as 867 Elmstone Place, Las Vegas, NV 89138.

8. As of December 14, 2023, I have been unable to locate any notes or transactional records in the Board's IT system to indicate that Ms. Erian attempted to update her contact information via the Board's on-line portal, via email, or through other means of communication.

9. Exhibit 4 is a true and correct copy of the twenty-one-day letter sent to Respondent in this case.

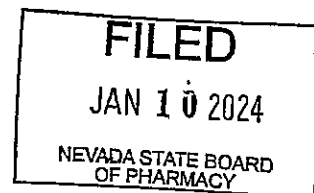
10. The address on Exhibit 2 accurately reflects that on December 14, 2023, I mailed a copy of the associated twenty-one-day letter to Odette Erian, RPH, to her last-known address on file with the Board. I mailed one copy to Ms. Erian via Certified U.S. Mail. It was returned as undeliverable.

I, Darlene Nases, declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of January 2024.



Darlene Nases
Assistant Board Coordinator
Nevada State Board of Pharmacy



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ODETTE ERIAN, RPH,
Certificate of Registration No. 16558,

Respondent.

Case No. 23-196-RPH-S

DECLARATION OF SHIRLEY
HUNTING

I, Shirley Hunting, hereby state the following:

1. Pursuant to NRS 53.045, I have made this declaration at the request of Gustaf A. Vanderdonck, Assistant General Counsel, for use in the above-entitled administrative action. I make this declaration for the purpose of authenticating Exhibits 1-3, attached hereto.

2. I am employed by the Nevada State Board of Pharmacy ("Board") as the supervisor of its Board Coordination team. In that capacity, I provide administrative support to the Board and the Board's staff, and I also serve as the Board's custodian of records.

3. I am knowledgeable about the Board's business processes and information systems as they pertain to the licensure and/or registration of persons who are subject to the Board's regulatory jurisdiction. I am also familiar with the use and operation of the Board's data management system and its processes for serving and filing accusations, notices of hearing, and related legal documents.

4. The Board maintains a searchable data management system that contains licensing information and records, including contact information, for the Board's licensees and registrants. Information and records are entered into the system in the regular course of the Board's business at or near the time by, or from information transmitted by persons with knowledge of such information and/or the contents of such records.

5. The Board also maintains an on-line portal through which the Board's licensees and registrants may obtain, renew, and/or update their licenses and/or registrations. This IT system generates a searchable record of all on-line transactions and stores it in the database. I am familiar with the operation of this system and the way in which the Board's registrants and licensees may access the system's portal to conduct business with the Board.

6. In addition to using the on-line portal, the Board's licensees and registrants may use email or regular mail to update their contact information on file with the Board.

7. I have searched the Board's database for information concerning Odette Erian, RPH, who holds Certificate of Registration No. 16558. As of November 29, 2023, the contact information in the database lists Ms. Erian's last-known address as 867 Elmstone Place, Las Vegas, NV 89138.

8. As of November 29, 2023, I have been unable to locate any notes or transactional records in the Board's IT system to indicate that Ms. Erian attempted to update her contact information via the Board's on-line portal, via email, or through other means of communication.

9. Exhibit 1 is a true and correct copy of the accusation and notice of hearing for this case. Page 4 of Exhibit 1 is a certificate of service that bears my signature.

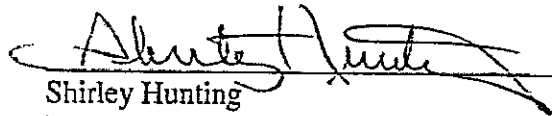
10. The certificate of service on Exhibit 1 accurately reflects that on November 29, 2023, I mailed copies of the Order to Show Cause and notice of hearing to Odette Erian, RPH, at her last-known address on file with the Board. I mailed two copies to Ms. Erian, one via Certified U.S. Mail and another via Standard U.S. Mail. Both copies were returned as undeliverable.

11. Exhibit 2 is a true and accurate copy of the returned Certified Mail envelope and USPS tracking information for the letter sent via standard mail.

12. Exhibit 3 is a true and accurate copy of the citation and fine sent to Ms. Erian on June 30, 2023.

I, Shirley Hunting, declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of JANUARY 2024.


Shirley Hunting
Board Coordinator and Custodian of Records
Nevada State Board of Pharmacy

5P

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

PONCIA B. REED, APRN,
Certificate of Registration No. CS23722,

Respondent.

Case No. 20-157-CS-S

STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its General Counsel, Peter K. Keegan, Esq., and Respondent Poncia B. Reed, APRN ("Reed"), Certificate of Registration No. CS23722 **HEREBY STIPULATE AND AGREE AS FOLLOWS:**

1. On or about September 28, 2023, Board Staff served Reed 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. In lieu of filing an Answer, Reed submits this Stipulation and Order for the Board's consideration.

3. Reed is aware of the right to seek the advice of counsel in this matter prior to entering this Stipulation.

4. Reed 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 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.

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Reed has failed to comply with the provisions of this Stipulation, Reed hereby freely and voluntarily waives the right 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.

JURISDICTION

6. The Board has personal jurisdiction over Respondent Poncia B. Reed, APRN, because the violations alleged herein, weigh on Respondent's character to hold a certificate of registration issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances. Since September 9, 2015, Respondent has held a license to prescribe controlled substances issued by the Board pursuant to NRS 453.226.

7. The Board has jurisdiction over the subject matter of this Accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals, and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

8. On or about September 9, 2015, the Board issued Respondent a Certificate of Registration to Dispense Controlled Substances, Certificate of Registration No. CS23722. This registration authorizes Respondent to write prescriptions for controlled substances.

9. Respondent Poncia B. Reed, APRN, was employed at a medical practice called Priority Medical Services LLC, located at 2655 South Rainbow Blvd., Suite 410, Las Vegas, NV 89146 at the time of the events alleged herein.

10. On July 2, 2020, Smith's Pharmacy #305, located at 3602 E. Bonanza Rd., Las Vegas, NV 89110 faxed a complaint to the Board showing that they were receiving prescriptions with stamped signatures from Respondent.

11. Between April 1, 2020, and July 20, 2020, Respondent wrote or authorized a total of thirty-three (33) prescriptions for schedule II-controlled substances.

12. A sample of the schedule II-controlled substance prescriptions show that at least six (6) of them included a stamped signature.

13. In a letter to Board Investigator Dena McClish, Respondent stated that she authorized her medical assistant ("MA") to use a signature stamp for her prescription.

APPLICABLE LAW

14. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

15. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

16. Only a practitioner holding a license to practice in this State may prescribe or write a prescription unless they qualify as an exception. NRS 639.100(1); NRS 639.235(1).

17. The Board may suspend or revoke any certificate, license, registration or permit if the holder has violated, attempted to violate, assisted, or abetted in the violation, or conspired to violate, or failed to report a violation, of any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12).

18. Each written prescription for a controlled substance must include the handwritten signature of the prescribing practitioner in nonerasable ink. NAC 453.440(2).

19. In lieu of a suspension or revocation, the Board may impose a fine of up to \$10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Violation of State Law – Assisting in Unauthorized Prescribing

20. Respondent's authorization of use of her signature stamp by her MA on schedule II-controlled substance prescriptions violated the requirements of NRS 639.100(1), NRS 639.235(1), and NAC 453.440(2) which specify that only a licensed practitioner may write a prescription for a controlled substance and that a written prescription must include the prescribing practitioner's handwritten signature. Therefore, Respondent is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255(1)(f) and (3).

COUNT TWO
Violation of State Law - Unprofessional Conduct

21. Respondent's authorization of use of her signature stamp by her MA on schedule II-controlled substance prescriptions Respondent violated NAC 453.440(2) and performed her duties in an incompetent, unskillful, or negligent manner, which constitutes unprofessional conduct in violation of NRS 639.210(4) as defined by NAC 639.945(1)(i). Therefore, Respondent is subject to discipline pursuant to. NRS 639.210(4) and NAC 639.945(1)(i); and/or NRS 639.255 and; and NAC 639.955.

CULPABILITY
(Respondent Reed)

22. Reed admits the truth of each and every factual allegation in this Stipulation.
23. Reed admits the truth of the alleged violations of law in this Stipulation.

DISCIPLINARY ORDER

24. In consideration of the foregoing admissions and stipulations, and to save the time and expense of litigating the alleged violations of law before the Board, the parties agree that the Board may issue and enter the following Disciplinary Order:

- A. Reed shall pay a fine of One Thousand Five Hundred Dollars (\$1,500.00) for the violations, by way of a single *check, 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 one hundred eighty (180) days of the effective date of the Board's Order; and
- B. Reed 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, by *check, 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) days of the effective date of the Board's Order.

25. Any failure by Reed 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 Reed 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 Reed, the Board may impose additional discipline upon Reed consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

26. The Board's 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 January 17, 2024. Reed will appear through its representatives and/or counsel at the meeting to answer questions from the Board Members. The Board Members may discuss and deliberate regarding this Stipulation, even if Reed is not present at the meeting.

27. The Board has discretion to accept this Stipulation, but it is not obligated to do so.

28. If the Board rejects any part or all this Stipulation, the parties agree that a full hearing on the merits of this matter may be heard by the Board, unless the parties reach an alternative agreement on the record which is approved 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.

29. Subject to the approval of this Stipulation by the Board, the Board and Reed 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 Reed 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 December 2023.


PONCIA B. REED, APRN
Certificate of Registration No. CS23722

Signed this 8th day of January 2024.


PETER K. KEEGAN, 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 Poncia B. Reed, APRN, Certificate of Registration Nos. CS23722, in Case No. 20-157-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective immediately upon execution below.

IT IS SO ORDERED.

Entered this ____ day of January 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5T

Exhibit 1



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**MATTHEW OKEKE, M.D.,
Certificate of Registration No. CS10935,**

Respondent.

Case No. 19-013-CS-S

**NOTICE OF INTENDED ACTION
AND ACCUSATION**

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

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

FACTUAL ALLEGATIONS

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as alleged above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied them to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) were not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent was convicted pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, was convicted pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners again disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described above. Discovery Mind Center was ordered to pay \$330,000 in restitution, and Respondent was sentenced to probation and ordered to pay \$300,000 in costs and penalties.

APPLICABLE LAW

14. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

15. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

16. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

17. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a

prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

18. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

19. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

20. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed \$10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE

Failure to Comply with Federal Registration Requirements

21. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO

Failure to Comply with State Registration Requirements

22. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE

Participating in Deceitful Transactions

23. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

24. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

25. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR

Issuing Presigned Prescriptions

26. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

27. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing presigned prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct, Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (physician assistant is subject to discipline for supplying patients with presigned prescriptions).

COUNT FIVE

Issuing Prescriptions from Unauthorized Locations

28. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

29. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

30. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

31. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

32. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN

Conviction of Crime Involving Dishonesty

33. As described herein, Respondent was convicted of a crime involving dishonesty. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving Discovery Mind Center. The Board may impose administrative discipline based upon that conviction because the underlying offense involved dishonesty. *See* NRS 639.210(7)(c).

COUNT EIGHT

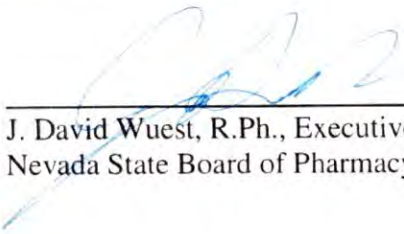
Prescribing Controlled Substances Without a Bona Fide Patient Relationship

34. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish a bona fide therapeutic relationship with one or more of these ostensible patients.

35. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

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

DATED this 29th day of JUNE 2023.



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). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, 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. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**MATTHEW OKEKE, MD,
Certificate of Registration No. CS10935,**

Respondent.

CASE NO. 19-013-CS-S

**STATEMENT TO
THE RESPONDENT
AND NOTICE OF HEARING**

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

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

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. 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.

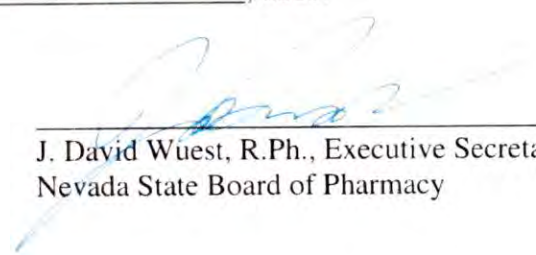
3. **The Board has scheduled your hearing on this matter for
Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the
following location:**

**Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123**

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. NRS 622A.350.

DATED this 29th day of June, 2023.



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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**MATTHEW OKEKE, MD,
Certificate of Registration No. CS10935,**

Respondent.

CASE NO. 19-013-CS-S

**ANSWER AND NOTICE
OF DEFENSE**

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

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, 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/she 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 _____, 2023.

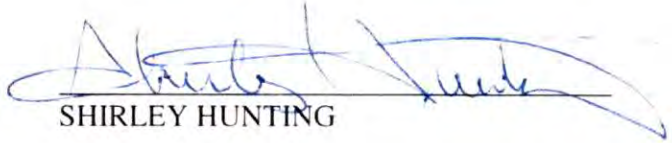
MATTHEW OKEKE, MD,

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of July 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
2021 S. Jones Blvd.
Las Vegas, NV 89146



SHIRLEY HUNTING

Matthew Okeke, MD
2021 S. Jones Blvd.
Las Vegas, NV 89146
NIAA 19-013-CS-S

9171 9690 0935 0307 2049 79



MAILED
7/20/23
Certified = 9.13
Standard = 1.83

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121
NIAA 19-013-CS-S

Liborius Agwara
8/14/23

Certified = 9.93
Standard = 1.83

9171 9690 0935 0307 2049 86

SENDER: COMPLETE THIS SECTION		COMPLETE THIS SECTION ON DELIVERY	
■ Complete items 1, 2, and 3. ■ Print your name and address on the reverse so that we can return the card to you. ■ Attach this card to the back of the mailpiece, or on the front if space permits.		A. Signature X <i>[Signature]</i> ☐ Agent ☐ Addressee	
1. Article Addressed to:		B. Received by (Printed Name) <i>E. Burriaga</i>	C. Date of Delivery
		D. Is delivery address different from item 1? ☐ Yes If YES, enter delivery address below: ☐ No	
2. Article Description:		3. Service Type ☐ Adult Signature ☐ Priority Mail Express® ☐ Adult Signature Restricted Delivery ☐ Registered Mail™ ☒ Certified Mail® ☐ Registered Mail Restricted Delivery ☐ Certified Mail Restricted Delivery ☐ Signature Confirmation™ ☐ Collect on Delivery ☐ Signature Confirmation Restricted Delivery	

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

9171 9690 0935 0307 2049 86

PS Form 3811, July 2020 PSN 7530-02-000-9053

19-013-S 0014 Domestic Return Receipt

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350307204986**[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 12:23 pm on July 24, 2023 in LAS VEGAS, NV 89121.

[Get More Out of USPS Tracking:](#)[USPS Tracking Plus®](#)

Feedback

Delivered

Delivered, Left with Individual

LAS VEGAS, NV 89121

July 24, 2023, 12:23 pm

[See All Tracking History](#)

Aguana
Answer Due 8/14/23

[Text & Email Updates](#)[USPS Tracking Plus®](#)[Product Information](#)[See Less ^](#)[Track Another Package](#)

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, Nevada 89521

Return Service Requested

Matthew Okeke, MD
2021 S. Jones Blvd.
Las Vegas, NV 89146

-R-T-S- 891462002-1N 07/26/23
RETURN TO SENDER
ATTEMPTED - NOT KNOWN
UNABLE TO FORWARD
RETURN TO SENDER



RECEIVED MAIL



Nevada State Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, Nevada 89521

9171 9690 0935 0307 2049 79

Return Service Requested

Las Vegas P8DC 89109
FRI 21 JUL 2023 PM

US POSTAGE

NIXIE 852 48 3 0107/25/23
RETURN TO SENDER
NOT DELIVERABLE AS ADDRESSED
UNABLE TO FORWARD
PC 89521428156 2104N706060-00141

Matthew Okeke, MD
2021 S. Jones Blvd.
Las Vegas, NV 89146



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MATTHEW OKEKE, M.D.,
Certificate of Registration No. CS10935,

Respondent.

Case No. 19-013-CS-S

**FIRST AMENDED NOTICE OF
INTENDED ACTION
AND ACCUSATION**

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

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

FACTUAL ALLEGATIONS

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as alleged above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied them to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent intentionally failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) were not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent entered a guilty plea pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, entered a guilty plea pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described in paragraph 10 above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described in paragraph 10 above. Discovery Mind Center was ordered to pay \$330,000 in restitution, and Respondent was sentenced to probation and ordered to pay \$300,000 in costs and penalties.

14. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was convicted pursuant to a plea agreement of one count of submitting false claims: Medicaid fraud, a category D felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and one count of obtaining and using personal identifying information of an older person for unlawful purposes, a category D felony in violation of NRS 205.463(1) and NRS 205.463(3)(a).

15. At the time of the offenses described in paragraph 14 above, Respondent owned, controlled, and/or managed Matthew Okeke, M.D., Ltd., a Nevada limited-liability company. Respondent entered guilty pleas on behalf of the company.

16. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was sentenced for the offenses described in paragraph 14 above. The company was ordered to pay a fine of \$100,000, among other fees and assessments.

17. Respondent was charged individually with the offenses described in paragraphs 9, 10, and 14 above. However, Respondent entered into plea agreements whereby he avoided individual convictions for all offenses except the gross misdemeanor offense described in paragraph 9 above.

18. On or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. The application specifically directed Respondent to disclose any charges, arrests, or convictions. Respondent disclosed the

conviction described in paragraph 9 above, referring to it as a "misdemeanor for record keeping," but he did not disclose the individual charges and/or arrests related to the felony fraud charges mentioned in paragraphs 10 and 14 above.

APPLICABLE LAW

19. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

20. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

21. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

23. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

24. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

25. Finally, the Board may revoke or suspend the registration of any practitioner who "[h]as 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 [NRS chapter 639]." *See* NRS 639.210(9).

26. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed \$10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE

Failure to Comply with Federal Registration Requirements

27. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO

Failure to Comply with State Registration Requirements

28. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE

Participating in Deceitful Transactions

29. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

30. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

31. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR

Issuing Pre-signed Prescriptions

32. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

33. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing pre-signed prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct, Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (a physician assistant is subject to discipline for supplying patients with pre-signed prescriptions).

COUNT FIVE

Issuing Prescriptions from Unauthorized Locations

34. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

35. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

36. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

37. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

38. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN

Failure to Establish Bona Fide Patient Relationships

39. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish bona fide therapeutic relationship with one or more of these ostensible patients.

40. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

COUNT EIGHT
Conviction of Crime Involving Dishonesty

41. As described above, Respondent was convicted of intentional failure to maintain adequate records, a gross misdemeanor.

42. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving the Discovery Mind Center and Matthew Okeke, M.D., Ltd., both limited-liability companies under the ownership and control of Respondent.

43. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, amounted to a conviction for a crime involving dishonesty. The Board may impose administrative discipline based upon that conviction. *See* NRS 639.210(7)(c).

COUNT NINE
Willfully Making False Statements in Connection with Renewal Application

44. As alleged above, on or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. On the application, Respondent falsely represented that he had never been charged with or arrested for a criminal offense other than a misdemeanor offense related to record keeping. When he made this representation, Respondent had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

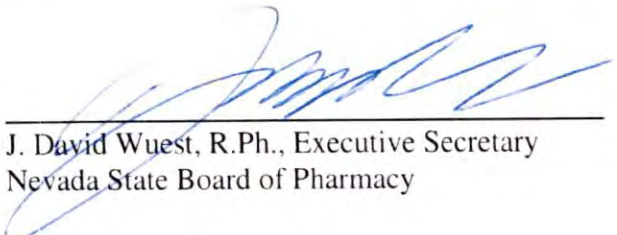
45. When he made the above false representation, Respondent knew that he had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

46. Respondent's false statement was material to the Board's determination whether to renew Respondent's certificate of registration to prescribe controlled substances.

47. Having willfully made a false representation as alleged above, Respondent is subject to discipline pursuant to NRS 639.210(9).

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

DATED this 26th day of September 2023.



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 First Amended 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). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, 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 First Amended 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. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 19-013-CS-S

Petitioner,

v.

**MATTHEW OKEKE, MD,
Certificate of Registration No. CS10935,**

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 First Amended 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 First Amended 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. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended 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 First Amended Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

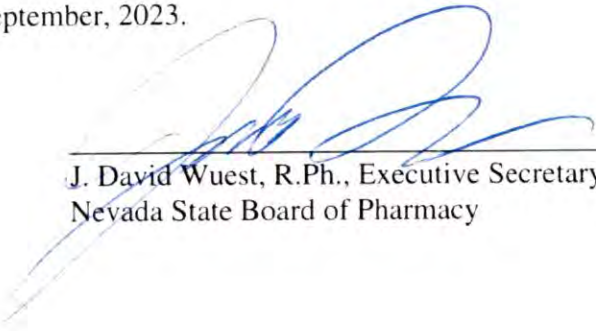
3. The Board has rescheduled your hearing on this matter for Wednesday, December 6, 2023, at 9:00 AM PST or soon thereafter at the following location:

**Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123**

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. NRS 622A.350.

DATED this 2nd day of September, 2023.



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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

**MATTHEW OKEKE, MD,
Certificate of Registration No. CS10935,**

Respondent.

CASE NO. 19-013-CS-S

**ANSWER AND NOTICE
OF DEFENSE**

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

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

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she 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 _____, 2023.

MATTHEW OKEKE, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of September 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
2700 S. Las Vegas Blvd., #4104
Las Vegas, NV 89101

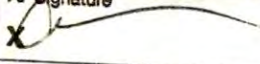

SHIRLEY HUNTING

Matthew Okeke, MD
2700 S. Las Vegas Blvd., #4104
Las Vegas, NV 89101

NIAA 19-013-CS-S

9171 9690 0935 0279 1497 28



SENDER: COMPLETE THIS SECTION		COMPLETE THIS SECTION ON DELIVERY	
- Complete items 1, 2, and 3. - Print your name and address on the reverse so that we can return the card to you. - Attach this card to the back of the mailpiece, or on the front if space permits.		A. Signature  B. Received by (Printed Name) C. Date of Delivery D. Is delivery address different from item 1? ☐ Yes If YES, enter delivery address below: ☐ No	
1. Article Addressed to: Matthew Okeke, MD 2700 S. Las Vegas Blvd., #4104 Las Vegas, NV 89101		3. Service Type ☐ Adult Signature ☐ Adult Signature Restricted Delivery ☒ Certified Mail® ☐ Certified Mail Restricted Delivery ☐ Collect on Delivery ☐ Collect on Delivery Restricted Delivery ☐ Priority Mail Express® ☐ Registered Mail™ ☐ Registered Mail Restricted Delivery ☐ Signature Confirmation™ ☐ Signature Confirmation Restricted Delivery	

MAILED
8/30/23
Certified = 9.73
Standard = 1.83
Delivery Due: 9/5

9171 9690 0935 0279 1497 28

PS Form 3811, July 2020 PSN 7530-02-000-9053

nd Delivery

Domestic Return Receipt

USPS Tracking®

[FAQs >](#)

Tracking Number:

[Remove X](#)**9171969009350279149728**[Copy](#)[Add to Informed Delivery \(https://informedelivery.usps.com/\)](https://informedelivery.usps.com/)

Latest Update

Your item was delivered to the front desk, reception area, or mail room at 4:02 pm on September 1, 2023 in LAS VEGAS, NV 89109.

[Get More Out of USPS Tracking:](#)[USPS Tracking Plus®](#)

Delivered

Delivered, Front Desk/Reception/Mail Room

LAS VEGAS, NV 89109

September 1, 2023, 4:02 pm

[See All Tracking History](#)[What Do USPS Tracking Statuses Mean? \(https://faq.usps.com/s/article/Where-is-my-package\)](https://faq.usps.com/s/article/Where-is-my-package)[Text & Email Updates](#)[USPS Tracking Plus®](#)[Product Information](#)[See Less ^](#)[Track Another Package](#)

Feedback



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

December 14, 2023

Matthew Okeke c/o Liborius Agwara, Esq.
2785 E Desert Inn Rd Suite 280
Las Vegas, NV 89121

Re: Matthew Okeke, and Case No. 19-013-CS-S

Dear Matthew Okeke,

The hearing for case number **19-013-CS-S** has been scheduled for Wednesday, 1/17/2024 at 9:00:00 AM PST or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

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.

If you have any questions, please feel free to contact the board staff.

Sincerely,
Darlene Nases
Assistant Board Coordinator

9171 9690 0935 0280 1502 32

Exhibit 2

From: [Gregory Zunino](#)
To: [LIBORIUS AGWARA](#)
Subject: Matthew Okeke, M.D.
Date: Thursday, December 14, 2023 11:07:00 AM
Attachments: [R071-19AP.pdf](#)
[23-483-CS-S.CS Suspension.Okeke.pdf](#)

Libo, the Board sent the attached letter to Dr. Okeke on December 1, 2023. I have also attached a copy of the applicable regulation. Dr. Okeke's status with the Board of Pharmacy is inactive and will continue as such unless Dr. Okeke petitions the Board to return his registration to active status. In the meantime, I am happy to discuss the stipulation that I emailed to you.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: [Gregory Zunino](#)
To: [LIBORTUS AGWARA](#)
Subject: Matthew Okeke, M.D.
Date: Monday, December 11, 2023 4:05:00 PM
Attachments: [Case No. 19-013-CS-S Matthew Okeke Stipulation.docx](#)

Libo, regarding the December 6 hearing. . . at my request the Board continued the case until January based upon Dr. Okeke's failure to appear. At the January hearing, I will take a default if Dr. Okeke does not appear. In connection with the default, I will recommend that the Board revoke Dr. Okeke's certificate of registration to prescribe controlled substances. The advantage of signing the stipulation (attached) is that it provides for a suspension as opposed to a revocation. With a revocation, there is no guarantee that Dr. Okeke's certificate of registration will ever be reinstated, which means that he could permanently lose his ability to prescribe controlled substances in Nevada. Additionally, the stipulation gives him greater assurance that the Board will accept the recommendation to suspend rather than revoke. Let me know if Dr. Okeke would like to sign the attached stipulation. Alternatively, please let me know if Dr. Okeke intends to appear for the January hearing to contest the charges. I will prepare accordingly. If you no longer represent Dr. Okeke, please advise.

Best,

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: [Gregory Zunino](#)
To: [LIBORIUS AGWARA](#)
Subject: RE: Matthew Okeke
Date: Tuesday, November 21, 2023 11:44:00 AM
Attachments: [Case No. 19-013-CS-S Matthew Okeke Stipulation.docx](#)

How is this? If your client agrees, how soon do you think you can return it to me with signatures?

Best,

Greg Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: LIBORIUS AGWARA <libolaw@yahoo.com>
Sent: Tuesday, November 21, 2023 9:41 AM
To: Gregory Zunino <zunino@pharmacy.nv.gov>
Subject: Re: Matthew Okeke

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Sounds good.

On Tuesday, November 21, 2023, 9:38 AM, Gregory Zunino <zunino@pharmacy.nv.gov> wrote:

I think we should get it done. I will make a few tweaks to the stipulation and send it anew. Thanks.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: LIBORIUS AGWARA <libolaw@yahoo.com>
Sent: Tuesday, November 21, 2023 6:05 AM

To: Gregory Zunino <zunino@pharmacy.nv.gov>

Subject: Re: Matthew Okeke

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Morning Greg and thanks for the proposed resolution. I forgot to tell you, but the status of Dr. Okeke's medical license is currently inactive. He decided to take a break from the active practice of medicine. With him not practicing, are we even able to enter into this resolution, or are we required to hold the proceedings in abeyance, pending when he returns to active practice? This is my first time dealing with this scenario. What do you think? Thanks.

Libo Agwara, Esq.

On Monday, November 20, 2023, 10:29 AM, Gregory Zunino
<zunino@pharmacy.nv.gov> wrote:

Libo, have you had an opportunity to discuss this with your client? If you get it back to me by tomorrow, I can include it in the board book. The board book is a large PDF file that we send to the Board members in advance of the meeting. If we miss the deadline for the board book, I will have to distribute paper copies at the meeting. They tend to frown on that. Alternatively, if you think that your client will contest this, we should probably continue until January. Let me know. Thanks.

Greg Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: Gregory Zunino
Sent: Tuesday, November 14, 2023 9:35 AM
To: LIBORIUS AGWARA <libolaw@yahoo.com>
Subject: Matthew Okeke

Libo, attached is a proposed settlement agreement. Let's discuss on

From: [Gregory Zunino](#)
To: [LIBORIUS AGWARA](#)
Subject: Matthew Okeke
Date: Tuesday, November 14, 2023 9:34:00 AM
Attachments: [Case No. 19-013-CS-S Matthew Okeke Stipulation.docx](#)

Libo, attached is a proposed settlement agreement. Let's discuss on Thursday. Thanks.

Greg Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: [Gregory Zunino](#)
To: [LIBORIUS AGWARA](#)
Subject: RE: Dr. Matthew Okeke
Date: Monday, November 6, 2023 8:32:00 AM

That works. Thanks.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: LIBORIUS AGWARA <libolaw@yahoo.com>
Sent: Friday, November 3, 2023 11:24 PM
To: Gregory Zunino <zunino@pharmacy.nv.gov>
Subject: Re: Dr. Matthew Okeke

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

How about 2:30 p.m. on the 13th? Thanks.
-Libo Agwara

On Friday, November 3, 2023, 11:26 PM, Gregory Zunino <zunino@pharmacy.nv.gov> wrote:

Let's plan to speak on November 13. I will put it on my calendar. Let me know if there is a good time to call.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: LIBORIUS AGWARA <libolaw@yahoo.com>
Sent: Friday, November 3, 2023 3:25 PM
To: Gregory Zunino <zunino@pharmacy.nv.gov>
Subject: Re: Dr. Matthew Okeke

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Mr. Zunino, thank you for your email below. I'm currently in Nigeria and won't be back in my office until Monday November 13, 2023. Will it be okay to talk then? Once again, thanks for reaching out. My client would like to resolve this matter.

-Libo

On Friday, November 3, 2023, 7:55 PM, Gregory Zunino <zunino@pharmacy.nv.gov> wrote:

Mr. Agwara,

Do you have time to discuss a settlement? If we can reach a settlement, I anticipate that we would present it to the Board of Pharmacy for approval at its December 6 meeting in Las Vegas. Let me know when you have some time to discuss.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: LIBORIUS AGWARA <libolaw@yahoo.com>
Sent: Wednesday, September 27, 2023 2:42 PM
To: Gregory Zunino <zunino@pharmacy.nv.gov>
Subject: Re: Dr. Matthew Okeke

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Thanks much Mr. Zunino.

Libo Agwara, JD, Ph.D.
Attorney at law

4693 E. Flamingo Rd.
Las Vegas, Nevada 89121
702-385-4800 Phone
702-385-4900 Fax

On Sep 27, 2023, at 1:18 PM, Gregory Zunino
<zunino@pharmacy.nv.gov> wrote:

Mr. Agwara, this is to confirm that I received your voice mail regarding the pending disciplinary matter against Dr. Okeke. I apologize that I did not return your call sooner. I was home sick when you called, and just got back into the office yesterday. I left a message with your receptionist.

I realize that the accusation was just recently served upon you. I further understand that Dr. Okeke had not yet engaged you as his attorney for this matter when the accusation was served. Understandably, you have requested an extension of the time for filing an answer and notice of defense, along with a postponement of the hearing as currently scheduled for October 11. With your permission, I will postpone the hearing. Regarding the answer and notice of defense, I will extend that time frame as well. Once we have spoken, we can pin down a date certain for the answer and/or the hearing. I look forward to your call.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: [Gregory Zunino](#)
To: [LIBORIUS AGWARA](#)
Subject: RE: Dr. Matthew Okeke
Date: Friday, November 3, 2023 11:55:00 AM

Mr. Agwara,

Do you have time to discuss a settlement? If we can reach a settlement, I anticipate that we would present it to the Board of Pharmacy for approval at its December 6 meeting in Las Vegas. Let me know when you have some time to discuss.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

From: LIBORIUS AGWARA <libolaw@yahoo.com>
Sent: Wednesday, September 27, 2023 2:42 PM
To: Gregory Zunino <zunino@pharmacy.nv.gov>
Subject: Re: Dr. Matthew Okeke

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Thanks much Mr. Zunino.

Libo Agwara, JD, Ph.D.
Attorney at law
4693 E. Flamingo Rd.
Las Vegas, Nevada 89121
702-385-4800 Phone
702-385-4900 Fax

On Sep 27, 2023, at 1:18 PM, Gregory Zunino <zunino@pharmacy.nv.gov> wrote:

Mr. Agwara, this is to confirm that I received your voice mail regarding the pending disciplinary matter against Dr. Okeke. I apologize that I did not return your call sooner. I was home sick when you called, and just got back into the office yesterday. I left a message with your receptionist.

I realize that the accusation was just recently served upon you. I further understand that Dr. Okeke had not yet engaged you as his attorney for this matter when the accusation was served. Understandably, you have requested an extension of the time

for filing an answer and notice of defense, along with a postponement of the hearing as currently scheduled for October 11. With your permission, I will postpone the hearing. Regarding the answer and notice of defense, I will extend that time frame as well. Once we have spoken, we can pin down a date certain for the answer and/or the hearing. I look forward to your call.

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
(775) 850-1440, ext. 124

Exhibit 3

1 **JOC**
2 AARON D. FORD
3 Attorney General
4 Behnaz Salimian Molina (Bar. No. 13752)
5 Senior Deputy Attorney General
6 State of Nevada
7 Office of the Attorney General
8 5175 South Durango Drive
9 Las Vegas, NV 89113
10 (702) 486-3420 (phone)
11 (702) 486-0460 (fax)
12 BMolina@ag.nv.gov
13 Attorneys for State of Nevada

8 DISTRICT COURT
9 CLARK COUNTY, NEVADA

10 THE STATE OF NEVADA,

11 Plaintiff,

12 vs.

13 MATTHEW OBIM OKEKE
14 (aka MATTHEW O OKEKE,
15 aka MICHAEL OKEKE),
16 ID #6021122,

17 Defendant.

Case No. C-22-364634-2

Dept. No. 17

17 JUDGMENT OF CONVICTION

18 WHEREAS, on the 8th day of September 2022, Defendant MATTHEW OBIM
19 OKEKE, pleaded guilty to one (1) count of INTENTIONAL FAILURE TO MAINTAIN
20 ADEQUATE RECORDS, a Gross Misdemeanor in violation of NRS 422.570(1).

21 WHEREAS, on the 6th day of December 2022, Defendant MATTHEW OBIM
22 OKEKE was present with his counsel, Liborius Agwara, and Senior Deputy Attorney
23 General Behnaz Salimian Molina was also present. Upon hearing statements from counsel,
24 and no sufficient cause being shown as to why judgment should not be pronounced against
25 Defendant, the Court rendered judgment as follows:

26 ///

27 ///

28 ///

1 That DEFENDANT MATTHEW OBIM OKEKE is adjudicated GUILTY of
2 INTENTIONAL FAILURE TO MAINTAIN ADEQUATE RECORDS, a Gross Misdemeanor
3 in violation of NRS 422.570(1).

4 COURT ORDERED, in addition to the \$25.00 Administrative Assessment fee,
5 \$300,000 in Enforcement Costs to the Nevada Attorney General's Office, Medicaid Fraud
6 Control Unit, \$3.00 DNA Collection fee, with the \$150.00 DNA Analysis fee including
7 testing to determine genetic markers, WAIVED as previously collected, and Defendant
8 SENTENCED to the Clark County Detention Center (CCDC) for NINETY (90) DAYS,
9 SUSPENDED; placed on PROBATION for an indeterminate period not to exceed TWELVE
10 (12) MONTHS with the following CONDITIONS:

11 Defendant to Abide by the Standard Conditions of Probation:

12 1. Reporting: You are to report in person to the Division of Parole and Probation
13 as instructed by the Division or its agent. You are required to submit a written report each
14 month on forms supplied by the Division. This report shall be true and correct in all
15 respects.

16 2. Residence: You shall not change your place of residence without first obtaining
17 permission from the Division of Parole and Probation, in each instance.

18 3. Intoxicants: You shall not consume any alcoholic beverages (whatsoever) (to
19 excess). Upon order of the Division of Parole and Probation or its agent, you shall submit
20 to a medically recognized test for blood/breath alcohol content. Test results of .08 blood
21 alcohol content or higher shall be sufficient proof of excess.

22 4. Controlled Substances: You shall not use, purchase or possess any illegal
23 drugs, or any prescription drugs, unless first prescribed by a licensed medical professional.
24 You shall immediately notify the Division of Parole and Probation of any prescription
25 received. You shall submit to drug testing as required by the Division or its agent.

26 5. Weapons: You shall not possess, have access to, or have under your control,
27 any type of weapon.

28 6. Search: You shall submit your person, property, place of residence, vehicle or

1 areas under your control to search including electronic surveillance or monitoring of your
2 location, at any time, with or without a search warrant or warrant of arrest, for evidence
3 of a crime or violation of probation by the Division of Parole and Probation or its agent.

4 7. Associates: You must have prior approval by the Division of Parole and
5 Probation to associate with any person convicted of a felony, or any person on probation or
6 parole supervision. You shall not have any contact with persons confined in a correctional
7 institution unless specific written permission has been granted by the Division and the
8 correctional institution.

9 8. Directives and Conduct: You shall follow the directives of the Division of
10 Parole and Probation and your conduct shall justify the opportunity granted to you by this
11 community supervision.

12 9. Laws: You shall comply with all municipal, county, state, and federal laws
13 and ordinances.

14 10. Out-of-State Travel: You shall not leave the state without first obtaining
15 written permission from the Division of Parole and Probation.

16 11. Employment/Program: You shall seek and maintain legal employment, or
17 maintain a program approved by the Division of Parole and Probation and not change such
18 employment or program without first obtaining permission. All terminations of
19 employment or program shall be immediately reported to the Division.

20 12. Financial Obligation: You shall pay fees, fines, and restitution on a schedule
21 approved by the Division of Parole and Probation (P&P). Any excess monies paid will be
22 applied to any other outstanding fees, fines, and/or restitution, even if it is discovered after
23 your discharge.

24 Defendant Shall Abide by these Special Conditions of Probation:

25 1. Abide by any directives from the State Board of Medical Examiners in terms
26 of licensing and practice.

27 2. Defendant is to report to P&P upon leaving Court.

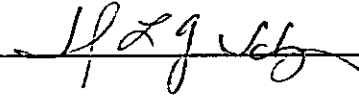
28 3. Defendant to pay enforcement costs of \$300,000.00 to the Nevada Attorney

1 General's Office, Medicaid Fraud Control Unit.

2 BOND, if any, EXONERATED.

3 THEREFORE, the clerk of the above-entitled court is directed to enter the Judgment
4 of Conviction as part of the record of the above-entitled matter.

5
6 Dated this 20th day of January, 2023

7 

8
9 69A 419 9E8B B043
Jennifer Schwartz
District Court Judge

10 Submitted by:
AARON D. FORD
Attorney General

11 /s/ Behnaz Salimian Molina
12 BEHNAZ SALIMIAN MOLINA
Senior Deputy Attorney General

1 CSERV

2 DISTRICT COURT
3 CLARK COUNTY, NEVADA

4
5
6 State of Nevada

CASE NO: C-22-364634-2

7 vs

DEPT. NO. Department 17

8 Matthew Okeke
9

10 **AUTOMATED CERTIFICATE OF SERVICE**

11 This automated certificate of service was generated by the Eighth Judicial District
12 Court. The foregoing Judgment of Conviction was served via the court's electronic eFile
13 system to all recipients registered for e-Service on the above entitled case as listed below:

14 Service Date: 1/20/2023

15 Behnaz Molina

bmolina@ag.nv.gov

16 Law Office

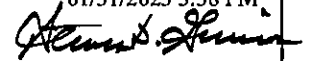
agwaralaw@yahoo.com

17 Liborius Agwara

libolaw@yahoo.com

18 Liborius Agwara

agwaralaw@yahoo.com


CLERK OF THE COURT

JOC
AARON D. FORD
Attorney General
Behnaz Salimian Molina (Bar. No. 13752)
Senior Deputy Attorney General
State of Nevada
Office of the Attorney General
5175 South Durango Drive
Las Vegas, NV 89113
(702) 486-3420 (phone)
(702) 486-0460 (fax)
BMolina@ag.nv.gov
Attorneys for State of Nevada

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

vs.

DISCOVERY MIND CENTER LTD
(aka DISCOVERY MIND CENTER LLC,

Defendant.

Case No. C-22-364634-1

Dept. No. 17

JUDGMENT OF CONVICTION

WHEREAS, on the 8th day of September 2022, Defendant DISCOVERY MIND CENTER LTD (aka DISCOVERY MIND CENTER LLC, by and through owner MATTHEW OBIM OKEKE, pleaded guilty to One (1) Count of SUBMITTING FALSE CLAIMS: MEDICAID FRAUD, a Category D Felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and One (1) Count of OBTAINING AND USING PERSONAL IDENTIFYING INFORMATION OF AN OLDER PERSON FOR UNLAWFUL PURPOSES, a Category B Felony in violation of NRS 205.463(1) and 205.463(3)(a).

WHEREAS, on the 17th day of January 2023, Defendant DISCOVERY MIND CENTER LTD was present with its counsel, Liborius Agwara, and Senior Deputy Attorney General Behnaz Salimian Molina was also present. Upon hearing statements from counsel, and no sufficient cause being shown as to why judgment should not be pronounced against Defendant, the Court rendered judgment as follows:

1 That DEFENDANT DISCOVERY MIND CENTER is ADJUDGED GUILTY of
2 COUNT 1: SUBMITTING FALSE CLAIMS: MEDICAID FRAUD, a Category D Felony in
3 violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and COUNT 2: OBTAINING AND
4 USING PERSONAL IDENTIFYING INFORMATION OF AN OLDER PERSON FOR
5 UNLAWFUL PURPOSES, a Category B Felony in violation of NRS 205.463(1) and
6 205.463(3)(a).

7 Pursuant to NRS 176.063, COURT ORDERED, in addition to the \$25.00
8 Administrative Assessment fee, \$3.00 DNA Collection fee, WAIVED AS DEFENDANT IS
9 A COMPANY, \$150.00 DNA Analysis fee including testing to determine genetic markers,
10 WAIVED AS A DEFENDANT IS A COMPANY, \$330,000.00 restitution payable to the
11 ATTORNEY GENERAL'S OFFICE.

12 Defendant SENTENCED to a MAXIMUM OF SIXTY (60) MONTHS AND A
13 MINIMUM OF EIGHTEEN (18) MONTHS in the Nevada Department of Corrections
14 (NDC), SUSPENDED; placed on probation for a period not to exceed THIRTY-SIX (36)
15 MONTHS. Only Condition:

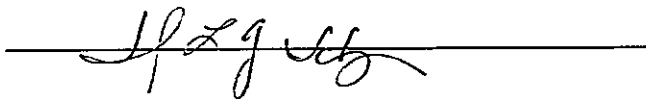
16 1. Restitution in the amount of \$330,000.00 payable to the Attorney General's Office.

17 COURT FURTHER ORDERED that the PSI be STRICKEN.

18 BOND, if any, EXONERATED.

19 THEREFORE, the clerk of the above-entitled court is directed to enter the Judgment
20 of Conviction as part of the record of the above-entitled matter.

21
22 Dated this 31st day of January, 2023

23 

24
25 Submitted by:
26 AARON D. FORD
Attorney General

FF9 92C 74E3 C068
Jennifer Schwartz
District Court Judge

27 /s/ Behnaz Salimian Molina
28 BEHNAZ SALIMIAN MOLINA
Senior Deputy Attorney General

1 CSERV

2 DISTRICT COURT
3 CLARK COUNTY, NEVADA
4

5
6 State of Nevada

CASE NO: C-22-364634-1

7 vs

DEPT. NO. Department 17

8 Discovery Mind Center LTD
9

10 **AUTOMATED CERTIFICATE OF SERVICE**

11 This automated certificate of service was generated by the Eighth Judicial District
12 Court. The foregoing Judgment of Conviction was served via the court's electronic eFile
13 system to all recipients registered for e-Service on the above entitled case as listed below:

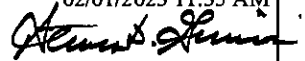
14 Service Date: 1/31/2023

15 Behnaz Molina

bmolina@ag.nv.gov

16 Liborius Agwara

libolaw@yahoo.com


CLERK OF THE COURT

JOC
AARON D. FORD
Attorney General
Behnaz Salimian Molina (Bar. No. 13752)
Senior Deputy Attorney General
State of Nevada
Office of the Attorney General
5175 South Durango Drive
Las Vegas, NV 89113
(702) 486-3420 (phone)
(702) 486-0460 (fax)
BMolina@ag.nv.gov
Attorneys for State of Nevada

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

vs.

MATTHEW OKEKE, M.D., LTD d/b/a
GRAND DESERT PSYCHIATRIC
SERVICES,

Defendant.

Case No. C-22-369136-2

Dept. No. 21

JUDGMENT OF CONVICTION

WHEREAS, on the 1st day of December 2022, Defendant MATTHEW OKEKE, M.D., LTD d/b/a GRAND DESERT PSYCHIATRIC SERVICES, by and through owner MATTHEW OBIM OKEKE, pleaded guilty to One (1) Count of SUBMITTING FALSE CLAIMS: MEDICAID FRAUD, a Category D Felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and One (1) Count of OBTAINING AND USING PERSONAL IDENTIFYING INFORMATION OF AN OLDER PERSON FOR UNLAWFUL PURPOSES, a Category B Felony in violation of NRS 205.463(1) and 205.463(3)(a).

WHEREAS, on the 26th day of January 2023, Defendant MATTHEW OKEKE, M.D., LTD d/b/a GRAND DESERT PSYCHIATRIC SERVICES was present with its counsel, Scott B. Olifant, and Senior Deputy Attorney General Behnaz Salimian Molina was also present. Upon hearing statements from counsel, and no sufficient cause being shown as to why judgment should not be pronounced against Defendant, the Court rendered judgment

1 as follows:

2 That DEFENDANT MATTHEW OKEKE, M.D., LTD d/b/a GRAND DESERT
3 PSYCHIATRIC SERVICES is ADJUDGED GUILTY of COUNT 1 – SUBMITTING FALSE
4 CLAIMS: MEDICAID FRAUD, a Category D Felony in violation of NRS 422.540(1)(a) and
5 NRS 422.540(2)(a), and COUNT 2 – OBTAINING AND USING PERSONAL
6 IDENTIFYING INFORMATION OF AN OLDER PERSON FOR UNLAWFUL
7 PURPOSES, a Category B Felony in violation of NRS 205.463(1) and 205.463(3)(a).

8 COURT ORDERED, in addition to the \$25.00 Administrative Assessment fee, a
9 \$5,000.00 Fine as to Count 1, a \$100,000.00 Fine as to Count 2, a \$150.00 DNA Analysis
10 fee, WAIVED, and \$3.00 DNA Collection fee, Defendant SENTENCED as to COUNT 1 to
11 a MINIMUM of NINETEEN (19) MONTHS and a MAXIMUM of FORTY-EIGHT (48)
12 MONTHS in the Nevada Department of Corrections (NDC); Defendant SENTENCED as
13 to COUNT 2 to a MINIMUM of THREE (3) YEARS and a MAXIMUM of TWENTY (20)
14 YEARS in the Nevada Department of Corrections (NDC), CONCURRENT WITH COUNT
15 1, SUSPENDED; placed on PROBATION for an indeterminate period not to exceed
16 TWENTY-FOUR (24) MONTHS. In addition to the Standard Conditions of the Division of
17 Parole and Probation (P & P), which are IMPOSED, Defendant must comply with the
18 following SPECIAL CONDITIONS:

19 1. Defendant to pay fines within TWENTY-FOUR (24) MONTHS.

20 COURT FURTHER ORDERED matter SET for status check on fine payment.

21 THEREFORE, the clerk of the above-entitled court is directed to enter the Judgment
22 of Conviction as part of the record of the above-entitled matter.

23 Dated this 1st day of February, 2023

24 

25
26 Submitted by:
27 AARON D. FORD
Attorney General

A6B F66 E43A 711D
Tara Clark Newberry
District Court Judge

28 /s/ Behnaz Salimian Molina
BEHNAZ SALIMIAN MOLINA

Senior Deputy Attorney General

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

1 CSERV

2 DISTRICT COURT
3 CLARK COUNTY, NEVADA
4

5
6 State of Nevada

CASE NO: C-22-369136-2

7 vs

DEPT. NO. Department 21

8 Matthew Okeke MD Ltd
9

10 **AUTOMATED CERTIFICATE OF SERVICE**

11 This automated certificate of service was generated by the Eighth Judicial District
12 Court. The foregoing Judgment of Conviction was served via the court's electronic eFile
13 system to all recipients registered for e-Service on the above entitled case as listed below:

14 Service Date: 2/1/2023

15 Behnaz Molina

bmolina@ag.nv.gov

16 Liborius Agwara

libolaw@yahoo.com

Exhibit 4

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

In the Matter of Charges and Complaint
Against
MATTHEW OBIM OKEKE, M.D.,
Respondent.

Case No. 19-22461-1

FILED

MAR - 9 2020

NEVADA STATE BOARD OF
MEDICAL EXAMINERS

By: _____

AMENDED SETTLEMENT AGREEMENT¹

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Robert Kilroy, Esq., General Counsel for the Board and attorney for the IC, and Matthew Obim Okeke, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, L. Kristopher Rath, Esq., of the law firm of Hutchison & Steffen, LLC, hereby enter into this Amended Settlement Agreement (Agreement) based on the following:²

A. Background

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on September 6, 2013 (License No. 14957).

2. On May 30, 2019, in Case No. 19-22461-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges two (2) violations of NRS 630.301(4), Malpractice (Counts I and IV), two (2) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Counts II and V), and

¹ This Amended Settlement Agreement takes the place of the previous Settlement Agreement and any Erratas previously approved by the Board in this case.

² All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

OFFICE OF THE GENERAL COUNSEL

Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 686-3359

1 two (2) violations of NRS 630.306(1)(g) Continual Failure to Exercise the Skill or Diligence or Use
2 the Methods Ordinarily Exercised Under the Same Circumstances by Physicians in Good Standing
3 Practicing in the Same Speciality or Field (Counts III and VI).

4 3. By reason of the foregoing, Respondent is subject to discipline by the Board as
5 provided in NRS 630.352.

6 4. Respondent was properly served with a copy of this Complaint, has reviewed and
7 understands this Complaint, and has had the opportunity to consult with competent counsel
8 concerning the nature and significance of this Complaint.

9 5. Respondent is hereby advised of his rights regarding this administrative matter, and of
10 his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has
11 certain rights in this administrative matter as set out by the United States Constitution, the Nevada
12 Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in
13 NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in
14 NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the
15 Complaint, the right to representation by counsel, at his own expense, in the preparation and
16 presentation of his defense, the right to confront and cross-examine the witnesses and evidence against
17 him, the right to written findings of fact, conclusions of law and order reflecting the final decision of
18 the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.
19 Respondent understands that, under the Board's charge to protect the public by regulating the
20 practice of medicine, the Board may take disciplinary action against Respondent's license,
21 including license probation, license suspension, license revocation and imposition of
22 administrative fines, as well as any other reasonable requirement or limitation, if the Board
23 concludes that Respondent violated one or more provisions of the Medical Practice Act.

24 6. Respondent understands and agrees that this Agreement, by and between
25 Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the
26 Board for consideration in open session at a duly noticed and scheduled meeting. Respondent
27 understands that the IC shall advocate for the Board's approval of this Agreement, but that the
28 Board has the right to decide in its own discretion whether or not to approve this Agreement.

1 Respondent further understands and agrees that if the Board approves this Agreement, then the
2 terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

3 **B. Terms & Conditions**

4 **NOW, THEREFORE,** in order to resolve the matters addressed herein, i.e., the matters
5 with regard to the Complaint, Respondent and the IC hereby agree to the following terms and
6 conditions:

7 1. **Jurisdiction.** Respondent is, and at all times relevant to the Complaint has been, a
8 physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set
9 forth in the Medical Practice Act.

10 2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement.**
11 Respondent acknowledges he is represented by counsel, and wishes to resolve the matters
12 addressed herein with said counsel. Respondent agrees that if representation by counsel in this
13 matter materially changes prior to entering into this Agreement and for the duration of this
14 Agreement, that counsel for the IC will be timely notified of the material change. Respondent
15 agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to
16 have a full consultation with and upon the advice of legal counsel.

17 3. **Waiver of Rights.** In connection with this Agreement, and the associated terms
18 and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection
19 with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives
20 all rights arising under the United States Constitution, the Nevada Constitution, the Medical
21 Practice Act, the OML, the APA, and any other legal rights that may be available to him or that
22 may apply to him in connection with the administrative proceedings resulting from the Complaint
23 filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in
24 the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board.
25 Respondent agrees to settle and resolve the allegations of the Complaint as set out by this
26 Agreement, without a hearing or any further proceedings and without the right to judicial review.

27 4. **Acknowledgement of Reasonable Basis to Proceed.** As of the time of entering
28 into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent

OFFICE OF THE GENERAL COUNSEL

Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2359

1 acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in
2 conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges
3 Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit
4 and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential
5 subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has
6 evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the
7 Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent
8 waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to
9 effectuate this Agreement.

10 5. Consent to Entry of Order. In order to resolve this Complaint pending against
11 Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent
12 engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly,
13 the following terms and conditions are hereby agreed upon:

14 a. Respondent admits to Count I (Malpractice, NRS 630.301(4)), Count II (Medical
15 Records, NRS 630.3062(1)(a)), and Count V (Medical Records, NRS 630.3062(1)(a)).

16 b. Respondent's license shall be suspended from the date of the Board's acceptance,
17 adoption and approval of this Agreement for two (2) years -- STAYED.

18 c. Respondent's license shall be subject to a term of probation for a period of time of
19 24 months from the date of the Board's acceptance, adoption and approval of this Agreement
20 (Probationary period). During this Probationary period, if Respondent fails to demonstrate
21 compliance with the terms and conditions of this Agreement, or otherwise violates the terms of
22 this Agreement, then the stayed suspension shall be immediately lifted and in effect. Should the
23 Board determine that Respondent violated the Medical Practice Act due to and/or arising from
24 any act or omission which occurs prior to the date the Board approves this Agreement, this said
25 violation shall not be considered a violation of this Agreement.

26 The following terms and conditions shall apply during Respondent's probationary period:

27 (1) Respondent must be supervised all times during any and all interactions with all
28 female patients with a formal monitoring agreement with approved and identified

monitors through the entire probationary period or until further order of the Board.

(2) Respondent shall engage and shall participate in an independent remediation and compliance monitoring program designed by the independent monitor Affiliated Monitors, Inc. (Affiliated Monitors), who, in consultation with Board staff, shall design, implement, and monitor Respondent's compliance with a program that must start within two weeks days from the Board's acceptance, adoption and approval from the execution of this Order and shall remain in place during the aforementioned probationary period. Affiliated Monitors shall provide quarterly reports based upon monthly interactions with Respondent, Respondent's staff/monitors, and other relevant information, including but not limited to medical records and other documentation relating to Respondent's practice. Respondent shall bear all costs and fees associated with this Affiliated Monitors program.

d. Respondent will pay the costs and expenses incurred in the investigation and prosecution of Case 19-22461-1, totaling \$6,800.36, within thirty days of the Board's acceptance, adoption and approval of this Agreement. The \$4,942.73 previously paid on April 15, 2019 for Invoice 801, referencing Case # 18-22461-1,³ shall be applied to the costs due and owing in Case 19-22461-1, leaving \$1,857.63 owing under this Agreement.⁴

e. Respondent shall pay a fine of \$500.00 within sixty days of the Board's acceptance, adoption and approval of this Agreement.⁵

f. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

g. Respondent shall receive a Public Letter of Reprimand.

h. The remaining counts of the Complaint, and any other claims arising from Board Investigation No.'s 16-16290, 18-17688, 18-17856, and 18-18000 shall be dismissed with prejudice.

³ This case was Investigation No. 16-16290.

⁴ This payment of \$1,857.63 was made by Respondent on October 7, 2019.

⁵ Respondent has paid this fine on November 20, 2019. Respondent has now paid all costs and fines required under Paragraphs 5(d) and 5(e) of this Agreement.

1 i. Upon successful completion of the probation requirements set forth herein,
2 Respondent may petition the Board to have his license removed from probation, have his license
3 status to be restored to good standing and have his suspension placed upon his license rescinded.
4 Following Respondent's demonstration of the aforementioned requirements, the Board will issue
5 an order to this effect.

6 6. Release From Liability. In execution of this Agreement, Respondent understands
7 and agrees that the State of Nevada, the Board, and each of its members, staff, counsel,
8 investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents
9 are immune from civil liability for any decision or action taken in good faith in response to
10 information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of
11 Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers,
12 committees, panels, hearing officers, consultants and agents from any and all manner of actions,
13 causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and
14 unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against
15 any or all of the persons, government agencies or entities named in this paragraph arising out of,
16 or by reason of, this investigation, this Agreement or the administration of the case referenced
17 herein.

18 7. Procedure for Adoption of Agreement. The IC and counsel for the IC shall
19 recommend approval and adoption of the terms and conditions of this Agreement by the Board in
20 resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of
21 this Agreement, counsel for the IC may communicate directly with the Board staff and the
22 adjudicating members of the Board.

23 Respondent acknowledges that such contacts and communications may be made or
24 conducted ex parte, without notice or opportunity to be heard on his part until the public Board
25 meeting where this Agreement is discussed, and that such contacts and communications may
26 include, but may not be limited to, matters concerning this Agreement, the Complaint and any and
27 all information of every nature whatsoever related to this matter. The IC and its counsel agree that
28 Respondent and/or Counsel for the Respondent may appear at the Board meeting where this

1 Agreement is discussed and, if requested, respond to any questions that may be addressed to the
2 IC or the IC's counsel.

3 8. Effect of Acceptance of Agreement by Board. In the event the Board accepts,
4 approves and adopts this Agreement, the Board shall issue a final order, making this Agreement
5 an order of the Board, and, pending full compliance with the terms herein, the case shall be closed
6 and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

7 9. Effect of Rejection of Agreement by Board. In the event the Board does not
8 accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and
9 effect except as to the following agreement regarding adjudications: (1) Respondent agrees that,
10 notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement
11 and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this
12 Agreement shall disqualify any member of the adjudicating panel of the Board from considering
13 this Complaint and from participating in disciplinary proceedings against Respondent, including
14 adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any
15 such member absent evidence of bad faith.

16 10. Binding Effect. If approved by the Board, Respondent understands that this
17 Agreement is a binding and enforceable contract upon Respondent and the Board.

18 11. Forum Selection Clause. The parties agree that in the event either party is
19 required to seek enforcement of this Agreement in district court, the parties consent to such
20 jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court,
21 State of Nevada, Washoe County.

22 12. Attorneys' Fees and Costs. The parties agree that in the event an action is
23 commenced in district court to enforce any provision of this Agreement, the prevailing party shall
24 be entitled to recover reasonable attorneys' fees and costs.

25 13. Failure to Comply With Terms. Should Respondent fail to comply with any term
26 or condition of this Agreement once the Agreement has been accepted, approved and adopted by
27 the Board, the IC shall be authorized to immediately suspend Respondent's license to practice
28 medicine in Nevada pending an Order To Show Cause Hearing, which will be duly noticed.

OFFICE OF THE GENERAL COUNSEL

Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

1 Failure to comply with the terms of this Agreement, including failure to pay any fines, costs,
2 expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may
3 result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).
4 Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a
5 condition of this Agreement may subject Respondent to civil collection efforts.

6
7 Dated this 4th day of March, 2020.

8
9 INVESTIGATIVE COMMITTEE OF THE
10 NEVADA STATE BOARD OF MEDICAL EXAMINERS

11 By: Sarah A. Bradley
12 Sarah A. Bradley, Esq., Deputy Executive Director
13 Attorney for the Investigative Committee
14

15 Dated this 4th day of March, 2020.

16 HUTCHISON & STEFFEN, LLC

17
18 By: LKR Rath
19 L. Kristopher Rath, Esq.
20 Attorneys for Respondent

21 Dated this 4 day of March, 2020.

22
23 Matthew Obim Okeke
24 Matthew Obim Okeke, M.D., Respondent
25
26
27
28

1 IT IS HEREBY ORDERED that the foregoing Amended Settlement Agreement (19-22461-1) is
2 approved and accepted by the Nevada State Board of Medical Examiners on the 6th day of March,
3 2020, with the final total amount of costs due of \$6,800.36

4
5 

6 Rachakonda D. Prabhu, M.D., President
7 NEVADA STATE BOARD OF MEDICAL EXAMINERS
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

**BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA**

* * * * *

In the Matter of Charges and Complaint

Case No. 21-22461-1

Against:

MATTHEW OBIM OKEKE, M.D.

Respondent.

FILED

DEC - 8 2022

**NEVADA STATE BOARD OF
MEDICAL EXAMINERS**

By: 

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

This case was presented for adjudication and decision before the Nevada State Board of Medical Examiners (Board), during a regularly scheduled Board meeting on December 2, 2022, located at 325 E. Warm Springs Road, Suite 225, Las Vegas, NV 89119 video conferenced to 9600 Gateway Drive, Reno, NV 89521. Matthew Obim Okeke, M.D. (Respondent), was properly served with a notice of the adjudication, including the date, time, and location. Respondent was present with his counsel Liborius Agwara, Esq. The adjudicating members of the Board participating in these Findings of Fact, Conclusions of Law (FOFCOL) and Order were: Nicola (Nick) M. Spirtos, M.D., Ms. Maggie Arias-Petrel, Victor M. Muro, M.D., Ms. Pamela Beal and Carl N. Williams, Jr., M.D., FACS. Sophia Long, Esq., Senior Deputy Attorney General, served as legal counsel to the Board.

The Board, having received and read the Complaint and exhibits admitted at the hearing of this matter, the Hearing Officer's Findings and Recommendations (Synopsis of Record)¹, and the transcript of the hearing, made its decision pursuant to its authority and provisions of the Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), NRS Chapter 622A, and NRS Chapter 233B, as applicable.

///

¹ The Hearing Officer's Findings and Recommendations were prepared by Charles Woodman, Esq., who was appointed as Hearing Officer under NRS 630.106 in this matter and presided over the hearing.

1 The Board, after due consideration of the record, evidence and law, and being fully
2 advised in the premises, makes its FINDINGS OF FACT, CONCLUSIONS OF LAW AND
3 ORDER in this matter, as follows:

4 **FINDINGS OF FACT**

5 **I.**

6 Respondent held a license to practice medicine in the State of Nevada issued by the Board
7 from September 6, 2013, to present.

8 **II.**

9 On October 26, 2021, the Investigative Committee filed its formal Complaint in Case No.
10 21-22461-1, alleging Respondent violated the Medical Practice Act. Respondent was served with
11 the Complaint on November 8, 2021, at his address of record with the Board. Pursuant to
12 NRS 630.254, each licensee shall maintain a permanent mailing address with the board to which
13 all communications from the Board to the licensee must be sent. A licensee who changes his or
14 her permanent mailing address shall notify the Board in writing of the new permanent mailing
15 address within 30 days after the change.

16 The Complaint alleges two (2) violations of the Medical Practice Act that constitute
17 grounds for initiating disciplinary action against a licensee, as follows: one (1) violation of
18 NRS 630.301(4) Malpractice and one (1) violation of NRS 630.3062(1)(a) Failure to Maintain
19 Proper Medical Records.

20 Respondent filed an answer to the allegations set forth in the Complaint on
21 January 11, 2022.

22 **III.**

23 An Early Case Conference was conducted January 21, 2022. Aaron B. Fricke, J.D.,
24 General Counsel at the time, (Mr. Fricke) was present on behalf of the Investigative Committee
25 (IC) of the Board, and Liborius Agwara, Esq., appeared telephonically on behalf of Respondent
26 along with Hearing Officer Charles Woodman, Esq. The parties agreed to dates for the prehearing
27 conference, exchange of documents, and the hearing date.

28 ///

1 In compliance with NAC 630.465, a Notice and Order Scheduling Prehearing and Hearing,
2 setting prehearing and hearing was filed on January 31, 2022, setting the prehearing conference
3 for March 25, 2022, at 10:00 a.m., and setting the hearing for April 28 and 29, 2022, at 9:00 a.m.,
4 at the Office of the Nevada State Board of Medical Examiners, 9600 Gateway Drive, Reno,
5 Nevada 89521 video conferenced to the Board's Las Vegas Office, located at 325 E. Warm
6 Springs Road, Suite 225, Las Vegas, NV 89119. The Scheduling Order was delivered to
7 Respondent's Counsel via USPS Certified Mail on February 2, 2022.

8 A second Notice and Order Scheduling Prehearing and Hearing was then filed on
9 June 7, 2022, changing the Prehearing Conference to June 21, 2022, and dates for the formal
10 Hearing to be determined at the Prehearing Conference. A copy of this Order was mailed to
11 Respondent's counsel on June 7, 2022, with courtesy copy by email.

12 The Prehearing Conference was held telephonically as noticed and ordered, at which time,
13 legal counsel for the IC, Sarah A. Bradley, J.D., Deputy Executive Director, appeared. Liborius
14 Agwara, Esq., appeared telephonically on behalf of Respondent along with Hearing Officer
15 Charles Woodman, Esq. Respondent and his counsel were timely and properly served with the
16 IC's Prehearing Conference Statement, filed June 16, 2022, and the mandated Prehearing
17 Disclosures in accordance with NRS and NAC Chapters 630, NRS Chapters 241, 622A and 233B,
18 and the requirements of due process, by Fed Ex 2-Day Priority Mail, delivered to Respondent's
19 counsel on June 17, 2022.

20 Following the Prehearing Conference, an Order After Pre-Hearing Conference was filed
21 June 27, 2022, setting the sate for a formal Hearing to be held July 28, 2022, at 9:00 a.m.
22 Respondent and his counsel were mailed a copy of the Order on June 28, 2022, with courtesy copy
23 by email.

24 A third Notice and Order Scheduling Hearing was filed August 19, 2022, rescheduling the
25 Hearing date for September 12, 2022, at 9:00 a.m. Respondent and his counsel were mailed a
26 copy of the Order on June 28, 2022, with courtesy copy by email.

27 ///

28 ///

1 IV.

2 On September 12, 2022, as duly noticed and ordered, a hearing was held before the
3 Hearing Officer to receive evidence and to hear arguments of both parties. Legal counsel for the
4 IC, Ms. Bradley, appeared. Respondent and his counsel appeared in the Las Vegas Board office.
5 Ms. Bradley presented the IC's case, offered documentary evidence and presented witness
6 testimony. Exhibits 1 through 15, were marked and admitted into evidence.

7 The Hearing Officer provided the Synopsis of Record, filed November 17, 2022. This
8 matter was scheduled for final adjudication on December 2, 2022, at a regularly scheduled Board
9 meeting.

10 The notice of the adjudication was sent via USPS Certified Mail to Respondent's counsel
11 on October 26, 2022.

12 A copy of the adjudication materials along with a copy of the Hearing Officer's Synopsis
13 of Record and second notice of the Board meeting were mailed via Fed Ex 2-Day mail to
14 Respondent's counsel and were delivered on Respondent's address of record on November 22,
15 2022.

16 V.

17 Pursuant to NRS 622A.300(5)(a), the Synopsis of Record of the Hearing Officer is hereby
18 approved by the Board with modification, and is hereby specifically incorporated and made part of
19 this Order by reference and attached hereto as **Exhibit 1**. The Board rejects the findings and
20 recommendations made by the Hearing Officer with respect to Count I.

21 VI.

22 The Board hereby finds that Count II, as set forth in the Complaint, and as recapitulated in
23 Paragraph II above, has been established by a preponderance of the evidence. The Board hereby
24 finds that Count I, as set forth in the Complaint, and as recapitulated in Paragraph II above, has
25 not been established by a preponderance of the evidence.

26 VII.

27 If any of the foregoing Findings of Fact is more properly deemed a Conclusion of Law, it
28 may be so construed.

CONCLUSIONS OF LAW

I.

The Board has jurisdiction over Respondent and the Complaint, and an adjudication of this matter by the Board members as set forth herein is proper.

II.

Respondent was timely and properly served with the Complaint, and all notices and orders in advance of the hearing and adjudication thereon, in accordance with NRS and NAC Chapters 630, NRS Chapters 241, 622A and 233B, and all legal requirements of due process.

III.

With respect to the allegations of the Complaint, the Board concludes that Respondent has violated the Medical Practice Act, as alleged in the Complaint, as follows: one (1) violation of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records. Accordingly, Respondent is subject to discipline pursuant to NRS 630.352.

IV.

The Board finds that, pursuant to NRS 622.400, recovery from Respondent of reasonable attorneys' fees and costs incurred by the Board as part of its investigation and disciplinary proceedings against Respondent is appropriate. The Board has reviewed the Investigative Committee's Memorandum of Costs and Disbursements and Attorneys' Fees, and the Board finds them to be the actual fees and costs incurred by the Board as part of its investigative, administrative and disciplinary proceedings against Respondent, and finds them to be reasonable and necessary based on: (1) the abilities, training, education, experience, professional standing and skill demonstrated by Board staff and attorneys; (2) the character of the work done, its difficulty, its intricacy, its importance, the time and skill required, the responsibility imposed and the prominence and character of the parties where, as in this case, they affected the importance of the litigation; (3) the work actually performed by the Board's attorneys and staff, and the skill, time and attention given to that work; and (4) the product of the work and benefits to the Board and the people of Nevada that were derived therefrom.

///

V.

If any of the foregoing Conclusions of Law is more properly deemed a Finding of Fact, it may be so construed.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, and good cause appearing therefore,

IT IS HEREBY ORDERED that:

1. Respondent has violated the Medical Practice Act, as alleged in the Complaint, as follows: one (1) violation of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records (Count II).

2. Pursuant to NRS 630.352(4)(e), the Board shall administer a written public reprimand to Respondent.

3. Respondent's license shall be suspended for two (2) years from the date of the Board's order. This suspension shall be stayed, and Respondent's license will be placed on probation for two (2) years from the date of the Board's order. If Respondent fails to comply with the terms and conditions of this Order, including a failure to timely comply with the terms and conditions of this Order, or commits a new violation of the Medical Practice Act during the probationary period, then, after an order to show cause wherein the IC proves by a preponderance of the evidence that the failure to comply or failure to timely comply or violation did occur, the stayed suspension will be immediately lifted and in effect. Matters currently being investigated by the Board and/or pending action by the Board will not be deemed a violation of this Order.

4. The following terms and conditions shall apply during Respondent's probationary period:

a. Respondent must be always accompanied by a chaperone during any and all interactions with female patients. A list of chaperones used by Respondent must be provided to Strategic Management Services or other monitoring company approved in the reasonable judgment of the Board and those chaperones must first be approved by Strategic Management

///

OFFICE OF THE GENERAL COUNSEL

Nevada State Board of Medical Examiners

9600 Gateway Drive

Reno, Nevada 89521

(775) 688-2559

1 Services or other monitoring company approved in the reasonable judgment of the Board before
2 use.

3 b. Respondent must be monitored by Strategic Management Services or other
4 monitoring company approved in the reasonable judgment of the Board. Strategic Management
5 Services or other monitoring company approved in the reasonable judgment of the Board shall
6 provide quarterly reports to the Board regarding its review of Respondent's charts and patient
7 records. Strategic Management Services or other monitoring company approved in the reasonable
8 judgment of the Board shall review 10% of Respondent's patient charts each quarter, not to
9 exceed fifty (50) charts per quarter and provide a report to the Board. At the end of the first year,
10 Strategic Management Services or other monitoring company approved in the reasonable
11 judgment of the Board shall review fifty patient charts and provide a report to the Board.
12 Strategic Management Services or other monitoring company approved in the reasonable
13 judgment of the Board will be reviewing all aspects of these patient charts, including legibility and
14 completeness of records, verification of the presence of a chaperone for visits with female
15 patients, and compliance with Nevada law regarding prescribing controlled substances, such as
16 proof of regular PMP queries for patients.

17 c. Respondent shall pay all costs associated with the monitoring of him and/or
18 his practice conducted by Strategic Management Services or other monitoring company approved
19 in the reasonable judgment of the Board.

20 d. At the end of the first year, after successful completion of monitoring and
21 charter review by Strategic Management Services or other monitoring company approved in the
22 reasonable judgment of the Board, Respondent may come to the Board at a public meeting and
23 request that the Board remove the requirement that he be monitored by Strategic Management
24 Services or other monitoring company approved in the reasonable judgment of the Board from his
25 probation.

26 e. Even if the Board removes the requirement that Respondent be monitored
27 by Strategic Management Services or other monitoring company approved in the reasonable
28 judgment of the Board as described above in paragraph b, Respondent shall continue to be

1 accompanied by a chaperone at all times during any and all interactions with female patients
2 during the remainder of his two (2) year probationary period or until such time as a request is
3 made and the Board removes this requirement.

4 5. Pursuant to NRS 630.352(4)(h), Respondent is hereby ordered to pay a fine of two
5 thousand five hundred dollars (\$2,500.00) to be paid within sixty (60) days from service of this
6 Order.

7 6. Because the IC prevailed on only one (1) count of the Complaint, the Board
8 reduced the costs assessed against Respondent in this matter from eighteen thousand two hundred
9 twenty-nine dollars forty-four cents (\$18,229.44) as shown in the IC's Memorandum of Costs
10 and Disbursements and Attorneys' Fees to ten thousand dollars (\$10,000).

11 7. The Board found that the reasonable, necessary, and actually incurred costs and
12 expenses for the investigation and prosecution of this case in the amount of ten thousand dollars
13 (\$10,000), shall be reimbursed by Respondent within ninety (90) days from the service of this
14 Order. The Board, and/or its designee, are granted the authority to collect any and all funds due
15 under this Order.

16 8. Respondent shall complete eight (8) hours of Continued Medical Education (CME)
17 on record-keeping and documentation and twenty-two (22) hours in the best practices in
18 prescribing in addition to the statutory required CME requirements for licensure. These CME
19 credits must be completed on or before December 31, 2023; and

20 9. This Order shall be reported to the appropriate entities and parties as required by
21 law, including, but not limited to, the National Practitioner Data Bank.

22 **IT IS SO ORDERED.**

23 DATED this 8th day of December, 2022.

24 NEVADA STATE BOARD OF MEDICAL EXAMINERS

25
26 By:



27 AURY NAGY, M.D.
28 *President of the Board*

CERTIFICATION

I certify that the foregoing is the full and true original **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER** on file in the office of the Board of Medical Examiners in the matter of **MATTHEW OBIM OKEKE, M.D.**, Case No. 21-22461-1.

I further certify that Aury Nagy, M.D., is the President of the Nevada State Board of Medical Examiners and that full force and credit is due to his official acts as such; and that the signature to the foregoing ORDER is the signature of said Aury Nagy, M.D.

IN WITNESS THEREOF, I have hereunto set my hand in my official capacity as Secretary-Treasurer of the Nevada State Board of Medical Examiners.

DATED this 8th day of December, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By:

Maggie Arias-Petrel

MAGGIE ARIAS-PETREL

Secretary-Treasurer and Public Member of the Board

EXHIBIT 1

EXHIBIT 1

1 **BEFORE THE BOARD OF MEDICAL EXAMINERS**

2
3 **OF THE STATE OF NEVADA**

4
5 **FILED**

6 **NOV 17 2022**

7 **NEVADA STATE BOARD OF**
8 **MEDICAL EXAMINERS**

9 By: 

10 **In the Matter of Charges and Complaint**

11 **Against**

12 **MATTHEW OBIM OKEKE, M.D.,**

13 **Respondent.**

14 **Case No.: 21-22461-1**

15 **SYNOPSIS OF RECORD**

16 **Hearing Officer Charles B. Woodman, having heard all formal pre-hearing**
17 **conferences, as well as the formal Hearing of this matter, hereby presents the Nevada State**
18 **Board of Medical Examiners with his Analysis of this case. This Analysis is based upon**
19 **all evidence adduced at the formal Hearing, and this Hearing Officer's findings of facts**
20 **and conclusions of law, which findings include the credibility of the witnesses who gave**
21 **evidence.**

22 **RELEVANT BACKGROUND**

23 **This case came on for hearing on September 12, 2022. Ms. Sarah A. Bradley, Esq.,**
24 **appeared on behalf of the Investigative Committee ("IC") of the Nevada State Board of**
25 **Medical Examiners. Liborius Agwara, Esq., appeared on behalf of and with Dr. Agwara.**
26 **Dr. Agwara and his counsel appeared at the Board's Southern Nevada office where the**
27 **official reporter was also located. Ms. Bradley appeared at the Board's Northern Nevada**
28 **office where the hearing officer was located. The parties were connected via video**
29 **teleconference communications.**

30 **NRS 233B.123 controls evidence admitted in contested administrative hearings.**
31 **That code states in pertinent part that "evidence may be admitted, except where precluded**

1 by statute, if it is of a type commonly relied upon by reasonable and prudent persons in the
2 conduct of their affairs.”

3 By conclusion of the formal hearing of this case, Exhibits 1 through 12, as well as
4 Exhibits 14 and 15 offered by the IC and were admitted into evidence. Those admitted
5 Exhibits are attached hereto. Exhibit 13 was excluded from evidence based on the
6 testimony of the IC’s main witness Dr. Jayleen Chen, M.D. Dr. Okeke chose not to
7 present a defense case, and accordingly did not offer any exhibits.

8 It is noteworthy that while certain medical records admitted into evidence are
9 several years old, Dr. Chen acknowledged that she did not review records or testify to facts
10 alleged to have occurred prior to 2017. (See Factual Evidence below.) Dr. Okeke’s
11 counsel argued that those records that predate 2017 and were not reviewed by Dr. Chen
12 should thus not be considered. However, all medical records admitted into evidence from
13 years prior to 2017, while not addressed by Dr. Chen, are still in evidence and thus part of
14 the record which can be considered in the determination of this case. Accordingly,
15 paragraphs 2 through 6 of the Complaint on file which allege facts prior to 2017 are not
16 legally barred from consideration.

17 FACTUAL EVIDENCE

18 The facts adduced at the formal Hearing of this matter, and which are considered
19 worthy of review by the Board, are as follows from the formal transcript. Except where a
20 quote begins with a “Q” denoting that counsel is asking the witness a question, all
21 testimony presented herein is that of Dr. Chen. A number at the beginning of a line
22 denotes the corresponding line number the on the page of the transcript where the quote is
23 found. All emphasis on the font of the typed testimony (italics and underlines) has been
24 supplied by the undersigned hearing officer for the Board’s assistance in pointing out
25 particularly significant testimony.

26 ///

27 ///

28 ///

1 Direct Examination of Dr. Chen by Ms. Bradley, Counsel for the IC

2

3 Page 47 ("P.47")

12 Q. Dr. Chen, what is your overall opinion regarding Dr. Okeke's care of Patient A?

14 *I felt there were some areas that fell below the standard of care, especially*
5 *regarding the thoroughness of documentation. When I was reviewing it, I did have some*
6 *difficulty, kind of, deciphering his medical decision-making.*

19 Q. When you say documentation, what do you mean by that?

21 *Just from looking at the progress notes, it was really hard for me to get a good*
7 *grasp of her symptomatology. It was difficult to see how severe her symptoms were at*
8 *what specific time. There were medication changes that I couldn't decipher the*
9 *justification for. And I just felt those areas were lacking.*

10 P.48

3 Q. Okay. I think there's some conversation -- well, some use by Dr. Okeke of
11 template material. What is template material?

6 *In the electronic medical records, there is a way to kind of expedite your notes*
12 *because documentation can be rather burdensome. So there are specific templates that you*
13 *can use that you can kind of set up your notes, so they are similar from patient to patient,*
14 *visit to visit, and it helps guide you or remember what to put in the note that might be*
15 *helpful.*

13 Q. Did you note Dr. Okeke's use of template material in notes?

15 *There was definitely a template that was used, and my concern was sometimes*
16 *information from one note to the other wasn't really changed, or it really just remained the*
17 *same. It didn't provide any updates, in my opinion, how she was doing in the interim from*
18 *visit to visit.*

21 Q. *So it sounds like what you're saying is there may have been a note made at one*
18 *visit, but then that note didn't get changed the next time?*

24 Yes. I would say so.

25 Q. So that's a pitfall for electronic records?

20 P.49

21 1 For sure.

22 2 Q. It's trying to help us, but it can fill in the same things?

23 4 Yes, unfortunately.

24 Page 53

8. *It's not always necessary to write a medication, but usually it's mentioned*
25 *somewhere in the note.*

18. *I feel that it could have been helpful to understand why each of these medications*
26 *were prescribed.*

27 ///

28

1 P.55
2 2 Yes. *It's hard for me to tell upon my first review whether the treatment medications*
3 *was what she was already on or what she's starting. I imagine it's what she was already*
4 *on, but I can't tell if there were any additional medications or not.*

4 P.56
5 2 Q. So you're comparing it with NSBME 0050, and that visit is dated September 11, 2017;
6 is that correct?
7 4 That's correct.
8 5 Q. *And you're saying the chief complaint looks like there's a lot of template material*
9 *copied over, right?*
10 8 Yes. *I think it's the same for the next visit as well.*
11 10 Q. *If we keep going to NSBME 0055, October 9, 2017, you're saying that's the same*
12 *template?*
13 12 Yes.
14 13 Q. *And does that continue like that?*
15 14 I think it does. *On the 11/6 visit, the 12/4 visit as well.*

11 P.57
12 8 ... I'm trying to look back at my previous notes that I had written when I was first
13 reviewing. *There were just a bunch of changes or additions of medications that didn't really have*
14 *a rationale behind that.*

14 P.58
15 1 I guess if there were complaints that they were still not feeling any efficacy from that dose,
16 I would, of course, gauge what symptoms they're still struggling with and increase or decrease
17 based on their answer.
18 6 Q. Would that be documented in your notes for that patient?
19 8 It would be.
20 9 Q. *So you would document a symptom that it's not improving, and that's your reason for*
21 *change?*
22 11 Correct.
23 24 Q. *Did you see in Dr. Okeke's records that the patient's medications were increased at*
24 *times?*

21 P.59
22 1 Yes, I did.
23 2 Q. *And did you see that they were decreased at times?*
24 4 Yes, I did.
25 5 Q. *Did you see that rationale documented in the records?*
26 7 I don't think always, no.
27 8 Q. *Sometimes?*
28 9 Yes, possibly.
10 Q. *But it sounds like not to the level that you would expect?*
11 12 Right.
12 Q. *Why is it so important to have this documentation in the records?*
13 15 I feel like it is just basic care. I mean, if there's a continuity of care, if they're switching
14 providers or someone needs to read the notes, then it's easy to clearly see what's been going on with
15 the treatment, throughout the treatment.

1 20 Q. How many patients do you normally see in your practice?
2 22 Probably 40 patients a week or more.
3 23 Q. So one of the reasons for good documentation is it helps you remember where the
4 patient is at?
5 25 For sure, yes.

6 P.60
7 1 Q. Because you can't remember every individual one?
8 3 Yes.
9 4 Q. Do you have other people who work with you in your practice?
10 6 I do.
11 7 Q. So they may also see your patients?
12 8 Yes.
13 9 Q. So it would be helpful for them to know what's going on?
14 11 Right.
15 12 *Q. So you had concerns, I think you said, regarding the documentation, regarding the*
16 *changes, increase and decrease. What about changes in medication? How does that work?*
17 17 *I would prefer seeing that documentation and reasoning why you would switch from one*
18 *medication to the next just to kind of get a better idea of the thought process that went behind the*
19 *medication changes.*

20 P.65
21 21 Q. So when you have a patient that has a history of substance abuse and needs medication
22 to help them, what does that mean to you as a clinician?
23 24 It definitely is a little bit of a red flag. I think you have to be a little bit more diligent to
24 make sure there are no diversion or abuse of these medications. We, at my clinic, have a controlled
25 substance agreement where they sign it. There's certain things that we request, like random drug
26 screens or any other lab work. If they want to get their prescription filled, they have to sign our
27 agreement.

28 P.66
29 8 Q. You have an agreement. Random drug screens. Do you also check the PMP --
30 12 Yes. That is mandatory.
31 13 Q. Mandatory?
32 14 Yes.
33 15 Q. When you say mandatory, what does that?
34 16 We must check their PMP when there is initiation of Schedule 2, or unscheduled
35 prescription, and I believe every three months during treatment as well.
36 20 Q. Okay. Every three months. So every three months that you continue to see the
37 patient, you have to check --
38 23 Yes.

39 P.67
40 20 *So in my opinion, I feel like baseline labs are very helpful just to kind of establish what the*
41 *baseline is, especially when they are taking medications that can have metabolic effects like the*
42 *anti-psychotics and to rule out any other medical issues that could contribute to symptoms, like a*
43 *thyroid issue or other hormonal imbalance. So it's just a good practice to get lab work done when*
44 *you can to establish a baseline.*

1 P.68
2 3 Q. How often would you order lab work?
3 4 In my practice, I try to get lab work done during the initial evaluation. If the patient says
4 they've seen a primary care, I'll try to request records, so I have it in my own chart.
5 8 Q. Did you see evidence then of Dr. Okeke ordering baseline or routine lab work or
6 conditioning?
7 10 I do not recall seeing any lab results in the chart.
8 12 Q. So your opinion, would that be failure to follow the standard of care?
9 14 I would say yes.
10 19 Q. Did you have concern regarding Dr. Okeke's monitoring of the potential medical
11 interactions for these drugs?
12 22 I did, just because of the dosages and how it can be, I guess, cumulative, the effects of
13 sedation and whatnot and some cognitive dulling.

14 P.69
15 17 Q. What is your opinion regarding Dr. Okeke's use of the Nevada Prescription Monitoring
16 Program for Patient A?
17 20 I don't think I can remember seeing he checked the PMP or not. Once you check the PMP,
18 it will log your patient request history, and I didn't remember seeing that.
19 24 Q. So based on your recollection, he didn't check the PMP for the patient?

20 P.70
21 1 I don't think so.
22 2 Q. Just so we're clear, I think earlier you said something about a law that requires the PMP
23 to be checked. Do you remember when that law went into effect?
24 7 I don't remember.
25 8 Q. Would it be helpful if I said it might have been 2017?
26 10 Yes.
27 11 Q. I think, at least the notes that I read, show the concern maybe wasn't in the initial visits
28 with her, but in 2018, he should have been checking -- So if I help you with remembering the status
of the law change, would it be at least part of the treatment? Maybe he didn't have to look at the
PMP, but at least at some point during the treatment, if he hasn't, he would have had to have?
21 21 Yes.
22 22 Q. As of May 2019, was it required to look at the PMP?
23 24 Yes.
24 25 Q. So he saw the patient through May of 2019. He should have been looking at the PMP
25 at that time frame, at least?
26 3 Yes.

27 P.76
28 18 ... And so I feel like this is another fault of the template system. It seems like the
current medications may have been mislabeled, and it's a running history of everything that she had
been prescribed before.
23 23 Q. If you look at the treatment plan about halfway through, it says -- it appears that
perhaps there's an error in the record with regards to the gender of the patient. See where it says,
patient was educated on the dangers of alcohol to him, physical health, and his symptoms. Do you
see that?
4 Yes, I see that.

1 P.78
2 1 Q. So let's turn to the next visit, August 14, 2017, and if we go to NSBME 0046. So we
3 have that list of current medications. Is it your understanding those are what she's currently taking,
4 or are you still thinking that's a list of the things she tried?
5 7 Yeah. I believe that's the list of things she's tried.
6 9 Q. Why would you think that?
7 10 Because Adderall is listed four different times at four different doses. If she was taking it
8 all at the same of the recommended dosaging. There are a few different anti-psychotics. So it
9 wouldn't be the practice to be on four different anti-psychotics, but yeah.
10 16 Q. Sounds like this isn't an accurate list then?
11 17 No; not of current medications.
12 18 Q. So then, if we turn to NSBME 0048, we see treatment medications, and that continues
13 to 0049. Are you thinking those are new medications?
14 21 I believe those are the current medications.
15 22 Q. So that's what she's taking today?
16 23 Yes. If you look above in the treatment plan, if we look, same note, patient was encouraged
17 to stay clean from alcohol. Patient was educated on the dangers of alcohol to him.
18 2 Does that appear to be the same note from before?
19 4 Yes.

12 P.82
13 7 Q. And I'm asking Dr. Chen if there were changes made to the treatment plan made for the
14 plaintiff based on her complaint that day?
15 10 From reviewing my notes, I had questions because Adderall was added to the treatment
16 medications without any discussion as to why.
17 19 Q. Okay. You would expect to see discussion about the addition of that?
18 21 Right.
19 22 Q. What kind of discussion?
20 23 Just indicating what it is being used for. Of course it's an ADHD medication. That should
21 be reflected in the updated diagnoses. It also was a little bit of a red flag to me because in that
22 chief complaint section, she had been complaining of anxiety, nervousness. It sounds like --
23 (Continued inaudible) exacerbate these symptoms if prescribed incorrectly, I guess.
24 13 Q. Just so I'm clear. Is Adderall given to people that don't have ADHD?
25 15 There have been some off-label uses to help with mood, I would say, in the elderly or other
26 populations, but there's no actual FDA approval, though.
27 18 Q. So if it's added, you would want to see a discussion somewhere in this record, why it's
28 being added, and also something added to the assessment that supports the diagnosis for doing
29 that?
30 22 Yes. Something like a rule-out, or something to explain why Adderall was added on in
31 light of these symptoms that were reported in the subjective section.

24 P.84
25 9 Q. And if we look at the diagnosis here, what does N-O-S mean?
26 11 It stands for "not otherwise specified," but that terminology has been replaced with the
27 DSM-5.
28 13 Q. So here, we see substance abuse more generic and others we've seen alcohol?
29 15 Right.
30 16 Q. Do you have any concerns about this report at all?
31 18 Just the diagnoses, yeah, since they are accepted in the DSM-5, it should be a little bit
32 more specific.

1 P.86
2 16 Q. Let's keep going. So if we look at NSBME 0085, this is March 6, 2018, and here she's
3 20 Yes.
4 21 Q. *Do you see that the medications were changed based on this conversation?*
5 23 I do.
6 24 Q. *Do you see a medical reason documented for that change?*
7 P.87
8 1 I don't.
9 2 Q. In your practice, if a patient came to you and said, I'd like to increase my medications,
10 what would you do?
11 5 I would ask why do you feel that's necessary. What symptoms would you like to target.
12 Just those basics.
13 8 Q. And would you note those in the records?
14 9 Yes.
15 10 Q. If they didn't have an answer, what would you do?
16 12 I probably would take a look at the overall picture and see if it's necessary or not. Try to
17 figure out a reason they're requesting such a change in medications.
18 16 Q. *Normally, you would say it's not the standard of care to change medications without*
19 *documenting it, it sounds like?*
20 19 Right.
21 20 Q. *And there needs to be a justification for the change?*
22 22 Correct.
23 P.88
24 13 Q. If we move on to April 3rd, 2018, and this is NSBME 0090. * * * Here, it sounds like
25 she's having some anxiety and other symptoms. Do you see changes of medications for the patient
26 in this visit?
27 22 The Trazodone was increased back up to 150 milligrams.
28 24 Q. And that was from 50, it looks like?
29 25 A hundred.
30 P.89
31 1 Q. No. A hundred. Is that a significant increase?
32 3 Not in my opinion, no.
33 4 Q. *Would you expect, though, to see that documented, the reason for changing it?*
34 6 Yes.
35 7 Q. *Do you see that documented here?*
36 8 No.
37 9 Q. I suppose we see the patient's complaints, but is that enough to document a change, just
38 the patient's?
39 11 I just don't see it mentioning anything about sleep.
40 13 Q. And that's what you would expect to see to increase that?
41 15 Right.
42 20 Q. What do you see happened with regards to her medication on this visit?
43 22 Her Valium was increased to 7.5 milligrams twice per day.
44 24 Q. Okay. 7.5?
45 25 Yes.

1 P.90
2 1 Q. And is there documentation for the reasons for that?
3 3 It did state that she had been taking this same dose at 5 milligrams twice a day for over 10
4 years.
5 5 Q. So it was increased, but it hadn't been that before?
6 7 *She had been on 5 milligrams twice a day for, it appears, over 10 years, and so now, since*
7 *she was having more anxiety symptoms, I can only imagine that's why it was increased.*
8 11 Q. But you're guessing?
9 12 Yes.
10
11 P.91
12 16 Q. I don't see a change in the multi-axial on Page 0107. Would that be necessary?
13 18 Given her diagnoses, I probably wouldn't have her on an anti-depressant, but I guess we
14 could change her current episode would be depressed instead of manic.
15 21 Q. So it sounds like then the medications aren't probably what you would want prescribed?
16 23 Correct, but --
17 24 Q. But at least there's justification for them?
18 25 There is, but *the only thing would be to change the diagnosis since she's not in a current*
19 *manic episode.*
20
21 P.92
22 3 Q. Okay. That hasn't been updated. What would you expect it to say?
23 5 Bipolar disorder or update it with current episode depressed.
24
25 P.93
26 19 *I think the issue here was that she had a seizure while she was in the hospital, and I feel*
27 *that should be added to her history because there are certain medications that could decrease the*
28 *seizure threshold that she has been prescribed later on.*
29 24 Q. If we look at NSBME 0130, it says no history of seizures there?
30
31 P.94
32 1 Right.
33 2 Q. But that's not accurate anymore?
34 3 Correct.
35
36 P.97
37 19 Q. I would then look at NSBME 0138. This is a visit dated October 19, 2018. I'm sorry.
38 Can we go back to the previous visit, 0135, and I note on that page, *the neurologic still shows no*
39 *history of seizures. Do you see that?*
40 23 Yes.
41 24 Q. So that's still not accurate?
42 25 Correct.
43
44 P.98
45 1 Q. Would you say that might be a use of a template just not being updated?
46 3 Yes. Another pitfall of templates.
47 25 Q. Do you see on Page 0140 under neurologic, *still has no history of seizures?*
48
49 P.99
50 2 Correct.

15 Q. I do note on NSBME 0150 the same error of no seizures is there?
 17 Correct.

2 P.100

3 6 Q. So the Valium was removed. But I still note NSBME 0155 still shows no history of
 seizures?
 8 Correct.
 9 Q. And the multi-axial says current episode manic, 0156. Would that be right?
 11 Probably not after a suicide attempt.
 12 Q. So was there any documentation regarding the Valium other than, I guess, the chief
 6 complaints?
 14 No.
 15 Q. Are there any other concerns that you have of this visit?
 17 So the Adderall was changed to 5 milligrams twice a day. I'm not concerned about that,
 8 but there's still no diagnosis of ADHD.
 9 20 Q. So you were concerned with the continued use of Adderall without medical
 justification?
 10 22 Right.

11 P.101

12 3 ... Looks like the next visit we have with Dr. Okeke is NSBME 0172, and it's a visit
 dated January 25th, 2019. What happened with the patient at this visit?
 13 7 She was not doing too well as far as mood goes and struggling with some sleep issues.
 9 Q. Sounds like she might also have been anxious or tense?
 14 11 Right. Anxiety.
 12 Q. What happened with her treatment plan?
 15 13 Belsomra was started for sleep, and Fanapt was given as samples to see if that would help
 with psychosis or mood stability.
 16 16 Q. Did you feel like this was adequate justification for those changes?
 17 18 A. For the Belsomra, yes.
 19 Q. Did you have other concerns?
 18 20 I didn't see any mention of why the Fanapt was chosen.
 22 Q. Did you tell us what Fanapt is used for?
 19 23 Fanapt is an anti-psychotic, but it can have indication to treat bipolar symptoms.
 25 25 Q. What would you expect to see symptom-wise that would justify it?

20 P.102

21 2 I would probably want to treat any mood instability, any mood swings, hypomanic,
 22 depression. Just help with mood overall. Because there wasn't mention of mood as much as there
 was of anxiety.

23 P.103

24 3 Q. And I see a note that says discuss tapering down Valium, but it doesn't look like Valium
 was prescribed.
 25 6 Yeah. It wasn't in the current treatment medication --

26 ///

27 ///

28

1 P.106

2 11 Q. So then the next visit that we have is NSBME 0200, and *this is dated April 24, 2019.*
3 *And the presenting problem there says client has been distraught since her marriage divorce. This*
4 *is the first time that we've seen the patient was married.*

5 17 Right.

6 18 Q. I think recently it was a boyfriend breakup?

7 19 Right.

8 P.107

9 5 Q. Okay. NSBME 0202 is the same date, April 24, 2019. This is an adult bio-
10 psychosocial assessment. Do you have any concerns regarding this report?

11 10 No. With the diagnoses again, it's not very clear.

12 12 Q. That's on 0204?

13 13 Yes.

14 14 Q. And you're saying that's not clear the multi-axial assessment?

15 16 Yes. *It's just with the bipolar disorders kind of contradicting each other.*

16 18 Q. *Because it says current episode depressed and current episode manic in the same?*

17 20 Yes.

18 21 Q. You wouldn't write it that way?

19 22 I would put a mixed episode or just leave it as a Bipolar Disorder Type 1.

20 P.108

21 16 Q. The next visit looks like NSBME 0205, and it was a visit dated May 9, 2019?

22 18 Yes.

23 19 What happened with the patient on this day?

24 20 This was just a therapy note, so there wasn't much mention of what was going on.

25 22 Q. Okay. I do note, though, if you look under vital signs, there's like in the middle of a
26 paragraph, there's symbols that are hard to read. Do you see those?

27 P.109

28 1 Yes.

29 2 Q. So that would be hard to decipher what's going on there?

30 4 Right.

31 5 Q. And I see the same assessment for the diagnoses that are conflicting, where it says
32 manic and depressed?

33 8 Correct.

34 Cross Examination of Dr. Chen by Mr. Agwara, Counsel for Dr. Okeke

35 P.115

36 1 Q. Okay. Now, moving on. *What recommendations would you make to Dr. Okeke going*
37 *forward based on what you identified as some of the concerns you had? What would you*
38 *recommend that he do different?*

39 5 *I guess my main concern was just the documentation and having a clear understanding of*
40 *the rationale or medical decision-making. I feel it's important if there's another physician looking*
41 *at your notes, it be a little more clear as to why you made changes to the treatment plan.*

42 11 Q. That's your major concern. *Any other concerns?*

1 13 I guess just dealing with the patient population who do have a history of self-injurious
2 behaviors, suicide attempts, substance abuse, I would really want to see more of a holistic
3 approach -- not holistic, but a whole approach as far as getting therapy on board; looking at AA,
4 NA for relapse prevention. Just trying to cover all the bases and provide as much support as she
5 can maintain for recovery, in addition to stabilize her mental health.

6 22 Q. And that would be a judgment call, correct?

7 23 Yes.

8 24 Q. Now, would you agree with me that if another physician looked at your records that
9 they could disagree with some of how you practice --

10 P.116

11 2 Yes, for sure. I'm sure they would.

12 3 Q. Was there anything that you saw in your review that endangered the patient's life?

13 5 I guess my main concern is just all the different medications she was taking and maybe not
14 getting a clear history of the medical prescriptions that she was also on. I know there were times in
15 that one drug screen, I do remember, I believe it was positive for opiates, so kind of wondering that
16 whole picture as far as medical treatment and how that plays into her psychiatric care was a
17 concern.

18 13 Q. I didn't ask about your concern. My question was whether or not you saw something
19 that posed a threat to the patient's life that Dr. Okeke did?

20 16 To answer that, I guess the combination of medications may have posed a threat.

21 18 Q. I do recall you stated in your testimony that the list of medications may be a function of
22 the software, and it maybe listed more medications than the patient was taking?

23 22 Correct.

24 23 Q. So with that in mind, I'll ask you the question one more time. Did you see anything
25 that Dr. Okeke did as a physician that endangered this patient's life? Not your concerns.

26 P. 117

27 2 I'd say no, not from reading the notes, but --

28 3 Q. Thank you.

29 4 Again, those concerns I've already listed.

30 5 Q. Do you know how long Dr. Okeke saw this patient?

31 7 I believe the first evaluation was back in 2014. So the initial psychiatric evaluation was in
32 October of 2013. And then I think she lost treatment for a while, and popped back up in July 2014,
33 and then off and on since then.

34 12 Q. Is there a reason why you started or limited your review and your testimony today,
35 starting from 2017?

36 15 I'm not quite sure.

37 16 Q. You're not sure of the reason, or you're not sure of what?

38 18 I'm not sure why everything started after 2017.

39 20 Q. So that wasn't your decision?

40 21 No.

41 P.119

42 5 Q. You said you see a lot of this with a lot of your colleagues, and you think the people
43 who do this are wrong, or do you think they're making stuff up? What exactly are you trying to
44 say?

45 9 So I guess what I'm saying is, if there isn't much change from visit to visit, I would say
46 there haven't been any changes. The patient reports to be doing well. No suicidal thoughts, no
47 homicidal thoughts. I guess in his notes, it did list a lot of review of symptoms that, you know, it

could be better summarized there were no changes, patient is doing well, instead of all these different symptoms that I don't know were these questions asked or not.

18 Q. *So your concern is not with the similarity of the notes on the three different dates, but with the questions that may or may not have been asked; is that correct?*

22 *I guess that's correct, yes.*

23 Q. Okay. Thank you. Let me ask you this: *Is there a recognized industry-wide standard for sufficiency of justifications for changing prescriptions or increasing or decreasing dosages?*

5 P.120

2 *There's not a standard, but I believe it's good practice to spell out your thinking process.*

4 Q. When is that enough? We went through a lot of records with you, and on many of them, you actually agreed with Dr. Okeke, but on some of them, you said, well, you didn't think that the explanations for why a drug was added or removed was sufficient. That's what I'm asking. Is there a standard for what is considered adequate explanation?

12 I would say with maybe lesser medications that are not controlled substances, it may not be as important, but given the patient's history and there wasn't a diagnosis of ADHD, and then Adderall just popped up on her treatment regimen, that was concerning to me.

18 Q. Why was it concerning to you?

19 Just in light of her other diagnoses that were listed without a clear reason to have the Adderall. It could exacerbate her manic symptoms or anxiety, further worsening her mental state.

23 Q. Would you agree that Adderall is used to treat aggression?

25 It can be off-label.

13 P.121

14 I Q. Is it your testimony that you did not see depression as a diagnosis in this patient's -- in the notes that you reviewed?

15 4 Her main diagnosis was bipolar disorder.

5 Q. I didn't ask about main.

16 6 A person with bipolar disorder, there is depression, and there are periods of mania or hypomania.

17 8 Q. So there was depression, correct?

18 9 But it isn't standard of care to treat bipolar with Adderall.

11 Q. No. I'm just asking. Did this patient suffer from depression or not?

19 13 Yes.

14 Q. *You already testified that sometimes you can use Adderall to treat depression; is that correct?*

20 16 *It would be off-label use.*

21 17 Q. *But acceptable use?*

22 18 *With good reason.*

19 Q. *Is that a yes?*

23 20 *With good reason.*

24 P.122

22 Q. Okay. Now, let me ask you this: Is it your testimony that because the records do not show discussions between Dr. Okeke and the patient that that means there were no such discussions?

26 P.123

27 1 No.

28 2 Q. Okay. You're just saying the records did not reflect some discussions that you would have liked to see; is that correct?

5 Yes.

1 6 Q. Is it your testimony that Dr. Okeke should have run the patient's PMP on every visit?
2 8 Not every visit. The standard is upon initiation of controlled substance, and I would say
every three months during treatment.
3 11 Q. And during your review, did you find that that wasn't the case?
4 13 *I found that wasn't the case just because in that report that, I think Kim Friedman had
requested, it didn't look like Dr. Okeke had requested any during the treatment time, but I could be
mistaken, I just didn't get that information.*
5
6 P.124
7 8 Q. Okay. Now, on how many occasions did you note changes without an explanation? I
mean, if you don't have that number, that's fine.
8 11 I don't have that number, unfortunately, but I had made notes to myself, but there were
definitely, I'd say over 10 times, as a guess.
9 14 Q. 10 out of how many? Would you say the majority of times?
10 16 I would say the majority of times where there were changes, there wasn't a rationale.
11 18 Q. Are you sure?
12 19 Yes.
13 20 Q. Okay. Do you want us to review every single one?
14 22 No.
15 23 Q. I'm okay if you don't know if it's a majority or not, but if you're stating it's a majority --
16 25 I don't know. I don't know. I don't know. I know there was enough times that it was
confusing for me to understand the process he was using.
17
18 P.125
19 3 Q. Okay. That's fine. Now, is it your testimony in the chief complaint section that the
complaints by the patient are not sufficient explanations for changing prescriptions or reducing the
dosage or increasing it?
20 7 There were definitely some notes which highlighted the symptoms that she was
complaining of that did warrant medication changes, but not all of them.
21
22 P.127
23 15 Q. What you're saying is you would not have chosen Adderall to treat the depression?
24 17 Yes. I would not have.
25 18 Q. And why is that?
26 19 Because, of course, bipolar is different than major depression, and with her history of
having, I guess, there was an indication there was psychotic symptoms before, the Adderall could
exacerbate that, and also could exacerbate her anxiety symptoms.
27
28 Closing Argument by counsel for Dr. Okeke
P.139
22 I will give you this much, that with respect to PMP, my client understands and
acknowledges that he probably did not check as often as he should have. He has made a lot of
changes in his practice, and he has now made that a frequent practice to check PMPs.
26 ///
27 ///
28

1 P.140

2 *As I pointed out in the beginning, in my opening statement, he has taken quite a few CEUs*
3 *in terms of recordkeeping and sufficiency of records. And to the extent that some of the records do*
4 *not have adequate notes in regards to the reasons to changing dosages, those have all -- well, I*
5 *shouldn't say they have been changed because you can't change them in the past, but going*
6 *forward, he has adopted new changes, and he's now doing a lot more to explain reasons why he*
7 *would change the dosage or the prescriptions.*

8 Beyond the testimonial evidence and exhibits referred to therein, Exhibit 14 is a
9 collection of articles printed off and contributed to the IC's case by Dr. Chen. While the
10 hearing officer discussed those articles with Dr. Chen on the record, (see below), she did
11 not testify substantively about any of those articles. The hearing officer has reviewed
12 them. In general, the articles are not helpful. Had Dr. Chen testified about them, some of
13 the articles may have been quite helpful, especially to a part of this case that is somewhat
14 troubling to the undersigned hearing officer. In particular, the MSDP Standardized
15 Documentation Training Manual's Psychiatry/Medication Progress Note may have been
16 significant to this case. It appears to give a sound example of best practices (and thus
17 possibly an applicable standard of care) for note-taking for psychiatrists. However, like a
18 couple of the other documents¹ included in Exhibit 14, Dr. Chen did not testify as to
19 whether such practices are the standard of care applicable in this case.

20 FINDINGS AND CONCLUSIONS OF THE HEARING OFFICER

21 1. Malpractice.

22 The Complaint on file alleges that Dr. Okeke malpracticed by committing the acts
23 alleged in paragraphs 2-14 thereof. Specifically, the malpractice is alleged to have
24 occurred when Dr. Okeke: failed to justify the use, increase and decrease, and then
25 subsequent increases in dosages of Patient A's medication; prescribed a combination of
26 controlled substances without documenting the medical justification or rationale; failed to

27
28 ¹ The Flow Chart For The Initial Prescribing Controlled Substances Under AB474 document, and the article
entitled Standard-of-Care Testimony: Best Practices or Reasonable Care? both could have been helpful
evidence had Dr. Chen testified as to whether those items define the standard of care applicable to Dr. Okeke
in light of the allegations in the Complaint.

1 review the PMP report prior to, during, and after the encounters with Patient A; failed to
2 assess Patient A's concurrent medication interactions; failed to assess Patient A for
3 possible drug abuse, drug diversion or any other non-medical related activity; failed to
4 assess Patient A for possible drug screens on a consistent basis, and; failed to diligently
5 monitor potential medication interactions in Patient A's changing treatment plans.

6 The legal definition of malpractice generally applicable here is the failure of a
7 physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily
8 used under similar circumstances. NAC 630.040. That definition requires evidence
9 proving what a physician using the reasonable care, skill, or knowledge ordinarily used
10 under circumstances similar to those under which Dr. Okeke was treating Patient A would
11 have implemented, thus showing that Dr. Okeke failed to use such reasonable care, skill, or
12 knowledge. Put most simply, the IC's evidence must prove that Dr. Okeke's treatment of
13 Patient A fell below the standard of care. It follows that proving just what the standard of
14 care is must be a necessity in order to show that Dr. Okeke fell below that standard.

15 "Standard of care" was mentioned five times in Dr. Chen's testimony. Each of
16 those is reviewed here.

17 The first mention is at page 47 of the transcript. Counsel asked Dr. Chen for her
18 "overall opinion" of Dr. Okeke's treatment of Patient A. Dr. Chen stated that she:

19 felt there were some areas that fell below the standard of care, especially
20 regarding the thoroughness of documentation. When I was reviewing it,
21 I did have some difficulty, kind of, deciphering his medical decision-making.

22 Counsel then asked "When you say documentation, what do you mean by that? Dr.
23 Chen responded that:

24 Just from looking at the progress notes, it was really hard for me to get a
25 good grasp of her symptomatology. It was difficult to see how severe her
26 symptoms were at what specific time. There were medication changes that
27 I couldn't decipher the justification for. And I just felt those areas were
lacking.

28 This testimony is helpful and certainly important in determining facts which are
critical to this case. Although it does not define the applicable standard of care.

1 The second mention of standard of care is at page 68 of the transcript. The
2 following is the series of counsel's questions and Dr. Chen's answers at that point in
3 presentation of the evidence, which begins on page 67 of the transcript:

4 Q. So did you see evidence in your review of the records in this case that Dr.
5 Okeke did the random urine drug screens that you were talking about?

6 A. I believe there were instances where I did see a urine drug screen, yes.

7 Q. Was it as frequent as you think it should have been?

8 A. That's up to the provider. I would say once a year at the very least would be
9 sufficient.

10 Q. Did you see that in this case then?

11 A. It's hard for me to recall the specifics as far as when they were ordered and how
12 frequent. I know there was at least one that I saw.

13 Q. At least one?

14 A. Uh-huh.

15 Q. What about your opinion regarding his ordering a baseline or routine lab work
16 for the patient?

17 A. So in my opinion, I feel like baseline labs are very helpful just to kind of
18 establish what the baseline is, especially when they are taking medications that can
19 have metabolic effects like the anti-psychotics and to rule out any other medical
20 issues that could contribute to symptoms, like a thyroid issue or other hormonal
21 imbalance. So it's just a good practice to get lab work done when you can to
22 establish a baseline.

23 Q. How often would you order lab work?

24 A. In my practice, I try to get lab work done during the initial evaluation. If the
25 patient says they've seen a primary care, I'll try to request records, so I have it in my
26 own chart.

27 Q. Did you see evidence then of Dr. Okeke ordering baseline or routine lab
28 work or conditioning?

 A. I do not recall seeing any lab results in the chart.

 Q. So your opinion, would that be failure to follow the standard of care?

1 A. I would say yes.

2 Q. I think we've talked about the multiple drugs that the patient was taking. Do
3 those have interactions with each other?

4 A. They definitely can.

5 Q. Did you have concern regarding Dr. Okeke's monitoring of the potential
6 medical interactions for these drugs?

7 A. I did, just because of the dosages and how it can be, I guess, cumulative, the
8 effects of sedation and whatnot and some cognitive dulling.

9 Q. When you say dosages, what do you mean? High dosages?

10 A. High dosages and just the different medications that have that same side effects.
11 So it's kind of a synergistic effect, I would say.

12 Q. You mean two medicines with the same kind of effect, like a sedating effect?

13 A. True. Yes.

14 Q. *And you would want to note that?*

15 A. *Yes. Or at least discuss it with the patient.* It seems like she had a high
16 tolerance to some of these medications, but there might be counteracting others, or
17 you know, causing different effects canceling each other out.

18 Q. Did you see discussion about that in Dr. Okeke's records regarding this patient?

19 A. No.

20 This testimony is critical in that Dr. Chen answers the direct question of whether
21 Dr. Okeke failed to follow the standard of care. However, some of Dr. Chen's surrounding
22 testimony can leave questions as to whether she is testifying as to standard of care, or
23 simply her own opinion of best practices, which can differ in that Dr. Chen's practices may
24 be higher than the standard of care. And again, the standard of care is not set out here.

25 The third mention of standard of care came up at page 72 of the transcript in a legal
26 argument between counsel about whether hearsay evidence was admissible. This mention
27 of the standard did not address any substantive matter in the case.
28

1 The next/fourth mention of the standard occurs at page 73 and arose in the context
2 of Dr. Chen explaining how she compiled the list of documents the IC presented as Exhibit
3 14. Her testimony was as follows:

4 *As with my peer-review, obviously, I kind of have my own opinion, and*
5 *then I look for things on the internet that could support my opinion. So*
6 *that's where these came from. There are guidelines as well for my own*
7 *research as to what other people may be doing as far as standard of care.*

8 HEARING OFFICER WOODMAN: How does anyone know that what
9 you are relying on here -- if you're doing an internet search, how do we
10 know what you're using and relying on is reliable, is credible, and that it
11 should be a part of the basis of your opinion?

12 THE WITNESS: I definitely see where you're coming from. *Like I said,*
13 *I formulate my own opinion first, and then I try to find supporting evidence*
14 *to put into my review as the Board wants to review materials. So they can*
15 *see my train of thought and see how others can review these same issues,*
16 *I guess.*

17 HEARING OFFICER WOODMAN: In the list, which I see 10 articles
18 listed, correct?

19 THE WITNESS: There are certain articles that I was able to print out.
20 I guess, for sake of paper, there are these practice guidelines. 2 and 3
21 are exhaustive --

22 HEARING OFFICER WOODMAN: I understand that, but there's a list
23 of 10 items that you used for your peer-reviewed materials?

24 THE WITNESS: Yes.

25 HEARING OFFICER WOODMAN: As the doctor that your CV tells us
26 that you are, is anything -- are any of these items in 1 through 10, did you
27 have any concerns with the reliability or credibility of anything listed
28 there in 1 through 10 in your professional medical opinion?

THE WITNESS: *I mean, I believe there are some that I would really take*
with a grain of salt, but I think it's helpful. I didn't really understand the
legal process myself, so I thought it was responsible of me to look at how
the law and medicine integrate together.

HEARING OFFICER WOODMAN: So anything in that list, 1 to 10, that
you have any concerns with, if any of that was being reviewed by the Board
itself, the state Board?

1 THE WITNESS: I don't think I would have any concerns.

2
3 This conversation gives some pause to the hearing officer. As mentioned, while
4 Dr. Chen's CV proves she is a very accomplished medical professional, and her
5 appearance and testimony at the hearing did not detract therefrom, it is not clear whether
6 some of her testimony was based on her own perception of best practices, as opposed to
7 the actual standard of care. And again, from her demeanor at the hearing, this hearing
8 officer would not be surprised in the slightest to discover that Dr. Chen's opinions on best
9 practices may well exceed the standard. In fairness to Dr. Okeke, the standard of care
10 against which he is measured must be clear. And if Dr. Chen is holding Dr. Okeke to her
11 own best practices standards, and those are higher than the actual standard of care due a
12 patient from her physician, then we are using the wrong yardstick to measure.

13 The fifth and final mention of the standard appears at page 121 of the transcript.
14 This was Dr. Chen's testimony on cross-examination by Dr. Okeke's counsel (beginning at
15 page 119):

16 Q. Okay. Thank you. Let me ask you this: Is there a recognized industry-wide
17 standard for sufficiency of justifications for changing prescriptions or increasing
18 or decreasing dosages?

19 A. There's not a standard, but I believe it's good practice to spell out your
20 thinking process.

21 Q. When is that enough? We went through a lot of records with you, and on
22 many of them, you actually agreed with Dr. Okeke, but on some of them, you
23 said, well, you didn't think that the explanations for why a drug was added or
24 removed was sufficient. That's what I'm asking. Is there a standard for what
25 is considered adequate explanation?

26 A. I would say with maybe lesser medications that are not controlled substances,
27 it may not be as important, but given the patient's history and there wasn't a
28 diagnosis of ADHD, and then Adderall just popped up on her treatment regimen,
that was concerning to me.

Q. Why was it concerning to you?

1 A. Just in light of her other diagnoses that were listed without a clear reason to
2 have the Adderall. It could exacerbate her manic symptoms or anxiety, further
3 worsening her mental state.

4 Q. Would you agree that Adderall is used to treat aggression?

5 A. It can be off-label.

6 Q. Is it your testimony that you did not see depression as a diagnosis in this
7 patient's -- in the notes that you reviewed?

8 A. Her main diagnosis was bipolar disorder.

9 Q. I didn't ask about main.

10 A. A person with bipolar disorder, there is depression, and there are periods
11 of mania or hypomania.

12 Q. So there was depression, correct?

13 A. But it isn't standard of care to treat bipolar with Adderall.

14 Q. No. I'm just asking. Did this patient suffer from depression or not?

15 A. Yes.

16 Q. You already testified that sometimes you can use Adderall to treat
17 depression; is that correct?

18 A. It would be off-label use.

19 Q. But acceptable use?

20 A. With good reason.

21 Q. Is that a yes?

22 A. With good reason.

23
24
25 Here we have the IC's expert witness testifying that: i) there is no standard of care
26 with regard to "justifications for changing prescriptions or increasing or decreasing
27 dosages" (thus nullifying the allegations in subparagraph "1)" of paragraph 18 of the
28

1 Complaint); ii) it is not standard of care to treat bipolar with Adderall, and; iii) with good
2 reason, Adderall could be used to treat depression, off label.

3 This testimonial exchange highlights the hearing officer's concerns about some of
4 the malpractice allegations in this case. While a generic legal definition of what the
5 standard of care is can be found in the NAC, a psychiatry-specific definition of that
6 standard is not within the record of this case. The hearing officer is left not knowing just
7 what is "the reasonable care, skill, or knowledge ordinarily used under similar
8 circumstances" to those of Dr. Okeke. However, there are other indications that are
9 helpful, as set out below.

10 We do know from Dr. Chen that: she felt generally that Dr. Okeke fell below the
11 standard of care regarding the thoroughness of documentation; she did not recall seeing
12 any lab results in the chart, nor did she see evidence of Dr. Okeke ordering baseline or
13 routine lab work or conditioning, and accordingly she "would say" that Dr. Okeke fell
14 below the standard in this regard, and; treating bipolar with Adderall is not within the
15 standard of care. But to be clear, according to the record, the hearing officer must either
16 take Dr. Chen at her word on what she said did not meet the standard, or must find that,
17 because the standard was not established, Dr. Okeke cannot be found to have breached it.

18 All of this confusion aside, and as alluded to above, there is yet another legal hurdle
19 for Dr. Okeke to overcome in the question of whether he committed malpractice. The
20 PMP is mandated to be reviewed regularly. Dr. Okeke's counsel acknowledges that this
21 was not done.² Because of its import, and the resulting legal requirement to review it on a
22 continuing basis, the failure to do so *must be* a failure to use the reasonable care, skill, or
23 knowledge ordinarily used under similar circumstances. In this regard, Dr. Okeke did fall
24 below the standard, and thus did commit malpractice. Hence, this hearing officer finds that
25 Count I of the Complaint is proven.

26
27 ² See Factual Evidence above, where Dr. Okeke's counsel stated that:

28 I will give you this much, that with respect to PMP, my client understands and
acknowledges that he probably did not check as often as he should have. He has made a lot of
changes in his practice, and he has now made that a frequent practice to check PMPs.

1 **2. Failure to Maintain Proper Medical Records.**

2 NRS 630.3062(1)(a) states that the failure to maintain timely, legible, accurate and
3 complete medical records relating to the diagnosis, treatment, and care of a patient is
4 grounds for initiating disciplinary action against a licensee. While there are a number of
5 questions in the evidence of this case as to if and how Dr. Okeke malpracticed, the record
6 is quite clear that he did not keep adequate records. His counsel stated:

7
8 As I pointed out in the beginning, in my opening statement, he has taken quite a few CEUs
9 in terms of recordkeeping and sufficiency of records. And to the extent that some of the
10 records do not have adequate notes in regards to the reasons to changing dosages, those
11 have all -- well, I shouldn't say they have been changed because you can't change them in
12 the past, but going forward, he has adopted new changes, and he's now doing a lot more to
13 explain reasons why he would change the dosage or the prescriptions.

14 Accordingly, it cannot reasonably be challenged that Dr. Okeke failed with regard
15 to his recordkeeping. The fact that he is working to improve his records practice is no
16 doubt an important precipitate of this proceeding. Count II of the Complaint is thus
17 proven.

18 Finally, with regard to credibility of witnesses, this HO found the IC's two
19 witnesses to be completely credible at all times. While Dr. Chen will -- assuming she
20 continues to testify as an expert -- learn more about the process of establishing a foundation
21 of and definition for the applicable standard, her presentation left the hearing officer no
22 question as to whether she was credible, and that she had no inappropriate motive in her
23 participation in the case. Accordingly, the hearing officer finds no reason to question the
24 testimony as presented. The IC has thus proven its two Counts alleged in the Complaint.

25 Respectfully submitted this 16th day of November, 2022.

26
27 

28 Charles B. Woodman, Hearing Officer

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint

Case No. 22-22461-1

Against:

FILED

MATTHEW OBIM OKEKE, M.D.,

MAR 03 2023

Respondent.

NEVADA STATE BOARD OF
MEDICAL EXAMINERS

By: VC

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Sarah A. Bradley, J.D., MBA, Deputy Executive Director for the Board and attorney for the IC, and Matthew Obim Okeke, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Liborius Agwara, Esq., of the Law Offices of Libo Agwara, Ltd., hereby enter into this Settlement Agreement (Agreement) based on the following:¹

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active-probation status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on September 6, 2013 (License No. 14957).

2. On September 13, 2022, in Case No. 22-22461-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges one (1) violation of NRS 630.306(1)(1) Failure to Report Criminal Action. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

¹ All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

1 3. Respondent was properly served with a copy of this Complaint, has reviewed and
2 understands this Complaint, and has had the opportunity to consult with competent counsel
3 concerning the nature and significance of this Complaint.

4 4. Respondent is hereby advised of his rights regarding this administrative matter, and
5 of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has
6 certain rights in this administrative matter as set out by the United States Constitution, the Nevada
7 Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is
8 contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is
9 contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on
10 the allegations in the Complaint, the right to representation by counsel, at his own expense, in the
11 preparation and presentation of his defense, the right to confront and cross-examine the witnesses
12 and evidence against him, the right to written findings of fact, conclusions of law and order
13 reflecting the final decision of the Board, and the right to judicial review of the Board's order, if
14 the decision is adverse to him.

15 5. Respondent understands that, under the Board's charge to protect the public by
16 regulating the practice of medicine, the Board may take disciplinary action against Respondent's
17 license, including license probation, license suspension, license revocation and imposition of
18 administrative fines, as well as any other reasonable requirement or limitation, if the Board
19 concludes that Respondent violated one or more provisions of the Medical Practice Act.

20 6. Respondent understands and agrees that this Agreement, by and between
21 Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the
22 Board for consideration in open session at a duly noticed and scheduled meeting. Respondent
23 understands that the IC shall advocate for the Board's approval of this Agreement, but that the
24 Board has the right to decide in its own discretion whether or not to approve this Agreement.
25 Respondent further understands and agrees that if the Board approves this Agreement, then the
26 terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

27 ///

28 ///

1 **B. TERMS & CONDITIONS**

2 **NOW, THEREFORE**, in order to resolve the matters addressed herein, i.e., the matters
3 with regard to the Complaint, Respondent and the IC hereby agree to the following terms and
4 conditions:

5 1. **Jurisdiction.** Respondent is, and at all times relevant to the Complaint has been, a
6 physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set
7 forth in the Medical Practice Act.

8 2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement.**
9 Respondent acknowledges he is represented by counsel, and wishes to resolve the matters
10 addressed herein with said counsel. Respondent agrees that if representation by counsel in this
11 matter materially changes prior to entering into this Agreement and for the duration of this
12 Agreement, that counsel for the IC will be timely notified of the material change. Respondent
13 agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to
14 have a full consultation with and upon the advice of legal counsel.

15 3. **Waiver of Rights.** In connection with this Agreement, and the associated terms
16 and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection
17 with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives
18 all rights arising under the United States Constitution, the Nevada Constitution, the Medical
19 Practice Act, the OML, the APA, and any other legal rights that may be available to him or that
20 may apply to him in connection with the administrative proceedings resulting from the Complaint
21 filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in
22 the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board.
23 Respondent agrees to settle and resolve the allegations of the Complaint as set out by this
24 Agreement, without a hearing or any further proceedings and without the right to judicial review.

25 4. **Acknowledgement of Reasonable Basis to Proceed.** As of the time of entering
26 into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent
27 acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in
28 conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

1 Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit
2 and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential
3 subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has
4 evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the
5 Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent
6 waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to
7 effectuate this Agreement.

8 5. Consent to Entry of Order. In order to resolve this Complaint pending against
9 Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent
10 engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act.
11 Accordingly, the following terms and conditions are hereby agreed upon:

12 a. Respondent admits to Count I, one (1) violation of NRS 630.306(1)(I),
13 Failure to Report Criminal Action.

14 b. Respondent will pay the costs and expenses incurred in the investigation
15 and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance,
16 adoption and approval of this Agreement, in the amount of one thousand three hundred three
17 dollars and ninety-two cents (\$1,303.92).

18 c. This Agreement shall be reported to the appropriate entities and parties as
19 required by law, including, but not limited to, the National Practitioner Data Bank.

20 d. Respondent shall receive a Public Letter of Reprimand.

21 e. The remaining counts of the Complaint, and any other claims arising from
22 the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

23 6. Release from Liability. In execution of this Agreement, Respondent understands
24 and agrees that the State of Nevada, the Board, and each of its members, staff, counsel,
25 investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents
26 are immune from civil liability for any decision or action taken in good faith in response to
27 information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of
28 Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers,

1 committees, panels, hearing officers, consultants and agents from any and all manner of actions,
2 causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and
3 unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against
4 any or all of the persons, government agencies or entities named in this paragraph arising out of,
5 or by reason of, this investigation, this Agreement or the administration of the case referenced
6 herein.

7 7. **Procedure for Adoption of Agreement.** The IC and counsel for the IC shall
8 recommend approval and adoption of the terms and conditions of this Agreement by the Board in
9 resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of
10 this Agreement, counsel for the IC may communicate directly with the Board staff and the
11 adjudicating members of the Board.

12 Respondent acknowledges that such contacts and communications may be made or
13 conducted ex-parte, without notice or opportunity to be heard on his part until the public Board
14 meeting where this Agreement is discussed, and that such contacts and communications may
15 include, but may not be limited to, matters concerning this Agreement, the Complaint and any and
16 all information of every nature whatsoever related to this matter. The IC and its counsel agree that
17 Respondent and/or Counsel for the Respondent may appear at the Board meeting where this
18 Agreement is discussed and, if requested, respond to any questions that may be addressed to the
19 IC or the IC's counsel.

20 8. **Effect of Acceptance of Agreement by Board.** In the event the Board accepts,
21 approves and adopts this Agreement, the Board shall issue a final order, making this Agreement
22 an order of the Board, and, pending full compliance with the terms herein, the case shall be closed
23 and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

24 9. **Effect of Rejection of Agreement by Board.** In the event the Board does not
25 accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and
26 effect except as to the following agreement regarding adjudications: (1) Respondent agrees that,
27 notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement
28 and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this

1 Agreement shall disqualify any member of the adjudicating panel of the Board from considering
2 this Complaint and from participating in disciplinary proceedings against Respondent, including
3 adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any
4 such member absent evidence of bad faith.

5 10. Binding Effect. If approved by the Board, Respondent understands that this
6 Agreement is a binding and enforceable contract upon Respondent and the Board.

7 11. Forum Selection Clause. The parties agree that in the event either party is
8 required to seek enforcement of this Agreement in district court, the party's consent to such
9 jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court,
10 State of Nevada, Washoe County.

11 12. Attorneys' Fees and Costs. The parties agree that in the event an action is
12 commenced in district court to enforce any provision of this Agreement, the prevailing party shall
13 be entitled to recover reasonable attorneys' fees and costs.

14 13. Failure to Comply with Terms. Should Respondent fail to comply with any term
15 or condition of this Agreement once the Agreement has been accepted, approved and adopted by
16 the Board, the IC shall be authorized to immediately suspend Respondent's license to practice
17 medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed.
18 Failure to comply with the terms of this Agreement, including failure to pay any fines, costs,
19 expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may
20 result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

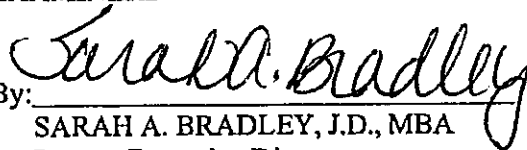
28 ///

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 31st day of January, 2023. DATED this 30th day of January, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL
EXAMINERS

LAW OFFICES OF LIBO AGWARA, LTD.

By: 

SARAH A. BRADLEY, J.D., MBA
Deputy Executive Director
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: bradleys@medboard.nv.gov
Attorney for the Investigative Committee

By: 

LIBORIUS AGWARA, ESQ.
2785 E. Desert Inn Rd., Ste. 280
Las Vegas, NV 89121
Tel: (702) 385-4800
Email: libolaw@yahoo.com
Attorney for Respondent

DATED this 29th day of Jan., 2023.

By: 

MATTHEW OBIM OKEKE, M.D.,
Nevada License No. 14957
Respondent

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 22-22461-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 3rd day of March, 2023.

DATED this 3rd day of March, 2023.

NEVADA STATE BOARD OF MEDICAL
EXAMINERS

By: _____


AURY NAGY, M.D.
Board President

Exhibit 5

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case Nos. 19-013-CS-S

Petitioner,

v.

MEMORANDUM OF
COSTS AND FEES

MATTHEW OKEKE, M.D.,
Certificate of Registration No. CS10935,

Respondents.

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigation Time (Investigator Dena McClish)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
2018-2019	Investigation	20 (Estimated)	\$50.00	\$1,000.00
Subtotal (Investigation):				\$1,000.00

Attorney Time (Gregory Zunino)

<u>Date(s)</u>	<u>Description</u>	<u>Hours</u>	<u>Rate</u>	<u>Amount</u>
2/22/2023	Review Report, Review Statutes and Regulations, Draft Accusation	4.5	\$60.00	\$270.00
9/18/23	Review Report, Public Records, Draft Amended Accusation	2.5	\$60.00	\$150.00
11/14/23	Draft Proposed Stipulation	1.25	\$60.00	\$75.00
11/21/23	Draft Amended Stipulation	.5	\$60.00	\$30.00
12/11/23	Email to Opposing Counsel	.25	\$60.00	\$15.00
1/11/2024	Assemble Exhibits	2.25	\$60.00	\$135.00
1/17/2024	Hearing (Estimated)	.75	\$60.00	\$45.00

Subtotal (Attorney Time) \$720.00

Administrative Costs

<u>Date(s)</u>	<u>Description</u>	<u>Amount</u>
7/20/2023	Postage	\$11.56
9/29/2023	Postage	\$11.56
12/14/2023	Postage	\$11.56
Subtotal (Administrative Costs)		\$34.68
Total Costs and Fees:		\$1,754.68

I, Gregory L. Zunino, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of costs and reasonable attorney's fees incurred by the Board in the above-entitled action.

DATED this 11th day of January 2024.

/s/ Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy

18A

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – January 18, 2024

EXPLANATION – Matter in *italics* is new; matter in brackets ~~[omitted material]~~ is material to be omitted. and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.0727

A REGULATION relating to pharmacy; ensuring that proper and adequate safeguards exist to allow registered nurses to dispense dangerous drugs.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

NAC 639.XXX A registered nurse who wishes to dispense dangerous drugs when engaged in the performance of any public health program approved by the Board must:

1. Apply for a certificate of registration from the Board;
2. Comply with all requirements for a dispensing practitioner; and .
3. May only dispense a dangerous drug under a protocol approved by the Board created to serve the health needs of an entire political subdivision by reducing the incidence and prevalence of a disease, subset of disease or a medical event approved by the Board or the Department of Behavioral and Public Health (DBPH). Protocols approved by DBPH are considered approved by the Board.
4. A registered nurse issued a certificate of registration pursuant to subsection 1 may not;
 - a. Prescribe a dangerous drug.
 - b. Utilize dispensing technician.
 - c. Operate a remote site.
 - d. Dispense a controlled substance.
 - e. Compound a prescription product.

NAC 639.010 Definitions. (NRS 639.070, 639.0727) As used in this chapter, unless the context otherwise requires:

1. "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.
2. "Board" means the State Board of Pharmacy.
3. "Controlled substance" has the meaning ascribed to it in NRS 0.031.
4. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.
5. "Direct supervision" means the direction given by a supervising pharmacist or dispensing practitioner who is:
 - (a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and
 - (b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.
6. "Dispensing practitioner" means:

- (a) A practitioner to whom the Board has issued a certificate of registration pursuant to NAC 639.742 to dispense controlled substances or dangerous drugs, or both, for human consumption; or
- (b) A licensed veterinarian to whom the Board has issued a certificate of registration pursuant to NAC 639.7423 to dispense controlled substances or dangerous drugs, or both, not for human consumption.
- (c) A registered nurse to whom the Board has issued a certificate of registration pursuant to NAC 639.XXX to dispense dangerous drugs when engaged in the performance of any public health program approved by the Board;

NAC 639.220 Schedule of fees; penalty for late renewal; exemptions from certain fees. (NRS 453.221, 639.070, 639.0727, 639.170)

1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist.....	Actual cost of the
examination For the investigation or registration of an applicant as a registered pharmacist.	\$200
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....	200
For the investigation or issuance of an original license to conduct a retail pharmacy.	500
For the biennial renewal of a license to conduct a retail pharmacy.....	

	500
For the investigation or issuance of an original license to conduct an institutional pharmacy.	500
For the biennial renewal of a license to conduct an institutional pharmacy	500
For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution.	500
For the biennial renewal of a license to conduct a pharmacy in a correctional institution.	500
For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to <u>chapter 449</u> of NRS.....	500
For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to <u>chapter 449</u> of NRS.....	500
For the issuance of an original or duplicate certificate of registration as a registered pharmacist.	50
For the biennial renewal of registration as a registered pharmacist.....	200
For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse).	100
For the initial registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing technician in training.	50
For the biennial renewal of registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing technician in training.....	50
For the investigation or registration of an intern pharmacist.....	40
For the biennial renewal of registration as an intern pharmacist.....	40
For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....	80
For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....	80
For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances.	200
For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances.	200
For authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances.	80
For the biennial renewal of authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances.	80
For the investigation or issuance of an original license to engage in business as an authorized warehouse or medical products provider.	500

For the biennial renewal of a license to engage in business as an authorized warehouse or medical products provider.....	500
For the investigation or issuance of an original license to a manufacturer or wholesaler.	1,000
For the biennial renewal of a license for a manufacturer or wholesaler.....	1,000
For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.	50
For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption, or a registered nurse when the nurse is engaged in the performance of any public health program approved by the Board	300
For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption, or a registered nurse when the nurse is engaged in the performance of any public health program approved by the Board	300
For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.	150
For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.	150
For the investigation or issuance of an original license for an automated drug dispensing system.	500
For the biennial renewal of a license for an automated drug dispensing system.	500
For the investigation or issuance of an original	

license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....	250
For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.	250

Supporting Statutes and Regulations.

NRS 639.0065 “Dispense” defined.

1. “Dispense” means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, 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.

(Added to NRS by [1995, 287](#))

NRS 639.074 Regulations: Registered nurses who participate in certain public health programs or provide certain mental health services. The Board may adopt such regulations as may be necessary to ensure that proper and adequate safeguards, including dispensing procedures, are followed to protect a registered nurse who:

1. Participates in a public health program approved by the Board; or
2. Provides mental health services to a patient at a rural clinic that is designated as such pursuant to [NRS 433.233](#) and that is operated by the Division of Public and Behavioral Health of the Department of Health and Human Services. (Added to NRS by [1977, 939](#); A [2003, 1018](#))

NRS 454.00973 “Public health program” defined. “Public health program” means a program of the government which is:

1. Administered by the officers and agents of:
 - (a) The Division of Public and Behavioral Health of the Department of Health and Human Services; or
 - (b) The local boards of health; and
2. Created to serve the health needs of an entire political subdivision by reducing the incidence and prevalence of a disease, subset of disease or a medical event.

(Added to NRS by [1991, 1955](#); A [1995, 556](#))

NRS 454.215 Authority to dispense dangerous drug. A dangerous drug may be dispensed by:

1. A registered pharmacist upon the legal prescription from a practitioner or to a pharmacy in a correctional institution upon the written order of the prescribing practitioner in charge;
2. A pharmacy in a correctional institution, in case of emergency, upon a written order signed by the chief medical officer;
3. A practitioner, or a physician assistant licensed pursuant to chapter 630 or 633 of NRS if authorized by the Board;
4. A registered nurse, when the nurse is engaged in the performance of any public health program approved by the Board;
5. A medical intern in the course of his or her internship;
6. An advanced practice registered nurse who holds a certificate from the State Board of Pharmacy permitting him or her to dispense dangerous drugs;
7. A registered nurse employed at an institution of the Department of Corrections to an offender in that institution;
8. A registered pharmacist from an institutional pharmacy pursuant to regulations adopted by the Board; or
9. A registered nurse to a patient at a rural clinic that is designated as such pursuant to NRS 433.233 and that is operated by the Division of Public and Behavioral Health of the Department of Health and Human Services if the nurse is providing mental health services at the rural clinic, except that no person may dispense a dangerous drug in violation of a regulation adopted by the Board.

(Added to NRS by 1979, 1682; A 1981, 747; 1983, 1516; 1987, 807, 1583, 1658; 1989, 915; 1991, 794; 2001, 790; 2001 Special Session, 242; 2003, 1017; 2007, 1867; 2013, 2090)

18B

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – January 18, 2024

EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

THORITY: NRS 639.070; NRS 639.0727

A REGULATION relating to pharmacy; The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standard.

CHAPTER 639 - PHARMACISTS AND PHARMACY

GENERAL PROVISIONS

- 639.010 Definitions.
- 639.020 “Consumer” interpreted.
- 639.30 “Date” interpreted.
- 639.31 “Dispensing practitioner” defined.
- 639.32 “Facsimile machine” interpreted.
- 639.040 “File” interpreted.
- 639.050 Storage and destruction of certain controlled substances.
- 639.055 Adoption by reference of guidelines concerning treatment of sexually transmitted diseases; revision of publication after adoption.
- 639.060 Marketing codes of conduct: Adoption of certain codes by reference.
- 639.065 Marketing codes of conduct: Periodic review of adopted codes.

STATE BOARD OF PHARMACY

- 639.100 Seal of Board.
- 639.110 Inactive regulations: Duties of Executive Secretary.
- 639.120 Conduct of disciplinary hearings.
- 639.130 Representation by counsel at disciplinary hearings.
- 639.140 Petitions to adopt, amend or repeal regulations.
- 639.150 Declaratory orders and advisory opinions.
- 639.160 Required time for receipt of application.
- 639.170 Waiver of regulation upon declaration of emergency: Authority; required notices.

CERTIFICATES, LICENSES AND PERMITS

- 639.200 Temporary certificates, licenses and permits.
- 639.205 Application to register as pharmacist: Completion required within 1 year.
- 639.208 Qualifications for registration by reciprocity; completion of requirements of Electronic Licensure Transfer Program.
- 639.210 Educational qualifications: Approval of accredited programs of education in pharmacy.
- 639.212 Educational qualifications: Advanced degree in pharmacy.
- 639.214 Application for license to operate pharmacy: Information required.
- 639.215 Application for license to operate pharmacy: Appearance of applicant before Board; execution on behalf of partnership or corporation; payment of expenses for special meeting of Board.
- 639.218 Application for inactive status.
- 639.219 Application for return to active status.
- 639.2195 Appearance of applicant for issuance or renewal of license, certificate or permit before Board under certain circumstances.
- 639.220 Schedule of fees; penalty for late renewal; exemptions from certain fees.
- 639.221 Payment of fees.
- 639.222 Period of validity for application; extension.
- 639.223 Electronic submission of fingerprints.
- 639.224 Submission of second set of fingerprints; name-based background check.
- 639.225 Notice to Executive Secretary of change of address.
- 639.226 Notice to Board by certain licensees of change of address.

- 639.227 Application or written notice to Board concerning change in ownership of pharmacy required under certain circumstances; suspension of license.
- 639.229 Report to Executive Secretary of conviction, administrative action or surrender of registration; appearance before Board before renewal of certificate, license or permit.
- 639.230 Voluntary surrender of certificate, license or registration to practice pharmacy in another state pursuant to agreement relating to disciplinary matter.

PHARMACEUTICAL TECHNICIANS

- 639.240 Requirements for registration of pharmaceutical technicians.
- 639.242 Registration of pharmaceutical technician in training; grounds for denial of application for registration; expiration of registration; certification by managing pharmacist.
- 639.245 Maintenance and availability of records regarding certain pharmaceutical personnel on duty; activities of pharmaceutical technicians.
- 639.247 Establishment and maintenance of policies and procedures for personnel; maintenance and availability of personnel records.
- 639.250 Restrictions on supervision.
- 639.252 Initialing of prescriptions, records and reports; responsibility for filled prescriptions.
- 639.254 Initial and biennial in-service training of pharmaceutical technicians working in or for pharmacy; maintenance of record by managing pharmacist; substitution of continuing education for in-service training.
- 639.256 Program of training: Approval by Board; testing of pharmaceutical technician in training for presence of alcohol or drug.
- 639.258 Participation in program of training for pharmaceutical technicians.
- 639.260 Disciplinary action against pharmacy.

INTERN PHARMACISTS

- 639.262 Application for registration; issuance of certificate of registration; maintenance of records relating to internship.
- 639.264 Employment at pharmacy as part of internship.
- 639.266 Supervision and training: Service as preceptor; duties; evaluation of internship.
- 639.268 Supervision and training: Responsibilities of registered pharmacist.

PHYSICIAN ASSISTANTS

- 639.269 "Physician assistant" defined.
- 639.270 Scope.
- 639.272 Requirements for registration certificate.
- 639.277 Change in location of practice or supervising physician.
- 639.280 Scope of authority to prescribe and dispense.
- 639.283 Prescriptions: Orders on charts of hospitalized patients.
- 639.285 Security and storage of controlled substances and drugs.
- 639.290 Substitution in case of illness or absence.
- 639.295 Grounds for denial of application or suspension or revocation of registration.

IMMUNIZATION BY PHARMACISTS, INTERN PHARMACISTS AND PHARMACEUTICAL TECHNICIANS

- 639.297 "Immunization" defined.
- 639.2971 Written protocol by physician authorizing administration; contents of and deviation from written protocol; restrictions to written protocol.
- 639.2972 Duties of authorizing physician.
- 639.2973 Training and certification to administer immunizations.
- 639.2974 Certification in basic cardiac life support; continuing education.
- 639.2975 Legal possession and control of drugs administered as immunizations; drugs to counteract adverse reactions.
- 639.2976 Reporting of certain information concerning immunizations.
- 639.2977 Maintenance of records.
- 639.2978 Confidentiality of records.

CONTINUING PROFESSIONAL EDUCATION

- 639.300 Definitions.
- 639.315 "Continuing education unit" defined.
- 639.320 "Provider" defined.
- 639.330 Registration and renewal of registration: Continuing education required; submission of proof.
- 639.333 Registration and renewal of registration: Acceptance of certificate issued by another state as proof of compliance with requirements for continuing education.
- 639.335 Registration and renewal of registration: Exceptions to requirement of continuing education.
- 639.345 Providers of continuing education: Records required; issuance of certificates of completion.
- 639.365 Providers of continuing education: Advertising, announcements and other promotional material.

639.390 Certificate of completion: Retention by pharmacist; copy to be submitted to Board upon request.

REMOTE SITES, SATELLITE CONSULTATION SITES AND TELEPHARMACIES

- 639.391 Pharmacist or dispensing practitioner required to obtain certificate of registration to dispense controlled substances or dangerous drugs at remote site or satellite consultation site.
- 639.392 Telepharmacies required to be located within State; requirements concerning accessibility of pharmacist or dispensing practitioner; procedure during interruption of communicative access between telepharmacy and remote site or satellite consultation site.
- 639.393 Requirements for pharmaceutical technicians and dispensing technicians.
- 639.395 Transmission of new prescription to telepharmacy; consultation with pharmacist or dispensing practitioner required before accessing controlled substances or dangerous drugs at remote site or satellite consultation site; prerequisites for dispensing at remote site or satellite consultation site.
- 639.396 Requirements for maintenance of records.
- 639.397 Requirements for labeling.
- 639.398 Establishment of policies and procedures for operation of remote site or satellite consultation site; monthly inspections.
- 639.399 Responsibility of pharmacist or dispensing practitioner concerning dispensing of controlled substances or dangerous drugs at remote site or satellite consultation site.

OFF-SITE PHARMACY PRACTICE

- 639.401 Pharmacist authorized to engage in practice of pharmacy only at licensed pharmacy; exceptions.
- 639.403 Engaging in practice of pharmacy at site other than licensed pharmacy: Approval of Board required under certain circumstances; submission of application.
- 639.406 Engaging in practice of pharmacy at site other than licensed pharmacy: Hearing to approve or deny application from pharmacist.
- 639.407 Engaging in practice of pharmacy at site other than licensed pharmacy: Approval of Board not required under certain circumstances; required access to computerized system and patient data.
- 639.408 Engaging in practice of pharmacy at site other than licensed pharmacy: Limitation on performance of services; requirements; prohibitions.
- 639.409 Grounds for revocation, suspension or placement of restrictions on approval granted to pharmacist to practice pharmacy at site other than licensed pharmacy.

INTERNET PHARMACIES

General Provisions

- 639.420 Definitions.
- 639.422 "Certified Internet pharmacy" defined.
- 639.424 "Internet pharmacy" defined.

Certification

- 639.426 Requirements for approval of application.
- 639.428 Access to premises and records; suspension for noncompliance.

CANADIAN PHARMACIES

- 639.430 Licensure: Requirement; application.
- 639.432 Restrictions on dispensing drugs.
- 639.434 Standards of practice.
- 639.436 Dissemination of certain contact information; printing of certain information on label of prescription.

MEDICAL FACILITIES AND CORRECTIONAL INSTITUTIONS

General Provisions

- 639.440 Definitions.
- 639.441 "Administer" defined.
- 639.442 "Chart order" defined.
- 639.445 "Compound" and "compounding" defined.
- 639.446 "Consultant pharmacist" defined.
- 639.4465 "Correctional institution" defined.
- 639.447 "Deliver" and "delivery" defined.
- 639.448 "Device" defined.
- 639.449 "Direct copy" defined.
- 639.450 "Dispense" defined.
- 639.451 "Distribute" defined.
- 639.452 "Floor stock" defined.
- 639.453 "Formulary" defined.
- 639.455 "Investigational drug" defined.
- 639.456 "IV admixture" defined.

- 639.459 "Unit dose" defined.
- 639.460 "Unit of use" defined.
- 639.461 Licensing.
- 639.459 Biennial registration.
- 639.460 Change of ownership.

Standards of Operation

- 639.464 Scope of services in hospital or correctional institution.
- 639.4645 Maintenance of registration certificates required.
- 639.465 Managing pharmacist.
- 639.466 Consultant pharmacist.
- 639.467 Staff pharmacists.
- 639.468 Establishment of policies, procedures and systems.
- 639.4685 Handling of medications in correctional institutions without pharmacies.
- 639.469 Standards for premises.
- 639.470 Security of premises.
- 639.472 Maintenance of reference library.
- 639.473 Procurement and storage of drugs.
- 639.474 Development and use of formulary.
- 639.475 Preparation and labeling of admixtures.
- 639.476 Prepackaging of drugs.
- 639.477 Policies and procedures for distribution of drugs.
- 639.478 Limitations on distribution of drugs.
- 639.479 Withdrawal of drugs when full-time pharmacist is absent.
- 639.480 Withdrawal of drugs when part-time or consultant pharmacist is absent.
- 639.481 Withdrawal of drugs when facility uses floor stock and pharmacy is closed.

Records

- 639.482 Maintenance and availability of records.
- 639.483 Statutes applicable to maintenance of records.
- 639.484 Contents and maintenance of chart orders.
- 639.482 Maintenance of records for controlled substances.
- 639.483 Maintenance of records of controlled substances administered from floor stock.
- 639.484 Maintenance of additional records.
- 639.485 Maintenance of records for distribution of controlled substances to another pharmacy or practitioner.
- 639.486 Separation of certain records.
- 639.487 Permission to use centralized system for keeping records.

Chart Order Processing Services

- 639.488 Definitions.
- 639.4911 "Chart order" defined.
- 639.49115 "Chart order processing services" defined.
- 639.4912 "Correctional institution" defined.
- 639.4914 "Remote chart order processing services" defined.
- 639.4915 Provision of services by pharmacies within certain hospitals and correctional institutions.
- 639.4916 Provision of remote services by pharmacist employed by or under contract with pharmacy located in hospital or correctional institution.

FACILITIES FOR INTERMEDIATE CARE AND FACILITIES FOR SKILLED NURSING

- 639.489 Definitions.
- 639.494 Prescriptions for controlled substances: Accountability record; handling of unused portions.
- 639.496 Maintenance of accountability record; examination of chart orders; issuance of receipt for controlled substances delivered to coroner.
- 639.498 Destruction of certain controlled substances: Requirement; procedure.

RECOVERY CENTERS AND SURGICAL CENTERS FOR AMBULATORY PATIENTS

- 639.4985 Definitions.
- 639.4987 "Compounding" defined.
- 639.4989 "Drug" defined.
- 639.4991 "Investigational drug" defined.
- 639.4992 Dispensing of controlled substances and dangerous drugs: Registration and licensing required.
- 639.4996 Establishment and review of policies and procedures by pharmacist.

639.4998 Duties of pharmacist who establishes policies and procedures.

PHARMACIES IN GENERAL

639.500 Ownership of pharmacies; application to conduct a pharmacy.

639.5005 Representative of pharmacy: General requirements; exceptions; approval; enforcement.

639.5007 Terms and conditions of license to conduct pharmacy for applicant required to designate representative.

639.501 Inspections; provision of self-assessment form.

639.5014 Completion of self-assessment form before annual inspections; suggestions relating to compliance by or improvement of pharmacy.

639.5016 Annual inspections: Review of self-assessment form; notes regarding discrepancies or deficiencies; correction of discrepancies or deficiencies.

639.5018 Protection of employee providing answers, information or suggestions on self-assessment form or during inspections.

639.5019 Annual review by Board of provisions of NAC 639.501 to 639.5019, inclusive.

639.503 Maintenance in pharmacy of current statutes, regulations and reference material.

639.505 Maintenance in pharmacy of reports of inspection, warning notices and special bulletins.

639.510 Maintenance and storage of pharmaceutical stock.

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

639.513 Class C packaging: Expiration date.

639.515 Stock of drugs in facility for skilled nursing or intermediate care.

639.517 Nurse employed by medical facility or agency to provide nursing in the home may maintain stock of certain drugs.

639.520 Security of prescription departments.

639.523 Physical address for delivery of drugs.

639.525 Minimum requirements for work area and equipment.

639.526 Drive-through facilities.

639.527 Required temperature in refrigerator or freezer used to store medicine.

639.528 Preparation and storage of food in prescription department of pharmacy.

639.530 Sanitation; required washbasins; exception.

639.535 Remodeling or relocation of pharmacy or prescription department.

639.540 Notice of employment and termination of employment of certain pharmaceutical professionals.

639.542 Identification of persons employed by pharmacy.

639.556 Meal periods and rest periods for employees of pharmacy.

639.570 Involuntary closure of pharmacy.

639.575 Voluntary closure of pharmacy.

639.580 Permanent closure of pharmacy.

NUCLEAR PHARMACIES

639.5802 Definitions.

639.5804 "Agreement state" defined.

639.5806 "Authentication of product history" defined.

639.5808 "Procedures to assure the quality of radiopharmaceuticals" defined.

639.581 "Qualified nuclear pharmacist" defined.

639.5812 "Radiopharmaceutical services" defined.

639.5814 "Testing to control the quality of radiopharmaceutical" defined.

639.5816 "Radiopharmaceutical" interpreted.

639.5818 Nuclear pharmacist: Certification; training and instruction; affidavit of experience and training.

639.582 Permit to operate.

639.5822 Space and equipment requirements; floor plan.

639.5824 Security.

639.5826 Records.

639.5828 Quality assurance procedures for radiopharmaceuticals.

639.580 Dispensing or transferring radiopharmaceuticals.

639.5832 Oral order for radiopharmaceutical: Requirement to keep record; contents of record.

639.5834 Outer shield of radiopharmaceutical container: Label required; contents of label.

639.5836 Inner label of radiopharmaceutical container; contents.

639.5838 Records of nuclear pharmacy when radiopharmaceutical is dispensed pursuant to investigational new drug application: Contents.

639.581 Required equipment.

WHOLESALESA

- | | |
|---------------------------|--|
| 639.585 | Definitions. |
| 639.587 | "Facility" defined. |
| 639.588 | "Manufacturer" defined. |
| 639.589 | "Ongoing relationship" defined. |
| 639.5893 | "Person who exercises significant influence over the operation" defined. |
| 639.5895 | "Purchaser" defined. |
| 639.5897 | "Purchasing wholesaler" defined. |
| 639.5902 | "Statement of prior sales" defined. |
| 639.5905 | "Supplier" defined. |
| 639.592 | "Wholesaler" defined. |
| 639.593 | Licensing requirements; consideration of transaction as wholesale transaction; new application if change of ownership; nontransferability of license; exception to submission of fingerprints. |
| 639.59305 | Submission of fingerprints of persons who exercise significant influence over the operation of wholesaler. |
| 639.5931 | Submission of fingerprints: Required method. [Replaced in revision by NAC 639.223 .] |
| 639.5932 | Provisional license: Prerequisites for issuance. |
| 639.5935 | Representative of wholesaler: General requirements; exceptions; approval; enforcement. |
| 639.5937 | Bond or other security: Amount required from certain wholesalers; reduction of amount; substitution. |
| 639.5938 | Filing of single bond for multiple sites. |
| 639.594 | Documentation of ongoing relationship; ongoing relationship attributed to affiliated wholesaler under certain circumstances. |
| 639.595 | Qualifications of employees who engage in storage or distribution of drugs. |
| 639.596 | Facilities: General requirements; maintenance of stock. |
| 639.597 | Facilities: Security. |
| 639.5975 | Prescription drugs: Restrictions on purchase and receipt; disposal of certain drugs. |
| 639.5977 | Prescription drugs: Sale to purchasing wholesaler. |
| 639.598 | Prescription drugs: Storage. |
| 639.599 | Prescription drugs: Examination of shipments; actions upon determination of certain conditions. |
| 639.601 | Prescription drugs: Separation and disposal of certain drugs. |
| 639.6015 | Prescription drugs: Destruction. |
| 639.602 | Prescription drugs: Records. |
| 639.603 | Prescription drugs: Requirements regarding statements of prior sales. |
| 639.6035 | Prescription drugs: Exclusion of certain transactions from statements of prior sales. |
| 639.604 | Maintenance and availability of list of wholesalers with whom manufacturer has ongoing relationship. |
| 639.605 | Establishment and maintenance of policies and procedures regarding prescription drugs. |
| 639.6053 | Wholesaler who employs person to sell or market drug, medicine or chemical: Annual submission of certain information to Board; review and contents of marketing code of conduct; exemption. |
| 639.6055 | Submission of certain information regarding sales and marketing staff: Submission of form after initial submittal; method of submission. |
| 639.6057 | Submission of certain information regarding sales and marketing staff: Incomplete, improperly completed or noncompliant submittal; correction of deficiencies. |
| 639.606 | Establishment and maintenance of lists regarding certain personnel. |
| 639.6065 | Annual submission of certain reports or proof to Board. |
| 639.607 | Inspections; examination of records and procedures; copies of documents. |

MANUFACTURERS

- | | |
|--------------------------------|--|
| <u>639.609</u> | “Manufacturer” defined. |
| <u>639.610</u> | Minimum standards for premises. |
| <u>639.615</u> | Equipment and requirements for operation; employees. |
| <u>639.616</u> | Manufacturer who employs person to sell or market drug, medicine or chemical: Annual submission of certain information to Board; review and contents of marketing code of conduct. |
| <u>639.617</u> | Manufacturer who employs person to sell or market device or appliance: Annual submission of certain information to Board; review and contents of marketing code of conduct. |
| <u>639.615</u> | Submission of certain information regarding sales and marketing staff: Submission of form after initial submittal; method of submission. |
| <u>639.616</u> | Submission of certain information regarding sales and marketing staff: Incomplete, improperly completed or noncompliant submittal; correction of deficiencies. |

WAREHOUSES

- 639.620 Definitions.
- 639.621 "Authorized person" defined.
- 639.622 "Authorized warehouse" defined.
- 639.623 "Chain warehouse" defined.
- 639.624 "Facility" defined.
- 639.625 "Goods" defined.
- 639.626 "Manufacturer" defined.
- 639.627 "Pharmacy" defined.
- 639.6282 "Third-party logistics provider" defined.
- 639.629 "Wholesaler" defined.
- 639.6305 Third-party logistics providers: General requirements.
- 639.631 Licensing: General requirements.
- 639.633 Contracts authorizing receipt, storage and shipment of prescription drugs and goods.
- 639.634 Enforcement of statutory liens.
- 639.635 Cessation of operation.
- 639.636 Change in legal ownership of facility resulting from legal proceeding.
- 639.637 Facilities: General requirements.
- 639.638 Facilities: Security.
- 639.639 Prescription drugs: Storage.
- 639.640 Prescription drugs: Shipment.
- 639.641 Prescription drugs: Records.
- 639.642 Establishment of policies and procedures regarding prescription drugs.
- 639.643 Inspections; examination of records and procedures.
- 639.644 Enforcement.

V VETERINARIANS: CONSIGNMENT OF APPROVED DRUGS FROM WHOLESALERS TO PHARMACIES

- 639.645 Definitions.
- 639.6455 "Approved drug" defined.
- 639.646 "Consign," "consigned" and "consignment" defined.
- 639.6465 "Licensed pharmacy" defined.
- 639.6475 "Licensed wholesaler" defined.
- 639.648 Requirements for veterinarian to engage in consignment; maintenance of records; counseling of client on matters to enhance therapy of animal.
- 639.6485 Requirements for wholesaler to engage in consignment; additional requirements for obtaining license as wholesaler.
- 639.649 Requirements for pharmacy to engage in consignment; additional requirements for obtaining license as pharmacy.
- 639.6495 Payment by pharmacy to veterinarian not considered unearned compensation.

VETERINARY DRUGS

- 639.650 Fee for and scope of permit to sell; penalty for late registration; prohibited sales; refrigeration.
- 639.655 Registration of euthanasia technician who possesses or administers sodium pentobarbital; registration revocable privilege.
- 639.660 Restriction on use of rabies vaccine.

COMPOUNDING AND DISPENSING DRUG PRODUCTS

General Provisions

- 639.661 Definitions.
- 639.6611 "Active ingredient" defined.
- 639.6613 "Ante-area" defined.
- 639.6615 "Barrier isolator cabinet" defined.
- 639.6617 "Beyond-use date" defined.
- 639.6619 "Buffer area" defined.
- 639.6621 "Chart order" defined.
- 639.6623 "Component" defined.
- 639.6625 "Compound" and "compounding" defined.
- 639.6627 "Compounding aseptic containment isolator" defined.
- 639.6629 "Compounding aseptic isolator" defined.
- 639.663 "Cytotoxic" defined.
- 639.6631 "Drug product" defined.

- 639.6633 "Gloved fingertip sampling" defined.
- 639.6635 "Hazardous drug" defined.
- ~~639.6637 "High-risk sterile compounded drug product" defined.~~
- 639.6639 "Immediate-use sterile compounded drug product" defined.
- 639.6641 "ISO Class 5" defined.
- 639.6643 "ISO Class 7" defined.
- 639.6645 "ISO Class 8" defined.
- ~~639.6647 "Low-risk sterile compounded drug product" defined.~~
- 639.6649 "Media fill test" defined.
- 639.665 "Medical facility" defined.
- ~~639.6655 "Medium-risk sterile compounded drug product" defined.~~
- 639.6665 "Nonsterile compounded drug product" defined.
- 639.667 "Nursing personnel" defined.
- 639.6673 "Parenteral nutrition" defined.
- 639.6677 "Sterile compounded drug product" defined.
- 639.670 Adoption of certain publications by reference; revision of publication after adoption.

Standards for Compounding and Dispensing Generally

- 639.6701 Inspection of materials and equipment; recordkeeping.
- 639.67013 Competency and proficiency of certain pharmaceutical personnel.
- 639.67015 Establishment of policies and procedures.
- 639.67017 Use of automated compounding devices.
- 639.67019 Retention of records.
- 639.6702 Records concerning drug products compounded in excess and in bulk quantities.

Standards for Compounding and Dispensing Nonsterile Products

- 639.6703 Labeling.
- ~~639.67033 Environmental standards.~~
- 639.67035 Establishment of policies and procedures.
- ~~639.67037 Safety procedures for storage, handling, compounding and disposal; training required.~~

Standards for Compounding and Dispensing Sterile Products

- ~~639.6705 Environmental standards.~~
- ~~639.67051 Air quality testing and certification.~~
- 639.67053 Tests for competency and proficiency of certain pharmaceutical personnel.
- 639.67055 Record verifying accuracy required to be made.
- 639.67057 Procedures following breach of seal of single-dose and multi-dose containers.
- ~~639.67059 Exemptions for certain institutional pharmacies.~~
- ~~639.67061 Low risk sterile compounding: Process and storage.~~
- ~~639.67063 Low risk sterile compounding: Radiopharmaceutical drug products.~~
- ~~639.67065 Medium risk sterile compounding: Process and storage.~~
- ~~639.67067 High risk sterile compounding: Process and storage.~~
- ~~639.67069 High risk sterile compounding: Sterilization.~~
- ~~639.67071 High risk sterile compounding: Testing of certain drug products.~~
- 639.67073 Immediate-use sterile compounding: Preparation and labeling.
- ~~639.67075 Immediate-use sterile compounding: Compounding standards.~~
- 639.67077 Sterile hazardous drugs: Safety procedures for storage, handling, compounding and disposal.
- 639.67079 Sterile hazardous drugs: Required training for certain pharmaceutical personnel.

Standards for Compounding and Dispensing Parenteral Solutions

- 639.672 Reference materials required to be located in or immediately available to pharmacy.
- 639.680 Labeling.
- 639.682 Record for each patient.
- 639.683 Delivery, storage and recordation of delivery.
- 639.686 Written policies and procedures for disposal of infectious materials and materials containing cytotoxic residues.
- 639.688 Written policies and procedures regarding provision of services related to parenteral therapy.
- 639.690 Pharmacist: Consultation with patient; proper training in safe handling, compounding and therapy related to parenteral solutions.

OUTSOURCING FACILITIES

- 639.691 Definitions.

- 639.6911 "Compounding" defined.
- 639.6912 "Outsourcing facility" defined.
- 639.6913 "Sterile drug" defined.
- 639.6915 Duties of facility.
- 639.6916 When licensure as pharmacy required.

PROVIDERS AND WHOLESALERS OF MEDICAL PRODUCTS

General Provisions

- 639.693 Definitions.
- 639.69305 "Accreditation and certification organization" defined.
- 639.6931 "Assistive equipment" defined.
- 639.6932 "Consumer" defined.
- 639.69325 "Customized orthotic or prosthetic device" defined.
- 639.6933 "Health professional" defined.
- 639.6934 "Life-sustaining equipment" defined.
- 639.6935 "Medical products" defined.
- 639.6936 "Medical products provider" defined.
- 639.6937 "Medical products wholesaler" defined.
- 639.6938 "Respiratory equipment" defined.
- 639.6939 Adoption by reference of code of ethics and code of professional conduct; revision of codes after adoption.
- 639.694 Employment of administrator required; duties; notice to Board of cessation of employment; sharing of common administrator at shared facility.
- 639.6941 Unprofessional conduct; responsibility of owner for acts of others.

Licensing and Fees

- 639.6942 Application for license; license required for each location; notification of change in information; license nontransferable; expiration.
- 639.6943 Board will not issue license to certain practicing health professionals.
- 639.6944 Licensing of applicants located outside of State.
- 639.6945 Waiver of license fee.

Medical Products Providers

- 639.6946 Duties of providers; repair and maintenance of medical products; hours of operation; restriction on location; procedure for consumer complaints.
- 639.6947 Change in controlling interest.
- 639.6948 Compliance with provisions by person or business who is not medical products provider.
- 639.6949 Provision of medical products to consumer with or without bona fide order or prescription; tracking requirements.
- 639.695 Maintenance of records.
- 639.6951 Communications and advisement of options and use of medical products; written record.
- 639.6952 Communications concerning use of medical products provided by written or oral order or prescription; written record.
- 639.6953 Assistive equipment.
- 639.69533 Customized orthotic or prosthetic devices: Approval by Board required.
- 639.69535 Customized orthotic or prosthetic devices: Accessibility of services and confidentiality.
- 639.69537 Customized orthotic or prosthetic devices: Practitioner's order required.
- 639.6954 Medical gases and associated equipment or respiratory equipment.
- 639.69543 Insulin pumps.
- 639.69545 Pressurized stockings.
- 639.6955 Life-sustaining equipment.
- 639.6956 Parenteral and enteral services and equipment.

Medical Products Wholesalers

- 639.6957 Duties of wholesalers; repair and maintenance of medical products; hours of operation; consumer complaints.
- 639.69573 Wholesaler who employs person to sell or market device or appliance: Annual submission of certain information to Board; review and contents of marketing code of conduct.
- 639.69575 Submission of certain information regarding sales and marketing staff: Submission of form after initial submittal; method of submission.
- 639.69577 Submission of certain information regarding sales and marketing staff: Incomplete, improperly completed or noncompliant submittal; correction of deficiencies.

Disciplinary Action

639.6958 Summary suspension of license.

TRADE PRACTICES

- 639.700 Performance of certain acts by pharmacists and pharmaceutical interns only.
- 639.701 Acts not required to be performed by pharmaceutical professionals.
- 639.702 Responsibility for acts and omissions of personnel who are not pharmacists.
- 639.704 Check of license or certification required before employment by pharmacy or wholesaler.
- 639.706 Marking of prescriptions with serial numbers; maintenance of files of prescriptions.
- 639.707 Counseling of patients: Duties of pharmacist, intern pharmacist or dispensing practitioner; exception; documentation.
- 639.708 Counseling of patients: Duties of pharmacy or dispensing practitioner.
- 639.709 Persons to whom pharmacy may furnish certain restricted products.
- 639.7102 Use of computer system for issuance and transmission of prescription.
- 639.7105 Electronic transmission of prescription.
- 639.711 Transmission of prescription by facsimile machine.
- 639.712 Transcribing prescription transmitted by oral order.
- 639.7125 Use of fulfillment pharmacy by dispensing pharmacy.
- 639.713 Transfer of information between pharmacies: Conditions; prohibitions.
- 639.714 Transfer of information between pharmacies: Procedure.
- 639.7145 Transfer of information between pharmacies: Requirements for transfer by facsimile machine.
- 639.715 Automated drug dispensing system or other mechanical device: Restrictions on use.
- 639.718 Automated drug dispensing system used by pharmacy: Licensure required for system; use to dispense prescription drugs to patients.
- 639.719 Automated drug dispensing system used by reproductive healthcare center: Licensure required for system; use to dispense prescription drugs to patients.
- 639.720 Mechanical device other than automated drug dispensing system: Licensure and use to furnish drugs and medicines for administration to registered patients in medical facility and to patients receiving treatment in emergency room of hospital.
- 639.725 Use of mechanical counting device for dispensing medication to be taken orally.
- 639.730 Inspection of damaged pharmaceuticals.
- 639.740 Container for dispensing prescribed medicine.
- 639.742 Dispensing of controlled substances or dangerous drugs for human consumption: Application by practitioner for certificate of registration at each site; application by facility required under certain circumstances; duties of dispensing practitioner, facility and federally-qualified health center vehicle relating to drugs; authority of dispensing practitioner and technician.
- 639.7421 Dispensing of controlled substances: Registered practitioner practicing in hospital or independent center for emergency medical care exempt from requirement to obtain certificate of registration to dispense at site.
- 639.7422 Dispensing of dangerous drugs: Application by dispensing practitioner to transport and dispense to patients of federally-qualified health center from federally-qualified health center vehicle; duties of dispensing practitioner; approval of vehicle not transferable.
- 639.7423 Dispensing of controlled substances or dangerous drugs not for human consumption: Application by veterinarian for certificate of registration; duties of veterinarian and veterinary facility; maintenance of records; exemption from certain regulations.
- 639.7424 Dispensing technician in training: Application and fee for registration; grounds for denial of application; issuance and expiration of registration; participation in training.
- 639.7425 Dispensing technician: Application and fee for certificate of registration; grounds for denial of application; issuance and expiration of certificate of registration; in-service training required for renewal of registration.
- 639.743 Restrictions on access to drugs by dispensing technician in training or dispensing technician; dispensing practitioner responsible for performance of functions by dispensing technician.
- 639.7435 Dispensing technician and dispensing technician in training: Registration transferable; notice of change of location of practice or supervisor.
- 639.744 Dispensing practitioner: Employment of multiple dispensing technicians.
- 639.7445 Dispensing practitioner: Disciplinary action for violation of NAC 639.742 to 639.7445, inclusive.
- 639.745 Duties of certain practitioners concerning dispensing of controlled substances and dangerous drugs; maintenance of records.
- 639.746 Registration of oncology group practice or group of practitioners practicing at reproductive healthcare center to maintain single inventory of dangerous drugs; issuance and renewal of certificate of registration;

authority and duties of registrant.

- 639.748 Identification of person who picks up controlled substance.
- 639.750 Dispensing of medication at certain locations when services of local retail pharmacy not available.
- 639.751 Requirements concerning signatures or initials to be placed on prescription.
- 639.752 Restrictions on filling or dispensing certain prescriptions.
- 639.753 Declination of pharmacist to fill prescription.
- 639.754 Refilling prescriptions: Restrictions; authorization by patient without specific request for particular refill.
- 639.755 Sale of preparations for treatment of asthma.
- 639.756 Retail community pharmacy: Required notice of availability of prescription readers; directions or advice on obtaining prescription reader.
- 639.757 Preparation and sale of compounded drugs by pharmacy or pharmacist: License as manufacturer not required under certain circumstances; unsafe or ineffective drug; restrictions on sale.
- 639.760 Return of unused drugs packaged in unit doses.
- 639.765 Disclosure by practitioner of certain ownership interests in pharmacy.

SELF-ADMINISTERED HORMONAL CONTRACEPTIVES

- 639.771 Requirements for pharmacist to dispense under protocol.
- 639.772 Adoption of certain eligibility criteria by reference; revision of publication after adoption.
- 639.773 Protocol for dispensing.
- 639.774 Risk assessment questionnaire.

DRUGS FOR PREVENTING THE ACQUISITION OF HUMAN IMMUNODEFICIENCY VIRUS

- 639.776 "Drug" defined.
- 639.777 Requirements for pharmacist to prescribe, dispense and administer.
- 639.778 Procedure for prescribing, dispensing and administering preexposure and postexposure prophylaxis drugs.
- 639.7785 Adoption by reference of certain guidelines; revision of publication after adoption.
- 639.779 Compliance with certain guidelines, laws and regulations; prescribing, dispensing and administering without laboratory testing; plan of care for treatment.

REPACKAGING OF PREVIOUSLY DISPENSED DRUGS

- 639.781 Definitions.
- 639.784 Duties of repackaging pharmacy.
- 639.788 Restrictions on repackaging pharmacy.

PRODUCTS THAT ARE PRECURSORS TO METHAMPHETAMINE

- 639.815 Real-time, stop sale system: Minimum requirements for approval by the Board.
- 639.817 Real-time, stop sale system: Duties of pharmacy; completion of sale or transfer despite an alert from or without first consulting the system authorized in certain circumstances.

PRESCRIPTIONS FOR CERTAIN CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

- 639.823 "Acute pain" interpreted.
- 639.826 "Course of treatment" interpreted.
- 639.831 Requirements included to "obtain informed written consent to the use of the controlled substance."
- 639.834 Review of medical history and physical examination of patient; good faith effort to obtain and review medical records; determination of whether medical record is necessary.
- 639.836 Practitioner not prohibited from prescribing or increasing dosage of controlled substance under certain circumstances.
- 639.838 Prescription medication agreement: Authority of patient to enter into agreement with group of practitioners; review and update by practitioner.

ADVANCED PRACTICE REGISTERED NURSES

General Provisions

- 639.841 "Collaborating physician" defined.
- 639.846 Change in location of practice or collaborating physician.

Prescribing

- 639.850 Certificate of registration: Application; appearance before Board.
- 639.854 Scope of authority to prescribe.
- 639.858 Authorization to write prescription in form of chart order or physician's order.

Dispensing

- 639.870 Certificate of registration: Application; fee; period of validity; appearance before Board; collaborating physician; late renewal.
- 639.879 Scope of authority to dispense.
- 639.892 Use of child-proof container.

639.898 Security and storage of controlled substances and drugs.

Disciplinary Action

639.900 Grounds for denial of application or suspension or revocation of registration.

COMPUTERIZED SYSTEMS

Recording of Information

639.910 Information to be provided by system; procedure to ensure information not lost or destroyed.

639.912 Requirements for use of system; maintenance of physical records.

639.914 Maintenance and availability of information relating to operation; entrance of each prescription into system required; issuance of consecutive numbers for prescriptions.

639.918 Written record of refills; exception.

639.921 Sharing information between systems; Conditions and requirements.

639.924 Computerized system to record prescriptions required for pharmacies licensed on or after August 27, 1996.

639.926 Transmission of information regarding dispensing of controlled substances to certain persons; adoption and availability of publication by reference.

639.930 Safeguards against access to and modification or manipulation of information.

639.935 Printed record of contents.

639.938 Auxiliary procedure to document prescriptions when system not functioning.

Automated Dispensing Systems

639.940 "Computerized system to fill prescriptions" defined.

639.9405 Authority to use system.

639.941 Written policies and procedures of operation.

639.9415 Written program for quality assurance.

639.942 Written plan for recovery.

639.9425 Written program for preventative maintenance of system.

639.943 Required security of drugs and records.

DISCIPLINARY ACTION

639.945 Unprofessional conduct; owner responsible for acts of employees.

639.951 Violations by employees of pharmacy concerning controlled substances or other drugs; screening tests.

639.955 Imposition of fines; authority to take disciplinary action.

639.960 Dissemination of certain orders and decisions to National Practitioner Data Bank and certain licensing authorities.

639.965 Failure to comply with order imposing disciplinary action: Issuance of order to show cause; hearing.

639.968 Failure to comply with order imposing disciplinary action: Contents of order to show cause.

639.972 Failure to comply with order imposing disciplinary action: Service of order to show cause.

639.976 Failure to comply with order imposing disciplinary action: Authority of Board to take action upon conclusion of hearing.

639.978 Failure of respondent to appear at hearing to show cause.

COMPOUNDING AND DISPENSING DRUG PRODUCTS

General Provisions

NAC 639.661 Definitions. (NRS 639.070, 639.2807) As used in NAC 639.661 to 639.690, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.6611 to 639.6677, inclusive, have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94; A by R035-06, 9-18-2008)

NAC 639.6611 "Active ingredient" defined. (NRS 639.070) "Active ingredient" means an ingredient added to a compounded drug product which provides the therapeutic effect desired from the compounded drug product. The term does not include an inert ingredient.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6613 "Ante-area" defined. (NRS 639.070) "Ante-area" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6615 "Barrier isolator cabinet" defined. (NRS 639.070) "Barrier isolator cabinet" means a device the interior of which creates an ISO Class 5 environment and provides an impermeable barrier to outside air at all times while

it is being used for compounding purposes. The term includes, without limitation, compounding aseptic isolators and compounding aseptic containment isolators.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6617 "Beyond-use date" defined. (NRS 639.070) "Beyond-use date" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6619 "Buffer area" defined. (NRS 639.070) "Buffer area" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1

of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6621 “Chart order” defined. (NRS 639.070) “Chart order” has the meaning ascribed to it in NAC 639.442.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6623 “Component” defined. (NRS 639.070) “Component” means an ingredient that is used to compound a drug product, including, without limitation, an ingredient that does not appear on the labeling of the compounded drug product.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6625 “Compound” and “compounding” defined. (NRS 639.070)

1. Except as otherwise provided in subsection 2, “compound” and “compounding” mean:

(a) The preparation, mixing or assembling of a drug product of which at least one component is a prescription drug; and

(b) The packaging and labeling incident to the preparation, mixing or assembling of a drug product for the purpose of selling or dispensing the drug product pursuant to a prescription or chart order.

2. The terms “compound” and “compounding” do not include the mixing or reconstituting of a nonsterile drug product that is performed in accordance with:

(a) The directions contained in the labeling of the drug product that have been approved by the Food and Drug Administration and provided by the manufacturer of the drug product; or

(b) Any other directions provided by the manufacturer of the drug product that are consistent with the labeling of the drug product that have been approved by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6627 “Compounding aseptic containment isolator” defined. (NRS 639.070) “Compounding aseptic containment isolator” has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6629 “Compounding aseptic isolator” defined. (NRS 639.070) “Compounding aseptic isolator” has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.663 “Cytotoxic” defined. (NRS 639.070, 639.2807) “Cytotoxic” means having the capability of killing living cells.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.6631 “Drug product” defined. (NRS 639.070) “Drug product” means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6633 “Gloved fingertip sampling” defined. (NRS 639.070) “Gloved fingertip sampling” has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6635 “Hazardous drug” defined. (NRS 639.070) “Hazardous drug” means:

1. A compounded drug product in which one or more of the components of the compounded drug product produce one or more of the following characteristics in humans or animals:

(a) Carcinogenicity;

(b) Teratogenicity or other developmental toxicity;

(c) Reproductive toxicity;

(d) Organ toxicity at low doses; or

(e) Genotoxicity; or

2. A compounded drug product in which the structure and toxicity profiles of the compounded drug product mimic an existing drug product which has components that produce one or more of the characteristics set forth in subsection 1.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~NAC 639.6637 "High-risk sterile compounded drug product" defined. (NRS 639.070) "High-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67067. (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.6639 "Immediate-use sterile compounded drug product" defined. (NRS 639.070) "Immediate-use sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67073.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6641 "ISO Class 5" defined. (NRS 639.070) "ISO Class 5" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 3,520 particles that are 0.5 micron or larger in diameter per cubic meter of air; or
2. Less than 100 particles that are 0.5 micron or larger in diameter per cubic foot of air.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6643 "ISO Class 7" defined. (NRS 639.070) "ISO Class 7" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 352,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or
2. Less than 10,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6645 "ISO Class 8" defined. (NRS 639.070) "ISO Class 8" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 3,520,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or
2. Less than 100,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~NAC 639.6647 "Low-risk sterile compounded drug product" defined. (NRS 639.070) "Low-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67061. (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.6649 "Media fill test" defined. (NRS 639.070) "Media fill test" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.665 "Medical facility" defined. (NRS 639.070, 639.2807) "Medical facility" has the meaning ascribed to it in NRS 449.0151.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

~~NAC 639.6655 "Medium-risk sterile compounded drug product" defined. (NRS 639.070) "Medium-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67065. (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.6665 "Nonsterile compounded drug product" defined. (NRS 639.070) "Nonsterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is not required to be sterile as described in NAC 639.6677.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.667 "Nursing personnel" defined. (NRS 639.070, 639.2807) "Nursing personnel" means an employee

of:

1. A medical facility who is licensed pursuant to chapter 632 of NRS;
2. A nursing pool as defined in NRS 449.0153; or
3. An agency to provide nursing in the home as defined in NRS 449.0015.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.6673 "Parenteral nutrition" defined. (NRS 639.070) "Parenteral nutrition" means nutrients provided intravenously.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6677 "Sterile compounded drug product" defined. (NRS 639.070) "Sterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is required to be sterile by either the provisions of chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, or the provisions of NAC 639.661 to 639.690, inclusive.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.670 Adoption of certain publications by reference; revision of publication after adoption. (NRS 639.070, 639.2807)

1. The Board hereby adopts by reference the following, all licensees must adhere to these standards when compounding:

~~(a) Federal Standard 209E, "Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones," as revised on September 11, 1992, by the Institute of Environmental Sciences. A copy of this publication may be obtained free of charge at the Internet address <http://www.set3.com/papers/209e.pdf>.~~

~~(b) NSF International Standard 49, "Class II (Laminar Flow) Biosafety Cabinetry," NSF/ANSI 49-2007, 2007 edition. A copy of this standard may be obtained from Techstreet, 3916 Ranchero Drive, Ann Arbor, Michigan 48108, or at the Internet address <http://www.techstreet.com/>, for the price of \$160. Clean room standards set by International Organization for Standardization (ISO), 1214 Verbier, Geneva, Switzerland.~~

~~(e) (a) United States Pharmacopeia - National Formulary, 2008²³ edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address <http://www.usp.org/products/>, for the price of \$755.~~

~~(d) (b) The Food Chemicals Codex, 6-13th edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address <http://www.usp.org/products/>, for the price of \$495.~~

~~(e) Reagent Chemicals: Specifications and Procedures, 10th edition, published by the American Chemical Society. A copy of this publication may be obtained from the Oxford University Press, 2001 Evans Road, Cary, North Carolina 27513, or at the Internet address <http://www.oup-usa.org>, for the price of \$274.50.~~

~~(f) (c) Appendix A of Publication No. 2004-165²⁰¹⁶⁻¹⁶¹, "Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings," published by the National Institute for Occupational Safety and Health. A copy of this publication may be obtained free of charge by telephone at (800) 232-4636 or at the Internet address <http://www.cdc.gov/niosh/docs/2004-1652016-161/>.~~

2. The Board will periodically review the standards and publications adopted by reference pursuant to paragraphs (b) to (f), inclusive, of subsection 1 and determine within 120 days after the review whether any change made to those standards or publications is appropriate for application in this State. If the Board does not disapprove a change to an adopted standard or publication within 120 days after the review, the change is deemed to be approved by the Board.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94; R035-06, 9-18-2008)

Standards for Compounding and Dispensing Generally

NAC 639.6701 Inspection of materials and equipment; recordkeeping. (NRS 639.070)

1. A pharmacy or pharmacist engaged in the practice of compounding drug products shall:

(a) Inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product;

(b) Ensure the proper use, cleanliness and maintenance of any equipment used in the process of compounding each drug product; and

(c) Prepare the records required to be prepared pursuant to NAC 639.661 to 639.690, inclusive, concerning the compounding of each drug product to ensure that an error has not occurred in the process of compounding each drug product.

2. A pharmacy or pharmacist engaged in the practice of compounding drug products may not allow any food or drink to be stored or consumed in or at an area or room in the pharmacy that is designated for compounding.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67013 Competency and proficiency of certain pharmaceutical personnel. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products:

(a) Is competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound;

(b) Complies with the provisions of NAC 639.661 to 639.690, inclusive, concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and

(c) Receives, on an ongoing basis, sufficient training to maintain that competency and proficiency.

2. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician:

(a) If the pharmacist or pharmaceutical technician is newly hired or is newly assigned to compound drug products, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound drug products; and

(b) If the pharmacist or pharmaceutical technician will be assigned to compound drug products that involve a higher level of risk than the drug products which the pharmacist or pharmaceutical technician had previously been trained to compound, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound those drug products.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67015 Establishment of policies and procedures. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:

(a) Policies and procedures for:

(1) The processes used by the pharmacy to compound drug products;

(2) The equipment used by the pharmacy to compound drug products;

(3) Ensuring that the actual weights and measures of each component are within plus or minus 5 percent of the theoretical weights and measures required for the drug products compounded by the pharmacy;

(4) Tracking, recalling and destroying the drug products compounded by the pharmacy, which must include a requirement that the pharmacy ensure that all drug products which could have been compounded with a particular component be located, recalled and destroyed; and

(5) Identifying the drug products or components of drug products that will be considered hazardous drugs.

(b) Control procedures for monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in the final compounded drug product.

(c) Control procedures to ensure that:

(1) Each component is accurately weighed, measured or subdivided, as appropriate;

(2) Any variation in the actual yield of a drug product compounded by the pharmacy is within plus or minus 10 percent of the theoretical yield of the compounded drug product; and

(3) If a component is transferred from its original storage container to a new storage container, the new storage container is labeled with the date of the transfer and information that is sufficient to trace the contents of the new container to the original storage container.

2. A member of the staff of the Board may require a pharmacy engaged in the practice of compounding drug products to provide a sample of a drug product that is being compounded at the time of the request and any records related to that compounded drug product for purposes of testing the compounded drug product for compliance with the provisions of NAC 639.661 to 639.690, inclusive. The Board will share the costs of testing such a sample equally with the pharmacy.

3. If a sample tested pursuant to subsection 2 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, the Board will notify the pharmacy of the failure to comply and the pharmacy must:

(a) Provide to the Board a written plan for remediating or addressing the noncompliance; and

(b) If requested by a member of the staff of the Board, provide an additional sample of the compounded drug product for testing. The costs of a test conducted pursuant to this paragraph must be paid solely by the pharmacy.

4. If the sample provided to the Board pursuant to paragraph (b) of subsection 3 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, the Board will take such action as it deems necessary to correct the noncompliance or to prevent further noncompliance, including, without limitation:

(a) Suspending the license of the pharmacy pursuant to NRS 639.210;

(b) Suspending the ability of the pharmacy to compound certain drug products; and

(c) Requiring the pharmacy to perform any other remedial or protective measures the Board deems necessary to correct the noncompliance or to prevent further noncompliance.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67017 Use of automated compounding devices. (NRS 639.070)

1. A pharmacy may use an automated compounding device to:

- (a) Assist with the compounding of a drug product; or
- (b) Produce a final compounded drug product.

2. If a pharmacy uses an automated compounding device as described in subsection 1, the pharmacy shall establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to NAC 639.67015, that address:

(a) The qualifications that a pharmacist or a pharmaceutical technician must have to use the automated compounding device;

(b) The routine maintenance and cleaning required to be performed on the automated compounding device which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the automated compounding device; and

(c) The testing required to be performed on the automated compounding device to ensure that the automated compounding device is measuring and dispensing the components of the compounded drug product and manufacturing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

3. If a pharmacy uses an automated compounding device to assist with the compounding of a drug product for parenteral nutrition, the pharmacy shall establish safe maximum limits for each additive that may be used in compounding such a drug product. The pharmacy shall ensure that:

(a) The automated compounding device will cease compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or

(b) If an automated compounding device cannot be programmed to cease the compounding process as described in paragraph (a):

(1) The automated compounding device is equipped with an audible alarm or some other mechanism that will alert the pharmacist if a maximum limit for an additive has been exceeded; and

(2) The pharmacy has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

4. If the pharmacy uses a computerized order entry system in conjunction with the automated compounding device, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

5. A pharmacy shall make and maintain records that evidence compliance by the pharmacy with the policies and procedures required by this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67019 Retention of records. (NRS 639.070)

~~1.~~ Except as otherwise provided in NAC 639.67055, each record required to be made pursuant to NAC 639.661 to 639.690, inclusive, must be:

(a) Maintained by the pharmacy for which the record was made for at least 2 years after the date the record was made; and

(b) Available for inspection and copying by the Board or its representative.

~~2.~~ Records made and maintained by a pharmacy pursuant to NAC 639.67055 must be available for inspection and copying by the Board or its representative after the 6-month period required by NAC 639.67055 if the pharmacy maintains the records longer than the required 6-month period.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6702 Records concerning drug products compounded in excess and in bulk quantities. (NRS 639.070) For each compounded drug product that is in excess of the amount required by the prescription or chart order and each compounded drug product that is compounded in bulk quantities, the pharmacist who compounded or supervised the compounding of the compounded drug product shall prepare a record, either on paper or in the pharmacy's computer system, that includes, without limitation:

1. The name of the compounded drug product;

2. A list of the components and quantities of components used to compound the drug product, including, without limitation, the manufacturer or supplier of the components used, the lot number of the components used and the expiration dates of the components used;

3. The internal control number assigned to the compounded drug product by the pharmacist or the number of the prescription of the compounded drug product;

4. The beyond-use date of the compounded drug product;

5. The date of preparation of the compounded drug product;

6. The initials of the pharmacist or pharmaceutical technician who compounded the compounded drug product;
 7. If the drug product was compounded by a pharmaceutical technician, the initials of the pharmacist who supervised the pharmaceutical technician; and
 8. The quantity of the final compounded drug product.
- (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Nonsterile Products

NAC 639.6703 Labeling. (NRS 639.070)

1. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall label each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order and any nonsterile compounded drug product that is compounded in bulk quantities. The label must include, without limitation:

(a) The name of the final compounded drug product or the name of each active ingredient present in the nonsterile compounded drug product and, as appropriate, the concentration of each active ingredient in the final compounded drug product;

(b) The internal control number assigned to the compounded drug product by the pharmacist; and

~~(c) The beyond use date of the compounded drug product.~~

~~2. Except as otherwise provided in subsection 3 or in the published data or data of the manufacturer, or as otherwise determined to be earlier in the judgment of the pharmacist, the latest beyond use date of a nonsterile compounded drug product is:~~

~~(a) For nonaqueous liquids and solid formations, not later than the expiration date of the active ingredient present in the nonsterile compounded drug product with the earliest expiration date or 6 months after the date on which the nonsterile compounded drug product was compounded, whichever is earlier;~~

~~(b) For compounds which contain nonsterile water, not later than 14 days after the date on which the nonsterile compounded drug product was compounded; and~~

~~(c) For compounds other than those listed in paragraph (a) or (b), not later than the intended duration of the therapy or 30 days after the date on which the nonsterile compounded drug product was compounded, whichever is earlier.~~

~~3. Except as otherwise provided in subsection 7 of NRS 639.2801, a pharmacy may use a beyond use date that is later than the dates described in subsection 2 if the pharmacy can prove by appropriate testing or published data that the nonsterile compounded drug product is safe and effective using the extended beyond use date.~~

2. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall ensure that each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order, and any nonsterile compounded drug product that is compounded in bulk quantities is stored in the pharmacy in a manner that:

(a) Maintains the efficacy of the nonsterile compounded drug product; and

(b) Ensures that the nonsterile compounded drug product remains free from contamination.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 639.67033 Environmental standards. (NRS 639.070)** A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall:~~

~~1. Designate a specific area of the pharmacy in which nonsterile compounded drug products will be compounded;~~

~~2. Ensure that the area described in subsection 1 has adequate space in which to place, in an orderly manner, the equipment and materials that will be used in the compounding process;~~

~~3. Ensure that the area described in subsection 1 is cleaned using an antiseptic cleaning method before and after any compounding occurs in the area to prevent cross-contamination between the previously compounded drug products and any subsequently compounded drug products;~~

~~4. Ensure that any equipment used to compound a nonsterile compounded drug product is cleaned after the compounding of that drug product is completed to prevent cross-contamination from occurring when the equipment is used in the compounding process of any subsequently compounded drug products;~~

~~5. If the pharmacy compounds both nonsterile compounded drug products and sterile compounded drug products, ensure that none of the equipment which is used to compound nonsterile compounded drug products is used to compound sterile compounded drug products unless the equipment is cleaned and sanitized before the compounding of sterile compounded drug products begins; and~~

~~6. Ensure that any employee of the pharmacy who compounds nonsterile compounded drug products washes his or her hands with soap and water or with an antimicrobial agent before and after compounding nonsterile compounded drug products.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67035 Establishment of policies and procedures. (NRS 639.070) A pharmacy engaged in the practice

of compounding nonsterile compounded drug products shall, in addition to the requirements of NAC 639.67015, establish and maintain written policies and procedures for compounding nonsterile compounded drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:

1. Policies and procedures for:

- (a) Making and maintaining records concerning the components used to compound each nonsterile compounded drug product;
- (b) The amount of each component used to compound each nonsterile compounded drug product;
- (c) The order of each step in the process of compounding each nonsterile compounded drug product; and
- (d) Including the information listed in paragraphs (a), (b) and (c) on the original hard copy of the prescription maintained in the written records of the pharmacy or in a computer system that may be accessed to provide information:
 - (1) For refilling the prescription; or
 - (2) Requested by the staff of the Board.

2. Control procedures for monitoring each final nonsterile compounded drug product and validating the processes for compounding that may be responsible for causing variability in the final nonsterile compounded drug product. Such control procedures must include, without limitation, procedures for evaluating:

- (a) Any variation of more than plus or minus 10 percent in the weight of the capsules, tablets or any other solid form of a dosage of the same nonsterile compounded drug product;
- (b) The adequacy of mixing to ensure uniformity and homogeneity of each nonsterile compounded drug product;
- (c) If applicable, the clarity, completeness and pH of a nonsterile compounded drug product;
- (d) If applicable, the even distribution of coloring agents; and
- (e) Any variation of more than plus or minus 10 percent in the actual yield of a nonsterile compounded drug product compounded by the pharmacy as compared to the theoretical yield of the nonsterile compounded drug product.

3. Control procedures to ensure:

- (a) If the final nonsterile compounded drug product is a capsule, that the capsule is properly locked;
- (b) If the final nonsterile compounded drug product is a tablet or any other solid form of dosage, that the final compounded drug product is of a uniform size and is intact;
- (c) If the final nonsterile compounded drug product is a suppository, that the suppository is properly sealed;
- (d) If the final nonsterile compounded drug product is an oral liquid, that, to the extent possible, the liquid is palatable to the patient;
- (e) If the final nonsterile compounded drug product is a suspension, that the visible suspended particles are of uniform size and are readily dispersed upon shaking; and
- (f) If the final nonsterile compounded drug product is a topical compounded drug product, that the final compounded drug product is smooth and not gritty and has a uniform viscosity unless grittiness is required for a particular therapeutic purpose.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67037 Safety procedures for storage, handling, compounding and disposal; training required. (NRS 639.070)

~~1. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs shall:~~

- ~~(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;~~
- ~~(b) Handle the components of the hazardous drugs with caution by using appropriate gloves while distributing, receiving, stocking, inventorying, and preparing for administering and disposing of the components of a hazardous drug or a final compounded drug product;~~
- ~~(c) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, face masks, eye protection, double gloves or chemotherapy gloves;~~
- ~~(d) Dispose of all waste relating to compounding hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and~~
- ~~(e) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.~~

~~2. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs and dispensing compounded nonsterile hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds nonsterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:~~

- ~~(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a nonsterile hazardous drug that will be administered or dispensed to a patient; and~~
- ~~(b) At least once each year thereafter.~~

~~3. The training required pursuant to subsection 2 must, at a minimum, include information concerning:~~

- ~~(a) Safe manipulation practices that minimize exposure to the hazardous drug and protect employees of the~~

pharmacy from any overt exposure to the hazardous drug;

- (b) Procedures for containment, cleaning and disposal with regard to breaks and spills; and
 - (c) Treatment of employees of the pharmacy with regard to exposure by contact and inhalation.
4. The pharmacy shall make and keep a record of any training given pursuant to subsection 2.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Sterile Products

~~NAC 639.6705—Environmental standards. (NRS 639.070)~~

~~1. Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile-compounded drug products shall provide an ISO Class 5 environment.~~

~~2. If a pharmacy uses a laminar airflow hood as its ISO Class 5 environment within which to compound sterile-compounded drug products, the pharmacy:~~

~~(a) Shall ensure that the laminar airflow hood is located within a room with a buffer area that maintains an ISO Class 7 environment under normal conditions of use.~~

~~(b) Shall maintain an ante area or space in close proximity to any entrance to the room containing the laminar airflow hood that maintains an ISO Class 8 environment under normal conditions of use.~~

~~(c) Shall ensure that the room that contains the laminar airflow hood maintains a constant temperature and humidity that:~~

- ~~(1) Ensures the safety and efficacy of the compounded drug products, components and equipment; and~~
- ~~(2) Provides an environment in which the employees of the pharmacy can work comfortably for the duration of the compounding that will be conducted in the room.~~

~~(d) Shall require each employee of the pharmacy who enters the buffer area containing the laminar airflow hood to:~~

- ~~(1) Remove all jewelry from his or her hands and arms;~~
- ~~(2) Perform sanitizing scrubbing; and~~
- ~~(3) Wear fresh protective clothing, including, without limitation, gowns, shoe covers or dedicated shoes, and hair covers, in the ante area or space in close proximity to an entrance to the room and to remove all such items of protective clothing whenever the employee leaves the room. A gown may be used more than once within a 12-hour period if it is removed in the ante area and is stored in the ante area until it is used again.~~

~~(e) Shall require an employee to wear nonpowdered gloves and a face mask and beard cover, as applicable, before the employee enters the buffer area.~~

~~(f) Shall ensure, to the extent practicable, that all items located in or brought into the room containing the laminar airflow hood have nonporous, smooth, impermeable surfaces that:~~

- ~~(1) Can withstand being cleaned repeatedly with a disinfectant; and~~
- ~~(2) Do not shed particles which may become airborne in the room.~~

~~(g) Must have floors, walls and ceilings in the room containing the laminar airflow hood that are made of materials that can withstand being cleaned and disinfected repeatedly with solutions and products.~~

~~(h) Shall ensure, before any compounding can occur within the laminar airflow hood, that the laminar airflow hood is used according to the manufacturer's directions with regard to starting and using the laminar airflow hood in a manner which ensures that the interior of the laminar airflow hood creates and maintains an ISO Class 5 environment.~~

~~(i) Shall ensure that:~~

~~(1) The ISO Class 5 environment is cleaned:~~

- ~~(I) At the beginning of each work shift;~~
- ~~(II) Before the compounding of each batch preparation begins;~~
- ~~(III) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;~~
- ~~(IV) After there has been a spill within the ISO Class 5 environment; and~~
- ~~(V) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.~~

~~(2) The counters and easily cleanable work surfaces in close proximity to the laminar airflow hood and in, or in close proximity to, the buffer area are cleaned at least once each day in which the ISO Class 5 environment is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.~~

~~(3) The floors are cleaned at least once each day in which the ISO Class 5 environment is used and whenever the floors may require cleaning as a result of its use throughout the working day.~~

~~(4) The walls, ceilings, storage, shelving and other surfaces that are not easily cleaned are cleaned at least once each month.~~

~~3. If a pharmacy uses a barrier isolator cabinet that maintains an ISO Class 5 environment at all times when it is in use as its ISO Class 5 environment within which to compound sterile-compounded drug products, the pharmacy shall ensure that:~~

~~(a) The barrier isolator cabinet is placed in the pharmacy at a location where:~~

- ~~(1) The compounding may occur without interruption or inconvenience; and~~
- ~~(2) The barrier isolator cabinet will not be compromised by its proximity to air vents, doorways or other~~

pharmacy fixtures or equipment.

~~(b) Before any compounding may occur within the barrier isolator cabinet, the barrier isolator cabinet is used according to the manufacturer's directions with regard to starting and using the barrier isolator cabinet in a manner which ensures that the interior of the barrier isolator cabinet creates and maintains an ISO Class 5 environment.~~

~~(c) The barrier isolator cabinet is cleaned:~~

~~(1) At the beginning of each work shift;~~

~~(2) Before the compounding of each batch preparation begins;~~

~~(3) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;~~

~~(4) After there has been a spill within the ISO Class 5 environment; and~~

~~(5) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.~~

~~(d) The counters and easily cleanable work surfaces in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.~~

~~(e) The floors in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever the floors may require cleaning as a result of its use throughout the working day.~~

~~4.—A barrier isolator cabinet that cannot maintain an ISO Class 5 environment at all times when it is being used shall be deemed a laminar airflow hood for purposes of satisfying the requirements of this section.~~

~~5.—As used in this section, "batch preparation" means the compounding of multiple units of sterile compounded drug products, not for immediate use, in a single process by the same person.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67051—Air quality testing and certification. (NRS 639.070)

~~1.—Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall test the air in each of its controlled environments to ensure that the environments attain the air quality required by the provisions of NAC 639.661 to 639.690, inclusive, for an ISO Class 5, ISO Class 7 or ISO Class 8 environment, as applicable.~~

~~2.—The air quality testing required by subsection 1 must be performed randomly with regard to:~~

~~(a) The time of day the air samples are collected;~~

~~(b) The staff who is on duty when the samples are gathered; and~~

~~(c) The locations within the pharmacy from which the samples are collected.~~

~~3.—A pharmacy engaged in the practice of compounding sterile compounded drug products shall have its ISO Class-5 environment certified pursuant to subsection 4:~~

~~(a) At least twice each year; and~~

~~(b) Before compounding a sterile compounded drug product after:~~

~~(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;~~

~~(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;~~

~~(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or~~

~~(4) The laminar airflow hood or barrier isolator cabinet is repaired.~~

~~4. The certification required by subsection 3 must be completed by a person who is independent of the pharmacy requesting the certification and who is capable of certifying that the ISO Class 5 environment can satisfy and maintain the minimum requirements set forth in NAC 639.6641 for air quality under normal conditions of use.~~

~~5.—A pharmacy engaged in the practice of compounding sterile compounded drug products shall have each of its ISO Class 7 and ISO Class 8 environments tested or certified pursuant to subsection 7 for particulates:~~

~~(a) At least twice each year; and~~

~~(b) Before compounding a sterile compounded drug product after:~~

~~(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;~~

~~(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;~~

~~(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or~~

~~(4) A laminar airflow hood or barrier isolator cabinet is added to or removed from the room that contains the laminar airflow hood or barrier isolator cabinet.~~

~~6.—The air quality testing required by subsection 5 must be performed randomly with regard to:~~

~~(a) The time of day the air samples are collected;~~

~~(b) The staff who are on duty when the samples are gathered; and~~

~~(c) The locations within the pharmacy from which the samples are collected.~~

~~7.—The testing or certification required by subsection 5 must be completed by the pharmacy or by a person who is~~

independent of the pharmacy requesting the certification and who is capable of testing or certifying that the ISO Class 7 or ISO Class 8 environment can satisfy and maintain the minimum requirements set forth in NAC 639.6643 and 639.6645, respectively, for air quality under normal conditions of use.

8. If the pharmacy performs the testing or certification required by subsection 5, the testing or certification process of the pharmacy must be validated semiannually by the managing pharmacist.

9. If any of the results of the air quality testing or certification required by this section exceed the tolerances set forth in NAC 639.6641, 639.6643 and 639.6645, for the particular controlled environment, the pharmacy shall take whatever action is necessary to remediate the deficiency and retest the environment until the environment produces results within the tolerances for the particular controlled environment.

10. The pharmacy shall make and maintain records concerning the air quality testing and certification and any corrections and retesting that were conducted pursuant to this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67053 Tests for competency and proficiency of certain pharmaceutical personnel. (NRS 639.070)

1. Except as otherwise provided in subsections 4 and 5, a 1. A pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which must be conducted compound in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform:

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile compounded drug product that will be administered or dispensed to a patient;

(b) At least once each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound low risk sterile compounded drug products or medium risk sterile compounded drug products; and

(c) At least twice each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound high risk sterile compounded drug products.

2. A pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall ensure the competency and proficiency of each pharmacist and pharmaceutical technician who compounds at the highest level of risk of compounding sterile compounded drug products the pharmacist or pharmaceutical technician is authorized by the pharmacy to perform by:

(a) Requiring the pharmacist or pharmaceutical technician to provide a sample for a gloved fingertip sampling which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;

(b) Testing a sample taken from a surface cleaned by the pharmacist or pharmaceutical technician to determine sterility;

(c) Ensuring the pharmacist or pharmaceutical technician receives, on an ongoing basis, sufficient training to maintain that competency and proficiency through attending in-house training programs or continuing education courses;

(d) Observing the pharmacist or pharmaceutical technician as he or she compounds sterile compounded drug products; or

(e) Correcting any error and initiating remedial measures for a pharmacist or pharmaceutical technician to take after an error has been noted with a sterile compounded drug product that was made or verified by the pharmacist or pharmaceutical technician.

2. A pharmacy shall make and maintain records concerning all the actions listed in subsection 1 2 which the pharmacy takes to ensure the competency and proficiency of each pharmacist and pharmaceutical technician who is authorized by the pharmacy to compound sterile compounded drug products.

3. A sterile compounded drug product that is compounded by a pharmacist or pharmaceutical technician who has not passed the media fill test required by paragraph (a) of subsection 1 may be dispensed and administered to a patient if:

a. The managing pharmacist of the pharmacy determines that it is appropriate to dispense and administer the sterile compounded drug product; and

b. The entire compounding process was personally witnessed by a pharmacist or pharmaceutical technician who passed the media fill test.

4. A pharmacy is not required to make a pharmacist or pharmaceutical technician pass a media fill test pursuant to paragraph (a) of subsection 1 if the pharmacist or pharmaceutical technician provides evidence of passing a media fill test:

a. Within the immediately preceding 9 months if the pharmacist or pharmaceutical technician will compound low risk sterile compounded drug products and medium risk sterile compounded products; or

b. Within the immediately preceding 5 months if the pharmacist or pharmaceutical technician will compound high

~~risk sterile compounded drug products.~~

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67055 Record verifying accuracy required to be made. (NRS 639.070)

1. For all sterile compounded drug products compounded by a pharmacy, other than an institutional pharmacy, and for all sterile drug products for parenteral nutrition and sterile antineoplastic drug products compounded by an institutional pharmacy, a pharmacist shall make a record verifying the accuracy of each sterile compounded drug product that the pharmacist:

- (a) Compounded;
- (b) Verified the accuracy of after it was compounded by a pharmaceutical technician; or
- (c) Dispensed for administration to a patient in a medical facility.

2. A pharmacist required to make a record pursuant to subsection 1 shall:

(a) Make the record contemporaneous with the completion of the compounding, verifying or dispensing of the sterile compounded drug product;

(b) Include in the record information identifying the patient for which the sterile compounded drug product was made and the date the sterile compounded drug product was compounded; and

(c) Initial the record if it is a written record or enter an initial or other identifying mark onto the record if the record is made in a computerized system.

3. A pharmacy for which a record was made pursuant to subsection 1 shall ensure that the record is maintained for at least 6 months after the date the sterile compounded drug product was compounded, verified or dispensed.

4. If a sterile compounded drug product is compounded by a pharmaceutical technician, the pharmaceutical technician shall make a record of the compounding in the same manner as a pharmacist is required to make a record pursuant to this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67057 Procedures following breach of seal of single-dose and multi-dose containers. (NRS 639.070)

~~1. If, in the course of compounding a drug product, the seal of a single dose container, including, without limitation, a bag, bottle, syringe or vial of a sterile drug product, is breached, the time and date of the breach must be marked upon the container and the contents of the container may be used:~~

~~(a) Within 1 hour after the breach of the seal if:~~

~~(1) The breach occurred in an environment with an air quality that is worse than ISO Class 5; and~~

~~(2) The container is subsequently stored in an environment with an air quality that is worse than ISO Class 7;~~

~~(b) Within 6 hours after the breach of the seal if:~~

~~(1) The breach of the seal occurred and the contents of the container were used in an environment with an air quality that satisfies or exceeds ISO Class 5; and~~

~~(2) The container is subsequently stored in an environment with an air quality that satisfies or exceeds ISO Class 7; or~~

~~(c) Within 24 hours after the breach of the seal if the breach occurred in an environment with an air quality that satisfies or exceeds ISO Class 5 and the container remains in an environment with an air quality that satisfies or exceeds ISO Class 5.~~

2. (1) If, in the course of compounding a drug product, the seal of a multi-dose container is breached:

(a) The container must be stored according to the requirements of the manufacturer; and

(b) The contents of the container may be used within 28 days after the breach of the seal occurred.

3. (2) Any drug product that is not used within the periods set forth in subsection 1 or 2 may not be used and must be destroyed.

4. (3) If the seal of a single-use ampule is breached or the entire seal has been removed from a multi-use vial and the contents are not used at the time of the breach, the contents may not be used and must be destroyed.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~NAC 639.67059 Exemptions for certain institutional pharmacies. (NRS 639.070) The Board may, upon application and for good cause shown, waive or modify any requirement set forth in NAC 639.6705 and 639.67051 for an institutional pharmacy engaged in the practice of compounding drug products if the institutional pharmacy serves an institution that:~~

~~1. Has less than 100 beds licensed for providing acute care; and~~

~~2. Is located in a county:~~

~~(a) Whose population is less than 100,000; or~~

~~(b) Whose population is 100,000 or more if the hospital is designated as a rural hospital by the Nevada Office of Rural Health within the University of Nevada School of Medicine.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67061—Low-risk sterile compounding: Process and storage. (NRS 639.070)

1. A compounded drug product is a low-risk sterile compounded drug product if:

- (a) The compounded drug product is required to be sterile for its effective administration;
- (b) The sterile compounded drug product is at a low risk of contamination; and
- (c) One or more of the following conditions are present:

(1) The compounding process involves aseptic manipulations that are performed entirely within an environment with an air quality of at least ISO Class 5 and uses only sterile ingredients, products, components and devices;

(2) The compounding process involves only transferring, measuring and mixing manipulations and uses not more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(3) The manipulations needed to compound the drug product are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile drug products and containers for storage and dispensing;

(4) The final compounded drug product contains a volume of 15 milliliters or less of a radiopharmaceutical and has an expiration time of 18 hours or less per dosage unit, including, without limitation, a dosage unit of a radiopharmaceutical prepared from an eluate by using a molybdenum-99technetium-99m generator; or

(5) The final compounded drug product contains commercially manufactured cyclotron radiopharmaceuticals which contain preservatives and which have expiration times of 72 hours or less.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a low-risk sterile compounded drug product must not exceed:

(a) Forty-eight hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Fourteen days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67063—Low-risk sterile compounding: Radiopharmaceutical drug products. (NRS 639.070) If a nuclear pharmacy compounds radiopharmaceutical drug products, the nuclear pharmacy shall ensure that, in addition to satisfying the requirements of NAC 639.5828:

1. The radiopharmaceutical compounded drug products are compounded in a vertical laminar airflow hood or Class II type B2 biological safety cabinet that is located in an environment with an air quality of ISO Class 8 or higher;

2. Only shielded vials, syringes and other devices and containers specifically manufactured for use with radiopharmaceutical components are used in the compounding process;

3. Each employee of the nuclear pharmacy who will compound radiopharmaceutical drug products is trained and knowledgeable with regard to compounding, handling, cleaning and any special techniques used with radiopharmaceutical drug products; and

4. Any special equipment or device that is used to compound radiopharmaceutical products, including, without limitation, a molybdenum-99technetium-99m generator, is used, stored and maintained according to the directions of the manufacturer of the equipment or device.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67065—Medium-risk sterile compounding: Process and storage. (NRS 639.070)

1. A compounded drug product is a medium-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is compounded using aseptic techniques pursuant to one of the conditions listed in NAC 639.67061 as a condition for a low-risk sterile compounded drug product; and

(c) One or more of the following conditions are present:

(1) Individual or small doses of sterile drug products are combined or pooled to prepare the final compounded drug product that will be administered to multiple patients or to one patient multiple times;

(2) The compounding process includes complex aseptic manipulations other than a single-volume transfer;

(3) The compounding process uses more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(4) The final compounded drug product does not contain broad-spectrum bacteriostatic substances and will be administered over a period which exceeds 24 hours; or

(5) The compounding process requires an unusually long duration, as determined by the managing pharmacist, including, without limitation, the period required to complete dissolution or homogeneous mixing.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before

administration of a medium-risk sterile compounded drug product must not exceed:

- (a) Thirty hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);
 - (b) Nine days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or
 - (c) Forty five days in a solid frozen state that is 10 degrees Celsius (14 degrees Fahrenheit) or colder.
- (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~NAC 639.67067—High-risk sterile compounding: Process and storage. (NRS 639.070)~~

~~1.—A compounded drug product is a high-risk sterile compounded drug product if:~~

- ~~(a) The compounded drug product is required to be sterile for its effective administration;~~
- ~~(b) The sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and~~
- ~~(c) One or more of the following conditions are present:~~
 - ~~(1) One or more of the ingredients or devices used in the compounding process are nonsterile; or~~
 - ~~(2) One or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment.~~

~~2.—Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed:~~

- ~~(a) Twenty four hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);~~
 - ~~(b) Three days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or~~
 - ~~(c) Forty five days in a solid frozen state that is 10 degrees Celsius (14 degrees Fahrenheit) or colder.~~
- (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~NAC 639.67069—High-risk sterile compounding: Sterilization. (NRS 639.070)~~

~~1.—Except as otherwise provided in subsection 5, a pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products shall ensure that each such compounded drug product is sterilized through filtration, by using steam in an autoclave or by dry heat. Except as otherwise provided in subsection 5, a pharmacist engaged in the practice of compounding high-risk sterile compounded drug products shall choose the method of sterilization that ensures the strength, purity, quality and packaging integrity of the final compounded drug product.~~

~~2.—If a pharmacy sterilizes high-risk sterile compounded drug products using the filtration method, the pharmacy shall:~~

~~(a) Use commercially available sterile filters that are:~~

- ~~(1) Pyrogen-free and have a nominal porosity of 0.2 micron or 0.22 micron; and~~
- ~~(2) Certified by the manufacturer to retain at least 10⁷ microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* on each square centimeter of upstream filter surface area under conditions similar to the conditions of sterilization of the high-risk compounded drug products;~~

~~(b) Ensure that the filters used have sufficient capacity to permit the sterilization process to be completed rapidly and without compromising the sterility of the filtration process; and~~

~~(c) Subject the filtration units to the manufacturer's recommended integrity testing, including, without limitation, the bubble point test, after the filtration of the high-risk sterile compounded drug products is completed.~~

~~3.—If a pharmacy sterilizes high-risk sterile compounded drug products using steam in an autoclave, the pharmacy shall:~~

~~(a) Expose each high-risk sterile compounded drug product to steam at 121 degrees Celsius (250 degrees Fahrenheit) under a pressure of 15 pounds per square inch for the duration of the sterilization process;~~

~~(b) Before starting the sterilization process, ensure that plastic, glass and metal devices are wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent microbial penetration after the sterilization of the high-risk sterile compounded drug products is completed;~~

~~(c) Ensure that the solutions that will be used to fill the vials which will be steam sterilized are passed through a filter having a porosity of not more than 1.2 microns to remove particulate matter immediately before filling those vials; and~~

~~(d) Verify the mass of the container that will be sterilized using steam in an autoclave to ensure that the container will be sterile after the period of exposure in that autoclave.~~

~~4.—If a pharmacy sterilizes high-risk sterile compounded drug products using dry heat, the pharmacy shall ensure that:~~

~~(a) The heated air is filtered and evenly distributed by a blower throughout the chamber or oven used for the sterilization process; and~~

~~(b) The chamber or oven used for the sterilization process is equipped with accurate temperature controls and a timer.~~

~~5. A pharmacy may only use dry heat as a method of sterilization for a high-risk sterile compounded drug product if the final high-risk sterile compounded drug product would be damaged by moisture or is impermeable to moisture.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

~~NAC 639.67071 High-risk sterile compounding: Testing of certain drug products. (NRS 639.070)~~

~~1. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for injection into the vascular system or central nervous system shall test a quantity of the high-risk sterile compounded drug product for:~~

~~(a) Sterility using a membrane filtration method or an equivalent method, as determined by the Board, before any of the compounded drug product may be administered or dispensed to a patient; and~~

~~(b) Excessive bacterial endotoxins using an appropriate test, as determined by the Board, for the particular product at issue before any of the compounded drug product may be administered or dispensed to a patient.~~

~~2. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for inhalation or ophthalmic use shall test a quantity of each such high-risk sterile compounded drug product for sterility.~~

~~3. The provisions of subsections 1 and 2 apply only to high-risk sterile compounded drug products:~~

~~(a) Compounded in groups of more than 25 identical individual single-dose packages;~~

~~(b) Compounded in multiple-dose vials for administration to multiple patients; or~~

~~(c) That will be exposed for a period of more than:~~

~~(1) Twelve hours to temperatures of at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or~~

~~(2) Six hours to temperatures exceeding 8 degrees Celsius (46 degrees Fahrenheit) before the compounded drug product is sterilized.~~

~~4. If any high-risk sterile compounded drug product tested pursuant to this section tests positive for antimicrobial growth or endotoxin production, the high-risk sterile compounded drug product must not be administered or dispensed to a patient.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

~~NAC 639.67073 Immediate-use sterile compounding: Preparation and labeling. (NRS 639.070)~~

~~1. A sterile compounded drug product is an immediate-use sterile compounded drug product if:~~

~~(a) The compounded drug product is intended only for the purpose of emergency care or immediate care of a patient;~~

~~(b) The compounding of the drug product occurs in an environment other than an ISO-Class 5 environment and the compounding process consists of simple aseptic measuring and transfer manipulations performed with not more than six sterile nonhazardous commercial drug products and diagnostic radiopharmaceutical drug products, excluding infusion solutions or diluents;~~

~~(c) The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour unless a period longer than 1 hour is required for the reconstitution of the compounded drug product;~~

~~(d) During compounding and before the administration of the compounded drug product, no part of the drug product or critical surfaces and ingredients of the drug product is directly exposed to contact contamination, including, without limitation, human touch, cosmetic flakes or particulates, blood or other bodily substances of a person or nonsterile inanimate sources; and~~

~~(e) Except as otherwise provided in paragraph (c), the administration of the compounded drug product begins not later than 1 hour after the start of the preparation of the compounded drug product and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the compounded drug product began or the compounded drug product is disposed of promptly and safely.~~

~~2. (1) If an immediate-use sterile compounded drug product is not immediately administered by direct injection into a patient by the person who compounded it, the compounded drug product must bear a label which includes, without limitation:~~

~~(a) The name and, if the patient has an identification number, the identification number of the patient;~~

~~(b) The name and amount of each ingredient of the compounded drug product;~~

~~(c) The initials of the person who compounded the compounded drug product; and~~

~~(d) The exact date and time of expiration of the compounded drug product.~~

~~3. (2) An immediate-use sterile compounded drug product must not be stored for later use. (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

~~NAC 639.67075 Immediate-use sterile compounding: Compounding standards. (NRS 639.070)~~

~~1. An immediate-use sterile compounded drug product that contains three or less commercial sterile drug products that will be stored more than 1 hour before administration is begun must comply with all compounding standards~~

~~applicable to low-risk sterile compounded drug products.~~

~~2. An immediate use sterile compounded drug product which contains more than three commercial sterile drug products or which requires complex manipulations or complex preparation must comply with all compounding standards applicable to medium-risk sterile compounded drug products.~~

~~3. An immediate use sterile compounded drug product that contains one or more nonsterile ingredients or components must comply with all compounding standards applicable to high-risk sterile compounded drug products.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67077 Sterile hazardous drugs: Safety procedures for storage, handling, compounding and disposal. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding sterile hazardous drugs shall:

(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;

(b) Handle the components of the hazardous drugs with caution by using appropriate gloves during preparation, handling and disposal of the components of the hazardous drug or final compounded drug product;

(c) Compound the hazardous drugs pursuant to the requirements set forth in NAC 639.661 to 639.690, inclusive, and applicable to the risk level of the compounded hazardous drugs;

(d) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, gloves, face masks, hair covers, shoe covers or dedicated shoes, and, if the hazardous drugs contain one or more antineoplastic agents or it is recommended by the drug manufacturer, double gloves or chemotherapy gloves;

(e) Dispose of all waste relating to the compounding of the hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and

(f) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.

2. A pharmacy shall ensure that the process of compounding sterile hazardous drugs is performed only in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator if one or more of the components of the hazardous drug are:

(a) An antineoplastic drug;

(b) A radiopharmaceutical drug; or

(c) A drug whose manufacturer has recommended that the drug only be compounded in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator.

3. The biological safety cabinet or compounding aseptic containment isolator described in paragraph (c) of subsection 2 must be vented to outside air during the compounding process through the use of high efficiency particulate air filtration if one or more of the components of the compounded hazardous drug are antineoplastic drugs.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67079 Sterile hazardous drugs: Required training for certain pharmaceutical personnel. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding sterile hazardous drugs and dispensing sterile compounded hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds sterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile hazardous drug that will be administered or dispensed to a patient; and

(b) At least once each year thereafter.

2. The training required pursuant to subsection 1 must include, at a minimum, information concerning:

(a) Safe aseptic manipulation practices;

(b) Negative pressure techniques for use with a biological safety cabinet, compounding aseptic containment isolator or compounding aseptic isolator;

(c) The correct use of a vial transfer device in a closed system;

(d) Procedures for containment, cleaning and disposal with regard to breaks and spills; and

(e) Treatment of employees of the pharmacy with regard to contact and inhalation exposure.

3. The pharmacy shall make and keep a record of any training given pursuant to subsection 1.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Parenteral Solutions

NAC 639.672 Reference materials required to be located in or immediately available to pharmacy. (NRS 639.070, 639.2807) Any pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have current reference materials located in or immediately available to the pharmacy. The reference materials must

include information on:

1. All drugs and chemicals used in services related to parenteral therapy; and
2. The activities involved in parenteral therapy, including manufacturing, dispensing, distribution and counseling.
(Added to NAC by Bd. of Pharmacy, eff. 8-14-87)

NAC 639.680 Labeling. (NRS 639.070, 639.2807)

1. In addition to any other requirements for labeling, the label of any parenteral solution must include:
 - (a) The name and concentrations of all ingredients contained in the parenteral solution, including the primary solution; and
 - (b) Instructions for storage and handling.
2. The label of a parenteral solution which is used by a patient in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located in that medical facility must include the telephone number of the pharmacy that furnished the parenteral solution.
3. Any cytotoxic agent must bear a special label which states:
 - (a) "Chemotherapy - Dispose of Properly;" or
 - (b) "Biohazard - Dispose of Properly."
4. As used in this section, "biohazard" means a biological agent that may be hazardous to persons or the environment.
(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

NAC 639.682 Record for each patient. (NRS 639.070, 639.2807)

1. A pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have on the premises or readily accessible:
 - (a) A record for each patient being treated with parenteral therapy;
 - (b) A summary of the most recent hospitalization of the patient or the patient's medical history; and
 - (c) Any notes taken by the pharmacist concerning the progress of the patient which document any contact with the patient or the practitioner concerning the parenteral therapy.
2. In addition to any other requirements for keeping records, the following records must be maintained in the pharmacy:
 - (a) Records concerning any prescriptions and medical supplies furnished to the patient.
 - (b) Information relevant to the patient's parenteral therapy, including, but not limited to:
 - (1) The patient's name, age, height, weight, sex and address and the telephone number of the location where the patient is receiving parenteral therapy;
 - (2) The diagnosis of the patient; and
 - (3) The patient's history of medication, including his or her current regimen concerning diet and medication and any allergies to drugs or food.
 - (c) Data of a laboratory relevant to the parenteral therapy.
 - (d) If the patient is using a parenteral solution in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located in that medical facility, records indicating that the care of the patient is coordinated by the pharmacy, practitioner and nursing personnel before the administration of the parenteral solution, including:
 - (1) Documentation of all orders for medication, laboratory tests or other treatment related to the medication of the patient.
 - (2) Documentation of all orders given by a practitioner which were communicated to nursing personnel by a pharmacist.
 - (3) Documentation that a total assessment of the patient has been performed.
 - (4) Documentation that a plan for the parenteral therapy of the patient has been developed by the pharmacy. The plan must include:
 - (I) The identification of any problem related to a drug that is administered to the patient; and
 - (II) Any suggested solution for that problem and the monitoring of the results of the therapy.
3. As used in this section, "total assessment" means an evaluation of the circumstances of the administration of parenteral therapy to a patient in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located within that medical facility that includes a review of:
 - (a) The state of the disease of the patient;
 - (b) The regimen of medication of the patient;
 - (c) The medical history of the patient;
 - (d) Any therapies other than parenteral therapy administered to the patient; and
 - (e) If the patient is using the parenteral solution in the patient's home, the ability of the patient to receive parenteral therapy in his or her home.
(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

NAC 639.683 Delivery, storage and recordation of delivery. (NRS 639.070, 639.2807) A managing pharmacist shall ensure that:

1. A sterile parenteral solution is furnished to a patient in a container which is capable of maintaining the appropriate temperature for the storage of the sterile parenteral solution;
2. A patient is advised of the appropriate conditions for the storage and disposal of the sterile parenteral solution; and
3. The delivery of a controlled substance listed in schedule II, as set forth in NAC 453.520, is documented and a receipt which indicates that the patient received that controlled substance is included with the records maintained at the pharmacy.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.686 Written policies and procedures for disposal of infectious materials and materials containing cytotoxic residues. (NRS 639.070, 639.2807) In addition to the requirements of NAC 639.67015 and 639.67017, any pharmacy providing parenteral solutions shall have written policies and procedures for the disposal of infectious materials and materials containing cytotoxic residues. The procedures must contain methods for the cleanup of spills and must be in conformance with the regulations of the local health authority. The pharmacy shall ensure the return of infectious materials and materials containing cytotoxic residues to the pharmacy or shall inform the provider of care of the procedures for the proper destruction of such materials.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A by R035-06, 9-18-2008)

NAC 639.688 Written policies and procedures regarding provision of services related to parenteral therapy. (NRS 639.070, 639.2807) In addition to the requirements of NAC 639.67015 and 639.67017, any pharmacy, other than an institutional pharmacy, engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures relating to:

1. The qualifications and training of employees of the pharmacy to compound and dispense parenteral solutions.
2. A determination of the necessity for administering the medication a patient requires in a parenteral form.
3. The compounding and control of the quality of parenteral solutions.
4. The distribution and delivery of parenteral solutions.
5. The clinical monitoring of parenteral therapy.
6. The availability of a practitioner, pharmacist and nursing personnel during the administration of parenteral therapy to a patient.
7. The availability of products and equipment which are necessary during the administration of parenteral therapy to a patient.
8. The communication of orders among the practitioner, pharmacist and nursing personnel for a patient who requires parenteral therapy.
9. The coordination of the care of a patient who requires parenteral therapy by the pharmacist, practitioner and nursing personnel, including documentation of participation in any conference relating to the care of that patient.
10. The education of a patient relating to:
 - (a) The self-administration of a parenteral solution;
 - (b) The proper maintenance and storage of a parenteral solution; and
 - (c) The operation of devices used to administer parenteral solutions.
11. The cleaning and maintenance of equipment used to administer a parenteral solution furnished to a patient by the pharmacy.
12. The provision of services relating to parenteral therapy furnished by the pharmacy in an emergency.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94; R035-06, 9-18-2008)

NAC 639.690 Pharmacist: Consultation with patient; proper training in safe handling, compounding and therapy related to parenteral solutions. (NRS 639.070, 639.2807)

1. Any pharmacy furnishing parenteral solutions shall ensure that a pharmacist is available 24 hours a day for consultation with the patient and the patient's primary provider of care concerning the proper use of any parenterals and related supplies furnished by the pharmacy.
2. The managing pharmacist shall ensure that all pharmacists engaging in compounding parenteral solutions have the proper training in the safe handling, compounding and therapy related to parenteral solutions, including cytotoxic agents.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

OUTSOURCING FACILITIES

NAC 639.691 Definitions. (NRS 639.070, 639.100) As used in NAC 639.691 to 639.6916, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.6911, 639.6912 and 639.6913 have the meanings

ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6911 “Compounding” defined. (NRS 639.070, 639.100) “Compounding” includes, without limitation, the combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6912 “Outsourcing facility” defined. (NRS 639.070, 639.100) “Outsourcing facility” means a facility at one geographic location or address that:

1. Is engaged in the compounding of sterile drugs; and
2. Has registered with the Secretary of Health and Human Services as an outsourcing facility pursuant to 21 U.S.C. § 353b.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6913 “Sterile drug” defined. (NRS 639.070, 639.100) “Sterile drug” means a drug that is:

1. Intended for parenteral administration;
2. An ophthalmic or oral inhalation drug in aqueous format; or
3. Required to be sterile pursuant to the provisions of federal law or the provisions of NAC 639.661 to 639.690, inclusive.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6915 Duties of facility. (NRS 639.070, 639.100) An outsourcing facility that is engaged in the compounding of sterile drugs in this State 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 by submitting an application on a form prescribed by the Board;
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.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015; A by R025-21, 4-11-2022)

NAC 639.6916 When licensure as pharmacy required. (NRS 639.070, 639.100)

1. Except as otherwise provided in subsection 2, an outsourcing facility is not required to be licensed as a pharmacy.
2. An outsourcing facility may dispense dangerous drugs or controlled substances for identified individual patients pursuant to a prescription only if the outsourcing facility is licensed by the Board as a pharmacy in accordance with NRS 639.230 or 639.2328, as applicable.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.757 Preparation and sale of compounded drugs by pharmacy or pharmacist: License as manufacturer not required under certain circumstances; unsafe or ineffective drug; restrictions on sale. (NRS 639.070)

1. A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if:
 - (a) The compounded drugs are prepared in a quantity that is:
 - (1) Necessary to fill a prescription or chart order; or
 - (2) Reasonably necessary to fill future prescriptions or chart orders based upon the previous history of practitioners and patients who regularly use the pharmacy;
 - (b) The compounded drugs are not sold or otherwise provided by the pharmacy or pharmacist to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs ~~or a practitioner who will be administering the drugs to a patient;~~
 - (c) The compounded drugs are dispensed pursuant to a prescription or chart order;
 - (d) ~~Except as otherwise provided in paragraph (e) and subsection 2, the~~ The following active ingredients may be used to compound ~~the~~ drugs:
 - (1) Comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;
 - (2) Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or
 - (3) Appear on FDA’s list of bulk drug substances that can be used in compounding (the 503A) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product; or

(4) Outsourcing facilities, may only compound using bulk drug substances (503B bulks list) or products that appear on FDA's drug shortage list at the time of compounding and dispensing.

~~(1) Are authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto; and~~

~~(e) Except as otherwise provided in subsection 2, for an active ingredient used to compound the drugs that does not have a monograph in the United States Pharmacopoeia—National Formulary, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, the active ingredient is:~~

~~(1) Prepared by a manufacturer or distributed by a distributor registered with the Food and Drug Administration;~~

~~(2) Accompanied by a certificate of analysis provided by the manufacturer or distributor of the ingredient; and~~

~~(3) Prepared to a grade that, at a minimum, satisfies the requirements set forth in:~~

~~(I) The Food Chemicals Codex, as adopted by reference in paragraph (d) of subsection 1 of NAC 639.670; or~~

~~(II) Reagent Chemicals: Specifications and Procedures, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, if the active ingredient is a certified analytical reagent, is for use in high pressure liquid chromatography, is for use in spectrophotometric applications or is a primary standard grade for use in standard solutions for analytical purposes;~~

~~2. In compounding a drug product, a pharmacy or pharmacist may use an active ingredient that does not satisfy the requirements of paragraphs (d) and (e) of subsection 1 if the pharmacy or pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient. A pharmacy shall make and maintain a record of the means that the pharmacy relied upon in determining that an ingredient was pure and safe pursuant to this subsection.~~

~~3. Except as otherwise provided in this subsection, a pharmacy or pharmacist shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective. A pharmacy or pharmacist may compound a drug for veterinary use that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective for use in humans if the drug remains available for veterinary use.~~

~~4. A pharmacy shall not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner, except that a pharmacy may sell or otherwise provide a compounded drug to:~~

~~(a) A practitioner who will be administering the drug to a patient; or~~

~~(b) A practitioner or another pharmacy if the compounded drug is:~~

~~(1) A highly concentrated drug product that is not commercially available; or~~

~~(2) Needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy;~~

~~5. The quantity of a compounded drug that is sold or otherwise provided to a practitioner or pharmacy pursuant to subsection 4 must not exceed the amount necessary for the practitioner or pharmacy to serve the present needs of the patients of the practitioner or pharmacy.~~

(Added to NAC by Bd. of Pharmacy by R032-02, eff. 5-31-2002; A by R035-06, 9-18-2008)

18B

Compounding
Public Comment

From: Chad Baker <CBaker@flavorx.com>
Sent: Friday, January 12, 2024 1:28 PM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Subject: Public Comment for 1/17 -1/18 Board of Pharmacy Meeting

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Members and Staff of the Nevada State Board of Pharmacy,

Thank you for providing me the opportunity to submit comments for your consideration at the upcoming Board of Pharmacy meeting. The attached pdf contains information I hope the Board finds relevant to the discussion around non-sterile compounding and USP 795 standards.

Regards,

Chad

Chad Baker | Senior VP, Government Relations | p: [REDACTED] | [REDACTED] Gerwig Lane, Columbia, MD 21046





January 12, 2024

To the Board Members and Staff of the Nevada State Board of Pharmacy,

I am writing in hopes that this letter will be reviewed and considered as part of the Board's discussion of USP compounding standards. While FLAVORx is not a Nevada-based company, we supply 279 pharmacies in your state with pediatric medication flavoring systems. I am writing on their behalf, and on behalf of the thousands of children and parents who benefit from medicine flavoring in Nevada every year.

Like most State Boards of Pharmacy, the Nevada State Board of Pharmacy does not currently subject the flavoring of commercially available pediatric liquid medications to USP compounding standards. This has been the case for more than two decades. Over those 20+ years, we estimate our Nevada-based pharmacy partners have flavored at least 2 million children's medications without a single incident of harm coming to a child. In fact, the whole point of flavoring is to prevent children from being harmed due to poor compliance to their medication regimens. Flavoring is one of the best tools pharmacists have to improve children's health outcomes.

Simply put, if the flavoring of commercially available medications suddenly becomes burdened with the new USP 795 requirements, you will see pharmacies cease to offer the service to their customers immediately. The time it takes to comply, the cost to comply, and the risk of being cited for non-compliance makes it impossible for most pharmacies to continue offering this basic pharmacy service. This very thing happened recently in California. Access to a widely available, highly valued pharmacy service in California dropped by 99.5% when the California State Board of Pharmacy made it clear they would subject flavoring to USP 795 standards in November. I encourage you to visit our website www.flavorx.com/regulatory-california for a quick glance at how stark the landscape has become in California. There is no reason to believe the same will not happen in Nevada if the Nevada State Board of Pharmacy follows California's lead. 279 pharmacies

currently providing medication flavoring to parents and children in urban, suburban, and rural settings across Nevada will drop to 2. The attached maps demonstrate what that will look like for parents and children across the state.

Most State Boards of Pharmacy have taken a more pragmatic approach to medication flavoring. Many say outright that flavoring is not compounding. Some do not go that far, yet they do not subject flavoring to USP 795 standards, provided basic safety, quality, and documentation guardrails are in place for the flavoring ingredients and processes being used. We created this website www.flavorx.com/regulatory to serve as an easy reference for how flavoring is treated across the country. Kentucky, Michigan, Missouri, Utah, Vermont, and West Virginia are good models for pragmatic language if the Board is looking for guidance in that regard.

A quick word on FLAVORx, who we are and what we do. We have been in business for over 25 years. Our mission is to improve pediatric compliance by giving kids a choice in how their medicine tastes and improving the palatability of said medicine. We supply over 35,000 pharmacies across the country with standardized flavoring systems, many of which are now fully automated reconstitution & flavoring machines. We test our flavors to ensure they do not impact the potency or pH of medications. Over 200 million liquid medications have been flavored with our products without a single reported incident of harm. I hope this provides the Board with some comfort that there are safe and effective ways to flavor children's medicines without the need for layers of new, burdensome regulations.

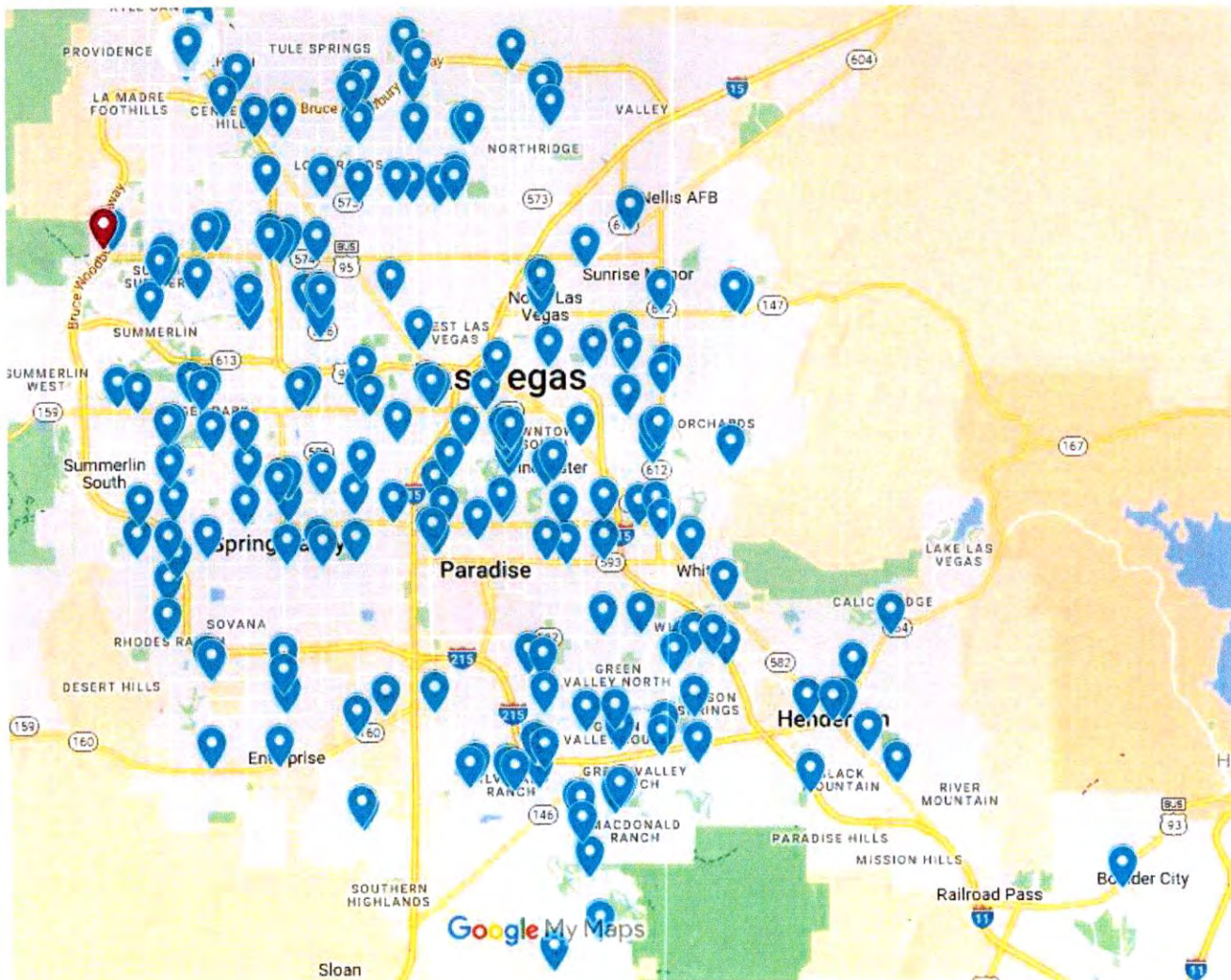
I appreciate you taking the time to read this letter. If you should require any additional input or information, I am at your disposal.

A handwritten signature in black ink, appearing to read 'Chad Baker', followed by a long horizontal line.

Chad Baker
Senior Vice President, Government Relations
FLAVORx, Inc.
cbaker@flavorx.com



Medicine Flavoring Availability in Las Vegas Area Current



Medicine Flavoring Availability in Las Vegas Area if USP 795 Standards are Enforced



Medicine Flavoring Availability in Western Nevada Area Current



Medicine Flavoring Availability in Western Nevada Area if USP 795 Standards are Enforced



1.5 CSP Categories

This chapter distinguishes three categories of CSPs: Category 1, Category 2, and Category 3, primarily based on the state of environmental control under which they are compounded, the probability for microbial growth during the time they will be stored, and the time period within which they must be used.

Category 1 CSPs are compounded under the least controlled environmental conditions and therefore are assigned a BUD of 12 h or less at controlled room temperature or 24 h or less when refrigerated, if compounded in accordance with all of the applicable requirements for Category 1 CSPs in this chapter.

Category 2 CSPs require more environmental controls and testing than Category 1 CSPs and may be assigned a BUD of greater than 12 h at controlled room temperature or more than 24 h if refrigerated, but not exceed the limits established in Table 13 (see 14. Establishing Beyond-Use Dates), if compounded in accordance with all of the applicable requirements for Category 2 CSPs in this chapter.

Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequency of environmental monitoring, and stability determination. Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in Table 14 (see 14. Establishing Beyond-Use Dates), if compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter (see 14.4 Additional Requirements for Category 3 CSPs).

The requirements that are not specifically described as applicable to Category 1, Category 2, or Category 3, are applicable to the compounding of all CSPs unless the CSP is otherwise described in 1.1 Scope.

Category 1, Category 2, and Category 3 CSPs can be compounded by using only sterile starting ingredients, or by using some or all nonsterile starting ingredients. If all components used to compound are sterile from the start, the sterility of the components must be maintained during compounding to produce a CSP.

14.4.4 Release testing for Category 3 CSPs

- Each time the Category 3 CSP is prepared, it is sterility tested and meets the requirements of <71> or a validated alternative method (see Table 14) that is noninferior to <71> testing.
- ~~Each time the Category 3 CSP is prepared, it is tested for endotoxins for acceptable results, if endotoxin testing is required under 12.3 Bacterial Endotoxins Testing.~~
- When using a new lot of an active CSP without a USP monograph for sterile preparation, the CSP must not exceed the endotoxin limit as described in <85> for appropriate route of administration.

Rationale: Once you have tested the endotoxin load of an active API and you are using that API for compounding along with sterile non-pyrogenic ingredients, all your CSPs should be within endotoxin limits.

12.2 Sterility Testing

Sterility testing is not required for Category 1 CSPs (see Table 12). For Category 2 CSPs assigned a BUD that requires sterility testing (see Table 13) and all Category 3 CSPs, the testing must be performed according to <71> or a validated alternative method (see <1223>) that is noninferior to <71> testing.

If sterility testing is performed, the minimum quantity of each container to be tested for each media is specified in <71>, Table 2, and the number of containers required to be tested in relation to the batch size is specified in <71>, Table 3, except as described below. The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units.

When compounding a batch up to 15 units, sterilization method validation maybe used in place of sterility testing, ie, bubble point test for filtration method or biological indicator testing if using moist heat (autoclave) or dry heat (oven).

If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in <71>, Table 3, additional units must be compounded to perform sterility testing as follows:

If 139 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number. For example:

~~If 1 CSP is compounded, 10% of 1 rounded up to the next whole number would indicate that 1 additional CSP must be prepared for sterility testing~~

If 39 CSPs are compounded, 10% of 39 rounded up to the next whole number would indicate that 4 additional CSPs must be prepared for sterility testing.

If more than 40 CSPs are prepared in a single batch, the sample sizes specified in <71>, Table 3 must be used.

If sterility testing is performed according to <71>, the Method Suitability Test from that chapter must be performed to ensure that contamination can be recovered. If performing sterility testing according to <71>, the Membrane Filtration method from that chapter is the method of choice when the CSP formulation permits. The preferred alternative is the <71>, Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium method. If an alternative method is used for sterility testing, the method must be validated (see <1223>) and demonstrated to be suitable for that CSP formulation.

Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented.

Rationale: Previous iteration of USP 797 allowed for sterilization method validation which did not increase patient risk. If approved, compounding an additional product for a testing will not be necessary.

Table 13. BUD Limits for Category 2 CSPs ^a				
Preparation Characteristics		Storage Conditions ^b		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°C to 25°C)	Refrigerator (2°C to 8°C)	Freezer (-25°C to -10°C)
Aseptically Processed CSPs	No	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
		Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
	<u>No but verified sterilization procedure</u>	<u>30 days</u>	<u>60 days</u>	<u>90 days</u>
	Yes (<u>required for batches of 15 or greater units</u>)	30 days	<u>4560 days</u>	<u>6090 days</u>
Terminally sterilized CSPs	<u>No but verified sterilization procedure</u>	<u>1430 days</u>	<u>2860 days</u>	<u>4590 days</u>
	Yes (<u>required for batches of 15 or greater units</u>)	<u>4530 days</u>	60 days	90 days

^a A shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit stated in the table.

^b May be extended up to 180 days for non-punctured container if sterility and stability studies are performed.

Table 14. BUD Limits for Category 3 CSPs ^a			
Preparation Characteristics	Storage Conditions ^b		
Compounding Method	Controlled Room Temperature (20°C to 25°C)	Refrigerator (2°C to 8°C)	Freezer (-25°C to -10°C)
<u>Aseptically Processed or terminally sterilized with verified sterilization method only (less than 15 units)</u>	<u>30 days</u>	<u>60 days</u>	<u>90 days</u>
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs <u>(required for batches of 15 or greater units)</u>	60 days	<u>90120 days</u>	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs <u>(required for batches of 15 or greater units)</u>	<u>9060 days</u>	120 days	120 days

^a A shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit stated in the table.

^b May be extended up to 180 days for non-punctured container if sterility and stability studies are performed.

Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and in the SCA^a

Site	Cleaning	Disinfecting ^b	Applying Sporicidal Disinfectant
PEC(s) and equipment inside the PEC(s)	Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected	Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected	• Monthly for entities compounding Category 1 and/or Category 2 CSPs • Weekly for entities compounding Category 3 CSPs
Removable work tray of the PEC, when applicable	• Work surface of the tray daily on days when compounding occurs • All surfaces and the area underneath the work tray monthly	• Work surface of the tray daily on days when compounding occurs • All surfaces and the area underneath the work tray monthly	• Work surfaces of the tray monthly • All surfaces and the area underneath the work tray monthly
Pass-through chambers	Daily on days when compounding occurs	Daily on days when compounding occurs	• Monthly for entities compounding Category 1 and/or Category 2 CSPs • Weekly for entities compounding Category 3 CSPs
Work surface(s) outside the PEC	Daily on days when compounding occurs	Daily on days when compounding occurs	
Floor(s)	Daily on days when compounding occurs	Daily on days when compounding occurs	
• Wall(s), door(s), and door frame(s); • Ceiling(s)^c • Storage shelving and bin(s) • Equipment outside the PEC(s)	Monthly	Monthly	Monthly

Rationale: Both category 2 & 3 may include non-sterile components and a category 3 batch requires additional sterility testing unless the Board allows batch processing without sterility testing in small batches (15 or less) with validation of sterilization method.

3.3 Garbing Requirements

Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed. Garb must be donned and doffed in an order that reduces the risk of contamination. The required garb, manner of storage, and order of garbing must be determined by the facility and documented in the facility's SOPs. When preparing Category 2 or Category 3 CSPs, all garb should be donned in a classified area before entering the buffer room. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb. Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands). Donning and doffing garb should not occur in the same area at the same time. The minimum garbing requirements ~~for preparing Category 1 and Category 2 CSPs~~ include the following:

- Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall)

- Low-lint covers for shoes

- Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair

- Low-lint face mask

- Sterile powder-free gloves

If using a RABS (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve.

Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing). If compounding Category 1 and Category 2 CSPs, gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination. When personnel exit the compounding area, garb, except for gowns, cannot be reused and must be discarded or laundered before reuse. The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

~~If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day:~~

- ~~Do not allow any exposed skin in the buffer room (i.e., face and neck must be covered).~~

- ~~All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used.~~

Disposable garbing items must NOT be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle.

The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

Rationale: Both Category 2 & 3 may include non-sterile starting ingredients already.

6.2.1 Viable air sampling timing and locations: Volumetric active air sampling of all classified areas using an impaction air sampler must be conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions. For all entities compounding ~~Category 1 and Category 2 CSPs~~, this must be completed at least every 6 months. ~~For entities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.~~ Air sampling sites must be selected in all classified areas.

Rationale: Both Category 2 & 3 may include non-sterile starting ingredients already and additional testing are required in category 3 unless the Board increases limits on Table 14.

6.3.1 Surface sampling timing and locations: Each classified area, including each room and the interior of each ISO Class 5 PEC and pass-through chambers connecting to classified areas, must be sampled for microbial contamination using a risk-based approach. Samples should be taken from the following classified areas:

- Equipment contained within the PEC
- Staging or work area(s) near the PEC
- Frequently touched surfaces

Surface sampling in the DCA must also be conducted in conjunction with media-fill testing to assess aseptic manipulation competency (see 2.3 Competency Testing in Aseptic Manipulation)

When conducted, surface sampling should be performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected.

For entities compounding Category 1 and Category 2 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be conducted at least monthly (see Microbiological Control and Monitoring of Aseptic Processing Environments <1116>).

For entities compounding any Category 3 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be completed prior to assigning a BUD longer than the limits established in Table 13, and at least weekly (see <1116>) on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. ~~Additionally, surface sampling must be conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used.~~ When a self-enclosed robotic device is used as the PEC to prepare Category 3 CSPs, surface sampling must be conducted at least once daily at the end of compounding operations, before cleaning and disinfection occurs.

Rationale: When compounding Category 3, sterility testing is required for a batch. How does surface sampling add an additional safety measure when you are already testing for batch sterility. If Board allows batch processing without sterility testing in small batches (15 or less) with validation of sterilization method, then surface sampling may add an additional safety layer.

March 17, 2022

Brenda Jensen, CPhT
Chairman, Compounding Expert Committee
U.S. Pharmacopeia
Twinbrook Parkway
Rockville, Maryland 20852



Dear Chairman Jensen and Committee Members:

On behalf of the Alliance for Pharmacy Compounding, I wish to offer general comments on the Compounding Expert Committees proposed changes to USP Chapter <797>. More detailed comments on both proposed changes to Chapter <797> and Chapter <795> are shared in appendices to this letter and were also submitted via the USP on-line comment portal.

As you may know, APC is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers. Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

I begin by recognizing the high stature of the United States Pharmacopeia as a standards-setting body. USP's integrity has long been rooted in its commitment not to politics or external pressures or mere whim, but to science. Over many years, USP has maintained a laser-like focus on hard data to document the standards it issues, and it is that focus that gives those standards credibility. As pharmacy compounders, we value the role USP plays in assuring that its standards for our profession are demonstrably scientific and are designed not merely to protect our patients from harm but also to assure those patients can access the highest quality compounded medications.

USP's reputation for scientific rigor stands to be jeopardized by the arbitrary and unscientific restrictions on batch size and beyond-use dates in Chapter <797> as recently proposed by the Compounding Expert Committee (CMP EC).

The CMP EC has provided no valid rationale or scientific evidence for how the proposed Category 3 CSP BUD limits and batch size restrictions will improve product quality or patient safety. And yet the effect of these proposals will indisputably impede patient access and medication quality. "How does this benefit patients?" remains an unanswered question. Accordingly, APC requests that USP remove any batch size limits for CSPs and allow Category 3 CSPs to be assigned BUDs of up to one year, regardless of sterilization method or storage temperatures, as supported by data from stability-indicating studies, until USP can:

1. Demonstrate that its proposed batch-size limitation and BUD restrictions are rooted in objective, replicable science and provide clear patient benefit;
2. Provide guidance as to stakeholder concerns over the effects of colder storage temperatures on compounded preparations, packaging, and patients themselves and the effects on patient access of cost-prohibitive stability studies.

Promulgating standards that restrict the batch size of compounds a 503A pharmacy may produce is not in USP's charter, nor is it consistent with any specific statutory authority Congress has given to FDA. Restricting compounding production will clearly be an effect of CMP EC's proposed restrictions in Chapter <797>.

The potential downstream implications of such restrictions are profound. It is a function of USP's credibility that most states incorporate USP compounding standards in whole or in part into the state's pharmacy regulatory framework. If Chapter <797> is formalized as proposed, state regulators will take for granted that the scientific basis for the proposed restrictions is valid and will adopt the chapter. In so doing, they will – largely unwittingly – formalize in regulation impediments for patients in their state who rely on compounded medications. Those impediments almost certainly include higher costs and the need for more frequent refills – both of which will have a negative effect on medication adherence and health outcomes.

In short, we urge the CMP EC to withstand pressures to implement arbitrary restrictions on batch size and Category 3 BUDs until it can clearly demonstrate the scientific basis for those restrictions and enunciate how patients are objectively better served by them. Not only will patients be harmed if the CMP EC proceeds in finalizing Chapter <797> with those restrictions, but so too will USP's high reputation.

Regarding the detailed comments on proposed Chapters <795> and <797> provided in the appendix to this letter, we urge the CMP EC to pay attention not only to the comment itself but the rationale we offer for it. We have noted that in recent CMP EC meetings in which comments are being reviewed, mention of commenters' rationale for recommendations has seldom been mentioned – but it should be, for that rationale can provide the CMP EC valuable context they might not otherwise consider.

One additional point that has not been much mentioned but deserves CMP EC's attention: USP <800> must also be re-opened for review; it was last reviewed in February 2016. Much has changed, and the chapter has been evaluated and critiqued by numerous groups, including many state boards of pharmacy, in that intervening period. We would assert that the lack of scientific basis we have cited as a flaw in the CMP EC's proposed changes to Chapter <797> also applies to Chapter <800>. For example, as it relates to sterile compounding, the "optimal" facility with a single ante room for both hazardous and non-hazardous sterile compounding is problematic in terms of donning and doffing PPE to contain HDs and prevent skin from contaminating controlled areas. Additionally, it can be argued that not all drugs that are hazardous need negative pressure ventilation. Our grave concern is that when Chapter <800> becomes compendially applicable, state regulators will have no means of reconciling its provisions with either science or Chapter <797>, and that will result in inconsistent or inappropriate enforcement.

We thank the Compounding Expert Committee for their work on these chapters and for their attention to our input. If you have questions, please reach me at scott@a4pc.org.

Sincerely,



Scott Brunner, CAE
Chief Executive Officer

ATTACHED:

Appendix A: Specific Comments on Proposed USP Chapter <797>

Appendix B: Specific Comments on Proposed USP Chapter <795>

ATTACHMENT A

ATTACHMENT B

ATTACHMENT C

Comment:

Remove "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, conventionally manufactured products) must be assessed to determine if these activities must be performed in a PEC or other closed system processing device (e.g., single-use containment glove bag) to reduce the potential exposure to personnel or contamination of the facility or CSPs (See 4.2 *Facilities Preparing Category 2 or Category 3 CSPs from Nonsterile Starting Component(s)*). The process evaluation must be carried out in accordance with the facility's SOPs and the assessment must be documented."

Rationale:

As written this text establishes no requirement or standard of practice other than the requirement to perform and document an "assessment." It is not clear what the scope of this assessment is (is it an assessment of airflow, viable counts and nonviable counts of surface and/or air contaminants, personnel exposure to chemicals?), what is required to be measured, what acceptance criteria would be, or what areas are being assessed (ISO 5 PEC, ISO 7 buffer room, ISO 8 anteroom, ISO 8 pre-sterilization process room, all of these?). This requirement would also be unnecessarily applicable to facilities that have a segregated ISO 8 pre-sterilization room separate from the ISO 8 and ISO 7 rooms used to perform aseptic manipulations. Without a clear scope, measurements, and expected acceptance criteria, regulators and compounders will have no way of knowing what compliance with this standard looks like. Additionally, if this text is retained, compounders should have the ability to have a single policy as opposed to creating unnecessary paperwork for evaluating each chemical and its need to be in the CVE.

10.1 Depyrogenation

Comment:

Replace the word "depyrogenated" with "sanitized" in the following sentence: "Items that are not thermostable must be depyrogenated by rinsing with sterile, nonpyrogenic water (e.g., *Sterile Water for Injection or Sterile Water for Irrigation*) and then thoroughly drained or dried immediately before use in compounding."

Rationale:

Section 10.1 seems to indicate that dry heat is the only acceptable method for depyrogenation, and that dry heat depyrogenation methods must demonstrate a greater than 3 log reduction in endotoxins. While non-dry heat, wash/rinse processes have been validated to achieve a greater than 3 log reduction in endotoxins, many regulators have not accepted them as "depyrogenation" processes simply because they do not use dry heat. Unless the CMP EC is willing to explicitly permit or acknowledge other methods or processes that demonstrate a greater than 3 log reduction in endotoxins as acceptable alternatives to meeting the depyrogenation requirements of 10.1, it should not use the word "depyrogenated" as the expected outcome of rinsing items with sterile, nonpyrogenic water.

12.2 Sterility Testing

Comment:

Delete "The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units."

Rationale:

The establishment of a maximum batch size of 250 units for CSPs that undergo sterility testing is completely arbitrary and based on no scientific data, evidence, or existing best practices of any kind; is illogical in that it applies only to CSPs that undergo sterility testing and NOT applicable to CSPs that do not undergo sterility testing; further, it creates the potential for INCREASING the likelihood of contaminating aseptically processed CSPs.

Based on the explanation provided in the *BUD Scientific Rationale for the 2021 Proposed Revisions to <797>* the CMP EC has created this batch size limit primarily based on the number of containers required for sterility testing per USP <71>. The requirements of USP <71> are that 10 units from a CSP batch be tested for sterility for batch sizes ranging from 100 units to 500 units. It appears the CMP EC has determined that this long-standing sample size of 10 units per 500 found in USP <71> is no longer appropriate to detect microbial contamination of sterile medications, and that a more appropriate minimum ratio to sample is 10 units per 250 units produced. While simple math demonstrates the probability of detecting a contaminated unit doubles when 10 samples are tested out of 250 vs out of 500, the CMP EC has provided no data or evidence to demonstrate the *necessity* to double the probability of detecting a contaminated sample, no evidence or data to support that doubling the probability of detecting a contaminated sample goes *far enough* to detect contamination within a batch (versus tripling or quadrupling the probability), and has provided no data, evidence, or explanation as to why limiting the batch size, rather than increasing the number of required samples, is the only allowable way to increase the probability of detecting contamination within a CSP batch.

A secondary rationale given by the CMP EC for limiting batch sizes to a maximum of 250 units is the belief that contamination risk increases with larger batch sizes, particularly for manual processes. We address the faults in that assumption later. But even if that assumption were true, and that is the CMP EC's position, it seems illogical that only CSPs that undergo sterility testing would be limited to a batch size of 250 units while CSPs that do not undergo sterility testing can exceed that batch size limit. Sterility testing sample size aside, if the CMP EC has determined that 250 units is the threshold beyond which larger batch sizes pose an unacceptable level of contamination risk, why not limit all CSPs, including those that do not undergo sterility testing, to the same 250-unit batch size? And the CMP EC has provided no data, evidence, or explanation for why it has concluded that contamination risk increases to an unacceptable level once a batch size exceeds 250 units.

Having established that the CMP EC has provided no evidence that CSP batch size limitations will improve the quality of CSPs prepared by compounders, we turn our attention to the practical effects these batch size limitations will have on potentially *increasing* the likelihood of CSP contamination. Let's say a compounder dispenses 800 units of a particular aseptically processed CSP every month. Today that compounder can produce all 800 units in a single batch, or perhaps produce two batches of 400 units to meet current patient need. The compounder has met all requirements of <797>, including completing and passing media fills for a batch of at least 800 units. BUD limitations aside, with a limit of 250 units per batch, that compounder will now be required to make four batches of that particular CSP every month instead of one or two. This means in order to meet patient need for this particular aseptically processed CSP, the compounder will now have to double or even quadruple the number of times per month they perform the process steps most likely to introduce contamination into the environment used to sterilize and aseptically manipulate the CSP, such as:

- Transferring materials from the unclassified areas of the facility into the ISO 8 anteroom, ISO 7 buffer room, and ISO 5 PEC.
- Donning sterile gloves and garb.
- Unpackaging and aseptically connecting sterilizing filters.

- Transferring materials and finished CSPs out of the classified areas at the completion of aseptic processing.

Additionally, decreasing the size but increasing the frequency of CSP batches will increase the total amount of time compounding staff will need to occupy ISO classified areas in order to meet patient need. For example, let's say for every batch of a particular aseptically processed CSP, regardless of batch size, a compounder needs a total of 15 minutes in the ISO 8 anteroom transferring materials, handwashing, and donning garb and gloves, and another 20 minutes in the ISO 7 buffer room transferring materials and setting up equipment and supplies prior to aseptic filling. That compounder will occupy the ISO 8 anteroom and ISO 7 buffer room for a minimum of 35 total minutes per batch solely to perform pre-aseptic fill tasks. For a compounder preparing 800 units per month in a single batch, those pre-aseptic fill tasks will require utilizing the ISO 8 and ISO 7 areas for 35 minutes a month. If a compounder is required to make four batches of 200 units per month, those same pre-aseptic fill tasks will require utilizing the ISO 8 and ISO 7 areas for 140 minutes (35 minutes x 4) every month. The practical impact of this batch size limitation is that it will cause people, the most common source of contamination in any ISO classified area, to spend more time in ISO classified areas in order to produce the same number of CSP units. By limiting CSP batch sizes, the CMP EC will be forcing compounders to increase the frequency with which they will make entries and exits to and from ISO classified aseptic processing rooms, and increase the amount of time personnel will be spending in ISO classified aseptic processing rooms, in order to meet current patient need for CSPs. This is in direct conflict with practices outlined in FDA's *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice* (Attachment A) which states:

“Both personnel and material flow should be optimized to prevent unnecessary activities that could increase the potential for introducing contaminants to exposed product, container-closures, or the surrounding environment. The layout of equipment should provide for ergonomics that optimize comfort and movement of operators. The number of personnel in an aseptic processing room should be minimized. The flow of personnel should be designed to limit the frequency with which entries and exits are made to and from an aseptic processing room and, most significant, its critical area. Regarding the latter, the number of transfers into the critical area of a traditional cleanroom, or an isolator, should be minimized. To prevent changes in air currents that introduce lower quality air, movement adjacent to the critical area should be appropriately restricted.”

So far we've established that the proposed batch size limit will not improve quality or mitigate likely risks to quality for CSPs. Now to the final, and most erroneous, basis the CMP EC provides for proposing a batch size limit on CSPs that undergo sterility testing in *BUD Scientific Rationale for the 2021 Proposed Revisions to <797>*: “The intent is to reduce the risk of patient harm from undetected contamination of CSPs by introducing a batch size limit,” it states. The CMP EC is in effect saying that after nearly a decade of work on revisions to <797>, the standards proposed in this most recent revision still remain inadequate to prevent unnecessary risk of patient harm from CSPs, and therefore the only option is to simply limit the amount of CSPs available to patients and simply wish and hope it helps. This is bafflingly unscientific.

14.2 Parameters to Consider in Establishing a BUD. Aseptic processing and sterilization methods:

Comment:

Edit “Table 11 allows for longer BUDs for terminally sterilized CSPs than for aseptically processed CSPs because terminal sterilization using a verified method provides reasonable assurance that a CSP will be sterile.” to read “Table 11 allows for longer BUDs for terminally sterilized Category 2 CSPs than for aseptically processed CSPs because terminal sterilization using a verified method provides reasonable assurance that a CSP will be sterile.”

Remove “and *Table 12* for Category 3 CSPs” from the following sentence “BUDs for CSPs must be established in accordance with *Table 10* for Category 1 CSPs, *Table 11* for Category 2 CSPs and ~~*Table 12* for Category 3 CSPs.~~”

Rationale:

See rationale for comments to **Section 14.4 Additional Requirements for Category 3 CSPs. Assigning Category 3 BUDs:**

14.3 Establishing a BUD for a CSP

Comment:

Remove the sentence “The BUD limits in these tables are based on the risk of microbial contamination or not achieving and maintaining sterility despite implementation of the requirements in this chapter.” If the CMP EC feels it necessary to provide some explanation of its basis for the Category 1 and Category 2 CSP BUD limits, we suggest replacing existing text with “In the absence of chemical, physical, and microbial stability data obtained from the stability-indicating studies required of Category 3 CSPs, the BUD limits for Category 1 and Category 2 CSPs are based on the probability of unstudied CSPs becoming chemically, physically, or microbially unstable.”

Rationale:

The statement in 14.3 “The BUD limits in these tables are based on the risk of microbial contamination or not achieving and maintaining sterility despite implementation of the requirements in this chapter” creates significant concern about the validity of the entire chapter. If the requirements of this chapter are insufficient to achieve or maintain sterility of a CSP then the chapter needs to be reconsidered.

14.4 Additional Requirements for Category 3 CSPs

Comment:

Remove Table 12.

Remove all references to Table 12.

Within **Assigning Category 3 BUDs:** replace “Category 3 CSPs must not be assigned a BUD longer than the limits in *Table 12.*” with “Category 3 CSPs must not be assigned a BUD longer than that supported by a stability-indicating study or 365 days, whichever is shorter.”

Rationale:

This rationale provides information to support our objection to the maximum allowable Beyond-Use Dates (BUDs) proposed for Category 3 Compounded Sterile Preparations (CSPs) found in Table 12 of the 2021 proposed USP General Chapter <797>, and provides the scientific, logical, and practical rationale to support our recommendation to allow all CSPs meeting the requirements of Category 3, regardless of storage conditions, to be assigned a BUD of up to 365 days.

Within this rationale we address the scientific, logical, and practical unsoundness of the rationale the USP Compounding Expert Committee (CMP EC) uses to justify the maximum allowable BUDs proposed in Table 12 for Category 3 CSPs. Specifically, we address:

- The healthcare needs for all CSPs prepared by 503A compounding pharmacies, not just those stored frozen, to be assigned a BUD of up to 365 days;
- The scientific rationale in support of, not against, the integrity and applicability of data obtained from the stability-indicating studies described within the proposed <797> and USP's "Stability Study Reference Document for the 2021 Proposed Revisions to <797>"; and
- The lack of data or evidence to support the CMP EC's assessment of the impacts facility-to-facility or batch-to-batch variability have on CSP stability, and the lack of consistency with general scientific principles or existing USP policy the CMP EC is employing to address this unsupported concern.

While we address these topics individually within this rationale, it is important to note that all of these areas combined comprise the basis for our position that the maximum allowable BUDs less than 365 days proposed in Table 12 for Category 3 CSPs are neither scientifically sound nor meet the healthcare needs of patients who rely on CSPs prepared by compounders. Instead, the maximum allowable BUDs for Category 3 CSPs proposed in Table 12 will only increase medication costs and potentially decrease the quality of Category 3 CSPs.

Most importantly, we want to make clear we strongly disagree with any baseline assumption that the root cause of past CSP quality events related to microbial contamination was due to a lack of standards found in the current <797> and/or extended storage periods for CSPs. While there is currently no cohesive system of gathering adverse events associated with compounded preparations, the most comprehensive list of compounding related adverse events can be found in Pew Charitable Trust's 2020 US Illnesses and Deaths Associated with Compounded or Repackaged Medications, 2001-19 (Attachment B). A review of available information related to adverse events associated with microbial contamination of CSPs reported on this list indicates all incidents of microbial contamination were the result of noncompliance with existing <797> standards, rather than a lack of standards. Creating standards that limit BUDs for Category 3 CSPs to those proposed in Table 12 will not solve for noncompliance with the standards in <797>. The BUD limits for Category 3 CSPs proposed in Table 12 will not increase the level of sterility assurance of CSPs prepared by compounders who are unwilling to comply with the standards of <797>. These proposed limits will, however, cause compliant compounders to alter sterilization methods, change CSP storage conditions, and increase the frequency with which they will have to make smaller batches to meet patient needs. All of these adjustments will actually increase the likelihood of quality issues with CSPs prepared by compounders fully compliant with <797>. In other words, the BUD limits proposed for Category 3 CSPs will do nothing to address the root cause of past adverse events associated with microbial contamination and have a high probability of creating an increase in future adverse events associated with CSPs.

Need for up to a 365-day BUD for all CSPs

The CMP EC itself is acknowledging the need for CSPs to be assigned a BUD of up to 180 days, but in doing so is misrepresenting the proposed <797> as allowing Category 3 CSPs *in general* to be assigned a BUD of up to 180 days, when in fact the proposed <797> only allows one type of Category 3 CSP -- a terminally sterilized Category 3 CSP stored frozen -- a maximum BUD of 180 days. The need in the healthcare system for CSPs with extended BUDs of 180 days or more goes beyond just terminally sterilized CSPs stored frozen, it is a need that applies to aseptically processed CSPs and CSPs stored refrigerated and at room temperature as well. In addition, the CMP EC has misrepresented the scope of compounding of CSPs by 503A pharmacies as being limited to only patient-specific prescriptions. As stated in 1. *Introduction and Scope* of the proposed <797>, the standards described in the chapter are applicable when preparing compounded sterile preparations for human AND animal drugs. Section 503A of the FDCA is specifically applicable to human health compounds, but is not applicable to animal health compounds, meaning the patient-specific requirements of 503A are not applicable to animal health compounds. In its draft GFI #256 FDA acknowledges the need, and allowance for,

the nonpatient-specific compounding of animal health medication by state licensed pharmacies. Animal health compounding is regulated by state boards of pharmacy, and currently at least 38 states explicitly allow 503A compounders to provide veterinarians with nonpatient-specific “office use” compounds. In addition to the regulatory framework allowing veterinarians to obtain office use compounds from 503A pharmacies, a recent survey of veterinarians demonstrates the practical need for this. Ninety-one percent of veterinarians surveyed responded that the ability to maintain office stock of compounded sterile preparations was either extremely or very important (Attachment C). Therefore, the CMP EC’s rationale for limiting BUDs for CSPs because “<797 is for patient-specific prescriptions that are not intended to be stored for long periods of time” is not a valid rationale for limiting BUDs of all Category 3 CSPs.

Stability Testing

While the CMP EC correctly points out the potential differences between stability studies for FDA approved manufactured drug products versus CSPs produced by compounders when referencing the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) stability study guidelines and the FDA guidance document on stability studies, this comparison fails to provide any scientific basis for limiting the maximum BUDs for CSPs to less than one year.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) stability study guidelines and the FDA guidance document on stability studies that CMP EC is referencing are standards for drug manufacturers to follow to obtain the data required to submit to FDA as part of a New Drug Application to obtain approval to assign a drug product an expiration date of generally one year or greater. As the CMP EC knows, CSPs produced at a 503A or 503B facility are exempt from FDA’s new drug approval requirements, so any comparison of the regulatory requirements for stability studies that are conducted on CSPs produced by a 503A or 503B facility and the requirements for stability studies that are conducted by a drug manufacturer as part of a new drug approval application are invalid. In terms of an actual scientific comparison between the two types of studies, again the CMP EC points out the differences, but fails to articulate the scientific significance of those differences and why the CMP EC believes those differences to be significant enough to limit the accuracy and reliability of stability studies conducted by compounders on CSPs. CMP EC is simply comparing the two to *imply* the stability studies by drug manufacturers are “better” than the stability studies for CSPs, without providing any scientific justification for why these differences make one “better” than the other.

Even FDA has recognized that the standards found in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use stability study guidelines and the FDA guidance document on stability studies are not always applicable to sterile products produced at a 503B outsourcing facility. In issuing draft GFI “Current Good Manufacturing Practices – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act” January 2020 (“Draft GFI”), FDA set out limited stability study guidelines for 503B facilities to use to assign sterile products up to a BUD of one year. Given this Draft GFI reflects FDA’s current thinking on stability studies for compounded products produced at a 503B facility, it is appropriate to compare the stability study requirements found in Appendix B of this Draft GFI with the stability study requirements the CMP EC is proposing for CSPs produced by 503A facilities.

Using the CMP EC’s original list of example differences in testing parameters below, please note the lack of differences between stability studies for CSPs produced by a 503A facility and those outlined in the Draft GFI for products produced at a 503B facility, along with some of the scientific basis for why the 503B standards differ from those required of drug manufacturers.

Three initial production lots are tested for stability, with the product in its final packaging.

The Draft GFI does not require outsourcing facilities to perform stability testing on three lots; it specifies one lot is sufficient to establish a BUD of up to one year.

Studies are conducted under accelerated, intermediate, and long-term stability conditions.

The Draft GFI only specifies stability samples to be evaluated under long-term storage conditions, also known as “real-time” conditions, for outsourcing facilities to establish a BUD of up to one year. As described in ICH Q1A(R2), drug manufacturers conduct stability studies under accelerated and intermediate storage conditions to obtain data to support a *projected* shelf life of a drug product for which they seek regulatory approval to market. In order to get that regulatory approval, the drug manufacturer must commit to perform long-term studies out to the projected expiration date *after* introducing the accelerated and intermediate data to obtain regulatory approval. In other words, accelerated and intermediate studies are used by drug manufacturers to predict a shelf life of a year or greater for a product in order to obtain FDA approval of that drug product with that predicted shelf life *before* obtaining the long-term stability data to confirm the shelf life. In the case of compounds produced by either 503A or 503B facilities, the compounded preparation cannot even be assigned a BUD and sold until long-term, or real-time, stability studies have been completed.

Degradation products and impurities are identified and quantified.

The Draft GFI does not require the outsourcing facility to identify or quantify any degradation products as part of a stability study. ICH Q1A(R2) describes the need for identifying impurities and degradants in new drug substances (i.e., new APIs) in order to understand the potential degradation pathways of these new drug substances. Since neither 503As nor 503Bs are producing new APIs, this requirement in Q1A(R2) is not applicable. ICH Q3B(R2) establishes guidelines for identifying and quantifying degradation products in new drug products but does not require this for all new drug products – ICH Q3B(R2) establishes threshold concentrations for degradants that, only if exceeded, require identification and quantification. These thresholds are established based on the maximum daily dose of the drug product. A drug manufacturer submitting an application for a new drug product approval will have established the maximum daily dose of that drug product, and therefore would be able to determine the threshold beyond which degradants would have to be identified and quantified. Because neither 503A nor 503B facilities are establishing maximum daily doses for the compounds they produce, nor are they required to take their compounds through the FDA approval process, the guidelines in ICH Q3B(R)2 related to identifying and quantifying degradants and impurities are not applicable.

Functional attributes, such as dissolution testing, are tested as part of the stability study.

The Draft GFI does not require dissolution testing to be included as part of the limited stability study for non-sterile or sterile products produced by a 503B facility. The functional attributes, such as dissolution, of a drug product are studied to establish the drug release profile in order to obtain the pharmacokinetic data needed to obtain FDA approval of a new drug product. Including these tests in a stability study allows a drug manufacturer to demonstrate that the drug release profile of a new drug product will not change over the shelf life of the drug product. Medications produced at 503A and 503B facilities are not required to go through the FDA approval process, and therefore testing to obtain data about a compounded medication’s pharmacokinetic profile is not applicable. Additionally, the dosage forms most commonly impacted by drug dissolution are oral tablets and capsules. The current and proposed USP <795> specify a default BUD of 180 days for oral tablets and capsules, meaning a compounder can assign up to a 180-day BUD on these dosage forms without performing any stability study at all, much less a dissolution study. Therefore, it is clear that the CMP EC itself takes the position that dissolution testing of compounded medications is not an important factor in assigning a compounded preparation a BUD of 180 days or less.

At least 1 production batch is studied for stability annually and every batch must pass release testing before being placed into the marketplace.

No annual or on-going stability studies are required in the Draft GFI for 503B facilities. ICH Q1A(R2) specifies "For long term studies, frequency of testing should be sufficient to establish the stability profile of the drug product. For products with a proposed shelf life of at least 12 months, the frequency of testing at the long term storage condition should normally be every 3 months over the first year, every 6 months over the second year, and annually thereafter *through the proposed shelf life*." This requirement is for drug products with a shelf life of one year or greater, and therefore is not applicable to any medication produced at a 503A or 503B facility that is assigned a BUD of up to one year. And as described above, this requirement is to ensure that a drug manufacturer who has submitted data to FDA for approval of a new drug product with a shelf life of many years *prior to* having completed the long-term study of the drug product's shelf life will obtain the necessary real-time data to ultimately support that drug product's shelf life.

A 5% change from initial results is considered significant and may halt a study or require more analysis.

The Draft GFI specifies that data from each time point be evaluated against the established specifications for the compounded drug product, and if data for any test fall outside that established specification, the BUD of the product is restricted to the last time point in which the data remained within specification. The "5% change from initial results" cited by the CMP EC is one of the conditions that define the term "significant change" within the ICH Q1A(R2) guideline. However, the term "significant change", as used within the ICH Q1A(R2) guideline, is only used when describing data obtained from accelerated or intermediate storage condition studies, which as established above, are used to predict, not confirm, the shelf life of a drug product and are therefore not applicable to drug products produced at 503A or 503B facilities. ICH guidelines for stability studies under long-term storage conditions, which are applicable to 503A and 503B products, do not use the term "significant change" or mention a 5% change from initial results as the basis for halting a study or requiring more analysis. In other words, this 5% variation from initial test results is not a standard that is applicable to long-term stability studies performed by any facility, including drug manufacturers and outsourcing facilities.

Any process change necessitates a repeat of the stability study and process validations.

The CMP EC's use of the word "any" in this statement is overly broad and does not accurately reflect the requirements described within the ICH Q1A(R2) guideline. In fact, neither the ICH guideline nor the FDA guidance document on stability studies address what production process changes would require a repeat of a stability study. The closest these two documents come to addressing this topic is in stating that the batches used in a formal stability study be "representative with regard to the critical manufacturing steps" compared to commercial production batches, with no further clarification as to what a "critical manufacturing step" is. In this instance the CMP EC is conflating the requirements of a stability study with the requirements to maintain the proper production process controls that will ensure the batch-to-batch applicability of data obtained from a stability study. We address the latter in more detail later in this document.

In the comments above we have provided clarification as to *why* the stability studies required of a drug manufacturer seeking FDA approval of a new drug product differ from the stability studies outlined by USP and FDA to establish a BUD for a CSP produced by a 503A or a 503B. We agree with the CMP EC in that there are differences between the stability study requirements for manufactured drug products versus CSPs produced by 503A and 503B facilities, and we agree that the stability studies used to establish a BUD of up to one year for a CSP would likely not be sufficient to establish a *predicted* multi-year shelf life for a manufactured drug product going through the new drug approval process. But the CMP EC has failed to provide, nor have we found, any evidence or scientific rationale to support the CMP EC's position that the

stability studies described for Category 3 CSPs in the proposed <797> and USP's "Stability Study Reference Document for the 2021 Proposed Revisions to <797>" are not appropriate to confidently establish a BUD of up to one year and are somehow only reliable enough to establish the shelf life of a CSP up to the maximum BUDs for Category 3 CSPs found in Table 12 of the proposed <797> .

We have also established that, while different from the stability studies a drug manufacturer would conduct to obtain new drug approval, the stability study requirements of a 503B outsourcing facility and those proposed by the CMP EC for a Category 3 CSP prepared at a 503A pharmacy are nearly identical, as provided in FDA's draft GFI "Current Good Manufacturing Practices – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act" and USP's "Stability Study Reference Document for the 2021 Proposed Revisions to <795> and <797>", respectively. The CMP EC has not addressed any scientifically significant differences between these two study guidelines, and has not provided any rationale or scientific justification for why it takes the position that the data obtained from a stability study conducted in accordance with the proposed <797> is any less reliable in establishing up to a one year BUD than the data obtained from a stability study conducted in accordance with FDA's Draft GFI for 503B facilities. If CMP EC believes there are additional steps compounders can take in designing and implementing stability studies that would improve the integrity of the stability study and/or data obtained from them in order to establish a BUD of up to 365 days for all Category 3 CSPs, we respectfully request that the CMP EC engage in stakeholder discussions about those additional steps prior to issuing a finalized <797>.

Diversity of practice settings, environments, processes, and analytical approaches

The CMP EC cites diversity of practice settings as a rationale for the limitations proposed on maximum BUDs for Category 3 CSPs in the proposed <797>. The CMP EC does not provide substantive insight into what specific process, practice setting, or environmental variability it is using as the basis for its position that data obtained by compounders from stability studies is valid only up to the point at which test samples' storage times have reached the maximum BUDs in Table 12 of the proposed <797>, and somehow stability data obtained from timepoints after those in Table 12 becomes too unreliable to use as the basis for a CSP BUD.

For example, let's say a compounder wants to extend the BUD of a CSP prepared via aseptic processes and stored at room temperature beyond the maximum default BUDs for Category 2 CSPs. The compounder partners with a testing lab to establish a stability-indicating study in conformance with the standards found in the proposed <797> and USP's stability study guideline. A validated stability test method is created and a testing protocol is established that specifies that all applicable physical, chemical, and microbial tests, along with container-closure and antimicrobial effectiveness tests, are to be conducted on day 0, day 30, day 45, day 60, day 90, day 120, and day 180 of the study. The compounder prepares a batch of the CSP in full compliance with the Category 3 requirements of the proposed <797>. The compounder pulls samples from this batch to be tested at the designated time points, ensuring storage is maintained at room temperature. Data from this stability study shows that the samples tested from this batch remained within acceptance criteria at all time points, indicating that the CSP is stable to at least 180 days. In this scenario, the CMP EC's current position is as follows:

- Assuming the compounder meets all other requirements for Category 3 CSPs when producing this CSP, the data obtained from this stability study on days 0, 30, 45, and 60 is acceptable to assign a 60 day BUD to future batches of this CSP prepared according to the exact formulation, packaged in the same container closures, and stored at the same room temperature conditions as the samples tested in the study. But the data obtained from this stability study on days 90, 120, and 180 is *not* acceptable to assign a longer than 60 day BUD to future batches of this CSP prepared according to the exact formulation, packaged in the

same container closures, and stored at the same room temperature conditions as the samples tested in the study.

- If this same compounder were to take the same steps to design and implement a stability study for this exact same CSP, only this time the study was designed to determine the stability of the CSP when stored refrigerated, and again assuming data from days 0, 30, 45, 60, 90, 120, and 180 all showed the test samples to be within acceptance criteria, the data obtained from the stability study on day 90 would now be acceptable to assign a 90 day BUD to future batches, and only data from days 120 and 180 would be unacceptable. And for the same CSP studied under frozen conditions, data obtained from the stability study on days 0 through 120 would now be valid enough to establish a 120 day BUD for this CSP, but data obtained from the stability study on day 180 would still not be valid.
- Let's say the CSP in this example is cyclosporine ophthalmic solution in corn oil intended for veterinary use. If the compounder prepared this CSP using cyclosporine API powder, then despite having the above stability data showing the CSP to be stable at day 180 when stored at room temperature, the compounder would be limited to assigning a BUD of only 60 days to future batches. However, if the compounder were to use cyclosporine oral liquid as the source of API and prepare the CSP in accordance with the official USP monograph for compounded cyclosporine ophthalmic solution, veterinary, the compounder could assign a 180 day BUD to the CSP when stored at room temperature without having conducted *any* stability study or obtaining *any* stability data on batches made by that compounder. In fact, it is not even clear if the compounder would need to meet the training, competency, and environmental monitoring requirements of Category 3 CSPs when assigning the 180-day BUD to this cyclosporine ophthalmic preparation made in accordance with the official USP monograph.

The CMP EC has taken the position that despite meeting acceptance criteria, stability study data collected from the exact CSP for which a compounder wishes to establish an extended BUD is not valid if obtained from samples tested past a certain point in the storage period of that CSP, can change from invalid to valid if the CSP is terminally sterilized or is stored refrigerated or frozen, and compounders do not need to obtain any stability data at all on the specific CSP they are preparing to establish extended BUDs beyond the maximums specified for Category 2 and Category 3 CSPs when those CSPs are prepared according to official USP monographs. The CMP EC has no scientific basis or rationale for this position on the applicability of stability data on assigning BUDs to CSPs. Data collected from stability studies is either valid or it is not. If it is not valid, it cannot be used to establish any extended BUD. If it is valid, it can be used to establish a BUD for the time period it shows the preparation to be stable.

In a practical setting, there is no dispute that stability study data used to assign a CSP a BUD is only applicable to future batches of that CSP when those batches are formulated, produced, and packaged in the same manner as the samples studied. It is here where the CEC is conflating the applicability of stability study data to the CSP samples studied versus the applicability of stability study data to future batches of the CSP produced by the compounder. These are two distinctly different things – the former is addressed with stability study design and implementation, the latter is addressed with operational controls.

When it created the Category 3 CSP requirements in the proposed <797> the CMP EC tightened operational controls related to sterility assurance, but it did not introduce additional operational controls to address the concerns it appears to have with compounders' ability to maintain batch-to-batch consistency of CSPs. To be clear, when we say batch-to-batch consistency, we mean consistency from one batch to another of an individual CSP prepared within an individual compounding facility. There is no doubt that variability exists between the compounding processes, environment, equipment, formulation, batch sizes, or container-closure configurations from one compounding facility to another, or even potentially between two different

CSPs produced in the same compounding facility. But this facility-to-facility or CSP-to-CSP variability is different than, and has no impact on, batch-to-batch consistency of an individual CSP prepared in an individual compounding facility, and therefore is not a valid rationale for limiting a compounder's ability to apply stability study data obtained on an individual CSP to future batches of that CSP. Systems to ensure batch-to-batch consistency of an individual CSP prepared in an individual compounding facility are relatively easy to implement for a compounder who already is willing to invest the time and money to perform stability studies to extend BUDs. For example, implementing a documented change control policy and procedure that includes a requirement to determine if changes to compounding formulations, processes, equipment, environments, or ingredients will impact the applicability of stability studies to future CSP batches; establishing acceptance criteria for the API, excipients, and packaging components used in a CSP to ensure ingredients and components used in future batches are equivalent to those used in the stability study batch; and including batch-level potency/assay testing as part of the batch release testing. If the CMP EC were to incorporate scientifically sound requirements to control batch-to-batch variability for Category 3 CSPs into <797>, there should be no concern or scientific rationale for limiting a compounder's ability to use stability study data to assign a BUD of up to 365 days to future batches of that CSP, regardless of storage conditions.

It is worth noting that while there is opportunity for the CMP EC to incorporate additional standards within <797> to control batch-to-batch variability to allow compounders to assign Category 3 CSPs up to 365-day BUDs using stability data, the CMP EC's current position that batch-to-batch variability is a rationale for limiting the applicability of stability study data to the maximum BUDs in Table 12 is logically and scientifically unsound for the following reasons:

- CSP storage temperature in no way controls or has an impact on the batch-to-batch variability in compounding processes, environments, ingredients, etc. The CMP EC seems to have some concern that within individual compounding facilities enough batch-to-batch variability exists during the preparation of an individual CSP to cause significant chemical, physical, and microbiological differences among multiple batches of that individual CSP compounded within a single compounding facility. The CMP EC has not clarified or provided examples of these "significant" differences it believes are resulting from these alleged batch-to-batch variations, nor has it provided what, if any, specific controls compounders should implement to adequately prevent these perceived variations. Instead the CMP EC has reached the conclusion, based on data not yet shared with stakeholders, that compounders are simply unable or unwilling to control batch-to-batch variability when compounding an individual Category 3 CSP; that this lack of control results in "significant" differences in the microbiological, chemical, and physical attributes of a CSP from one batch to another (and from the stability-studied batch to future batches); and that the impacts of these "significant" variations in microbiological, chemical, and physical attributes on the stability of the CSP are of no concern when the CSP is stored for up to 60 days at room temperature. But beyond 60 days of storage at room temperature the impact of these variations on the stability of the CSP does become a concern, and those concerns can be overcome simply by storing the CSP in the refrigerator or freezer for up to 120 days or 180 days, respectively. In other words, when a compounder meets Category 3 requirements in preparing an aseptically processed CSP, the CMP EC is confident that the CSP will be prepared and packaged in a manner that ensures a lack of microbial contamination and/or proliferation for the first 60 days of the CSP's shelf life when stored at room temperature, but starting on day 61, because that CSP sat on the shelf for one additional day, it is suddenly contains a microbial load that makes it unsuitable for use. The same concept applies to an aseptically processed Category 3 CSP that is stored refrigerated – the CMP EC asserts that CSP will lack microbial contamination for the first 120 days, but beginning on day 121 the CSP becomes a risk to patient safety.

- At the same time the CMP EC is using batch-to-batch variability as a basis for limiting a compounder's ability to apply stability data obtained from their own CSPs to the BUDs of future batches of that CSP, the CMP EC has no concerns about how batch-to-batch or even facility-to-facility variability impacts the chemical, physical, or microbial stability of CSPs prepared in accordance with official USP monographs. Of the 21 official USP monographs for compounded sterile preparations, 19 can be assigned BUDs that exceed those for Category 2 CSPs found in Table 11 of the proposed <797>, and 12 of those 19 can be assigned a BUD that exceeds those for Category 3 CSPs found in Table 12 of the proposed <797>. The compounding processes described in these monographs lack the detail to ensure facility-to-facility consistency with respect to compounding processes, environment, and batch release criteria, let alone batch-to-batch consistency, and it is not even clear whether or not these monographed compounds are required to be made under Category 3 conditions. Yet the CMP EC allows 12 of these monographed compounds to be assigned BUDs longer than the maximum BUDs it allows for Category 3 CSPs.

If the CMP EC maintains its position that batch-to-batch variability, or a lack of control over batch-to-batch consistency, is a rationale for limiting Category 3 CSPs to the BUDs in Table 12 of the proposed <797>, it calls into question the value of USP even publishing <797> or official USP monographs for compounded sterile preparations at all. If the standards the CMP EC is establishing for CSPs in <797>, especially Category 3 CSPs in <797>, are not sufficient to adequately prevent any significant batch-to-batch variation of a CSP that would cause the microbial, chemical, or physical stability data obtained by either compounders themselves or from stability studies performed on official USP monographs to be invalid, then neither <797> nor official USP CSP monographs offer any value in ensuring the quality of CSPs.

Conclusion

Through extensive research and data collection we have demonstrated within this rationale and supporting documents the scientific, practical, and logical rationale for why there is no reason to limit CSPs meeting the Category 3 requirements in the 2021 proposed USP <797> to BUDs of less than 365 days, regardless of storage conditions. We have also demonstrated that the CMP EC's rationale for the BUDs published in the proposed <797> for Category 3 CSPs is not based on a cohesive application of scientific information, logic, and practical healthcare needs.

15.1 Use of Conventionally Manufactured Single-Dose Containers

Comment:

Clarify that the "use-by" time assigned to an entered or punctured single-dose vial used as the source of a CSP ingredient does not require the BUD of the CSP to be limited to that same "use-by" time.

Rationale:

In instances where a conventionally manufactured single-dose container of sterile medication is the source of an ingredient in a CSP, and that container is assigned a 12-hour use-by time after initial entry, regulators may interpret any subsequent ingredients being withdrawn from that single-dose container as having an assigned "BUD" of 12 hours or less. This, combined with the requirement in Section 14.3 that states "Additionally, the BUD must not exceed the shortest remaining expiration date or BUD of any of the starting components." may lead the to the expectation that the BUD of the finished CSP be limited to 12 hours or less. The intent of establishing maximum "use-by" times in Sections 15.1 and 15.2 appears to be assuming that the finished CSP will have a BUD independent of the time within which an entered or punctured container can be used.

10A



STATE LICENSE SERVICING
1751 Route 17A, Suite 3
Florida, NY 10921
Tel, 845/544-2482
Fax. 845/544-2481
statelicensesservicing.com

Date: 09/14/2023
To: Nevada Board of Pharmacy
Re: Change of DR for LifeScience Logistics, LLC
Facility Address: 1211 Person Street, Durham, NC 27703

Dear Sir/Madam:

Please be advised that I represent LifeScience Logistics, LLC as their Attorney-in-Fact for licensing purposes. Please find enclosed a completed Designated Representative Application for the new DR, Jeremy Wayne Bullock. This is to change the DR from Chad Anthony Surber to Jeremy Bullock. If you have any questions or need any additional documentation, please do not hesitate to contact me.

Kind regards,

Jennifer Schneider
VP, Client Services
LSL@SLSNY.COM
(845) 544-2482

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

1. Is at least 21 years of age;
2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
2. The Board must approve the natural person so designated.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LifeScience Logistics, LLC

Pharmacy/Wholesaler License # (if applicable) Initial is pending

Physical Address 1211 Person Street

City Durham State NC Zip 27703

Mailing Address (if different from physical address) c/o State License Servicing 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephone (845) 544-2482 Website www.lslog.com

Licensing Company Email LSL@slsny.com

Section 2: Personal Information

First Jeremy Middle Wayne Last Bullock

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [REDACTED] SSN or ITIN [REDACTED] Sex ☒ M ☐ F ☐ X

Mailing Address [REDACTED] New Milford Rd

City Cary State NC Zip 27519

Telephone [REDACTED] Email JBullock@lslog.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name East Carolina University		From - To (MM/YY – MM/YY) 08/2005 – 05/2009	
Address E 5th Street	City Greenville	State NC	Zip 27858
Diploma/Degree obtained, if any BS, Health and Human Performance			
School Name Northwest Halifax High School		From - To (MM/YY – MM/YY) 09/2001 – 06/2005	
Address 8492 NC-48	City Littleton	State NC	Zip 27850
Diploma/Degree obtained, if any High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY) 08/2023 - Present	Address [REDACTED] New Milford Rd	City Cary	State NC	Zip 27519
From - To (MM/YY – MM/YY) 01/2019 - 8/2023	Address [REDACTED] Farm Gate Rd	City Raleigh	State NC	Zip 27606
From - To (MM/YY – MM/YY) 02/2016 - 01/2019	Address [REDACTED] Sienna Terrace, Apt. 304	City High Point	State NC	Zip 27265
From - To (MM/YY – MM/YY) 01/2012 - 02/2016	Address [REDACTED] Aragon Drive, Apt. 308	City Knightdale	State NC	Zip 27545
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name LifeScience Logistics, LLC		From - To (MM/YY – MM/YY) 06/2022 - Present	
Business Address 1211 Person Street	City Durham	State NC	Zip 27703
Phone (817) 565-2543	Title Operations Manager	Number of Employed Hours ~ 2,599 hrs	
Description of Duties Currently overseeing 15+ employees within the warehousing and distribution process. Within that team I'm responsible for leading one supervisors and his team of 10+ employees. Proven history of enabling success, optimizing key business metrics and leading short/long term continuous improvement projects to maximize production output, profitability, cost effectiveness and customer satisfaction.			
Business Name Guerbet		From - To (MM/YY – MM/YY) 09/2021 - 06/2022	
Business Address 8800 Durant Rd	City Raleigh	State NC	Zip 27616
Phone (919) 878-2930	Title Manufacturing Director	Number of Employed Hours ~1,557 hrs	
Description of Duties Oversaw 120+ employee within formulation, filling, packaging, maintenance and compliance. Within that team I'm responsible for leading 9 Supervisors across 3 shifts. Implemented "Training Pay" for employees working on the assembly floor. Help lead an entire plant shift restructure from 10 hours shifts to 12 hour rotating shifts successfully.			
Business Name Guerbet		From - To (MM/YY – MM/YY) 08/2019 - 09/2021	
Business Address 8800 Durant Rd	City Raleigh	State NC	Zip 27616
Phone (919) 878-2930	Title Production Manager	Number of Employed Hours ~ 4,333 hrs	
Description of Duties Oversaw 100+ employee within Operations (formulation, filling and packaging). Within that team I'm responsible for leading 8 Supervisors across 3 shifts. Implemented a Self-Development program within my Supervision team where specific reading is encouraged and the thought process learned is used in our daily decisions.			
Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Continue on next page if additional space is needed.			

N/A

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Make copies of this page OR use a separate piece of paper if additional space is needed.			

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacture or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following where applicable:

Date of Event/Arrest	Disposition Date	State	City	County
Case #	Governing, licensing, Arresting Presiding Body/Agency/Court			
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Jeremy Wayne Bullock, certify that as the designated representative for
LifeScience Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JWB I am at least 21 years of age;
3. JWB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JWB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JWB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JWB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JWB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeremy Wayne Bullock

Print Name (First, Last)

Jeremy W. Bullock

Original Signature (electronic, copies or stamps not accepted)

01 Sept 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeremy Wayne Bullock

Print Name (First, Last)

Jeremy W. Bullock

Original Signature (electronic, copies or stamps not accepted)

01 Sept 2023

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Jeremy Wayne Bullock, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jeremy W. Bullock

Original Signature

Jeremy Wayne Bullock

01 Sept 2023

Date

Subscribed and Sworn to before me this 15th day of SEPTEMBER.

SHAUN PEREIRA

Notary Public Signature

SHAUN PEREIRA

SHAUN PEREIRA
NOTARY PUBLIC
WAKE COUNTY, N.C.
My Commission Expires 12-16-2023

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

**Medical Products Provider and Wholesaler –
Medical Devices, Equipment and Gases (MDEG) Administrator Application**

Rev (06/21/2022)

NAC 639.694

1. Each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:
 - a. Be a natural person;
 - b. Have a high school diploma or its equivalent;
 - c. Have:
 - i. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
 - ii. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
 - d. Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
 - e. Be approved by the Board.
2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.
4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

NAC 639.6946

1. Except as otherwise provided in NAC 639.6945, a medical products provider shall:
 - a. Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance.
 - b. Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

NAC 639.6957

1. A medical products wholesaler shall:
 - a. Employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler.

Please mail this completed application and all other required documents with your MDEG and/or Wholesaler Application to the address indicated above.

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

**Medical Products Provider and Wholesaler –
Medical Devices, Equipment and Gases (MDEG) Administrator Application**

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG LifeScience Logistics, LLC MDEG License # (if applicable) N/A
Physical Address 1211 Person Street
City Durham State NC Zip 27703
Mailing Address (if different from physical address) c/o State License Servicing, 1751 State Route 17A, Ste 3
City Florida State NY Zip 10921
Telephone (845) 544-2482 Website www.lslog.com
Licensing Company Email LSL@slsny.com

Section 2: Personal Information

First Jeremy Middle Wayne Last Bullock
Alias(es, nicknames, name changes, etc.) N/A
Date of Birth [REDACTED] SSN or ITIN [REDACTED] Sex ☒ M ☐ F ☐ X
Mailing Address [REDACTED] New Milford Rd
City Cary State NC Zip 27519
Telephone [REDACTED] Email JBullock@lslog.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)

- | | Yes | No |
|--|-----|----|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)

- | | Yes | No |
|--|-----|-----|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | N/A |

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)				
School Name East Carolina University			From - To (MM/YY - MM/YY) 08/2005 - 05/2009	
Address E 5th Street		City Greenville	State NC	Zip 27858
Diploma/Degree obtained, if any BS, Health and Human Performance				
School Name Northwest Halifax High School			From - To (MM/YY - MM/YY) 09/2001 - 06/2005	
Address 8492 NC - 48		City Littleton	State NC	Zip 27850
Diploma/Degree obtained, if any High School Diploma				
School Name			From - To (MM/YY - MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY - MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY - MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)				
From - To (MM/YY - MM/YY) 08/2023 - Present	Address [REDACTED] New Milford Rd	City Cary	State NC	Zip 27519
From - To (MM/YY - MM/YY) 01/2019 - 08/2023	Address [REDACTED] Farm Gate Rd	City Raleigh	State NC	Zip 27606
From - To (MM/YY - MM/YY) 02/2016 - 01/2019	Address [REDACTED] Sienna Terrace, Apt. 304	City High Point	State NC	Zip 27265
From - To (MM/YY - MM/YY) 01/2012 - 02/2016	Address [REDACTED] Aragon Drive, Apt. 308	City Knightdale	State NC	Zip 27545
From - To (MM/YY - MM/YY)	Address	City	State	Zip
From - To (MM/YY - MM/YY)	Address	City	State	Zip
From - To (MM/YY - MM/YY)	Address	City	State	Zip
From - To (MM/YY - MM/YY)	Address	City	State	Zip
From - To (MM/YY - MM/YY)	Address	City	State	Zip
From - To (MM/YY - MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name LifeScience Logistics, LLC		From - To (MM/YY - MM/YY) 06/2022 - Present	
Business Address 1211 Person Street		City Durham	State NC
Phone (817) 565-2543	Title Operations Manager		Zip 27703
Description of Duties Currently overseeing 15+ employees within the warehousing and distribution process. Within that team I'm responsible for leading one supervisors and his team of 10+ employees. Proven history of enabling success, optimizing key business metrics and leading short/long term continuous improvement projects to maximize production output, profitability, cost effectiveness and customer satisfaction.		Number of Employed Hours ~ 2,772 hrs	
Business Name Guerbet		From - To (MM/YY - MM/YY) 09/2021 - 06/2022	
Business Address 8800 Durant Rd		City Raleigh	State NC
Phone (919) 878-2930	Title Manufacturing Director		Zip 27616
Description of Duties Oversaw 120+ employee within formulation, filling, packaging, maintenance and compliance. Within that team I'm responsible for leading 9 Supervisors across 3 shifts. Implemented "Training Pay" for employees working on the assembly floor. Help lead an entire plant shift restructure from 10 hours shifts to 12 hour rotating shifts successfully.		Number of Employed Hours ~1,557 hrs	
Business Name Guerbet		From - To (MM/YY - MM/YY) 08/2019 - 09/2021	
Business Address 8800 Durant Rd		City Raleigh	State NC
Phone (919) 878-2930	Title Production Manager		Zip 27616
Description of Duties Oversaw 100+ employee within Operations (formulation, filling and packaging). Within that team I'm responsible for leading 8 Supervisors across 3 shifts. Implemented a Self-Development program within my Supervision team where specific reading is encouraged and the thought process learned is used in our daily decisions.		Number of Employed Hours ~ 4,333 hrs	
Business Name		From - To (MM/YY - MM/YY)	
Business Address		City	State
Phone	Title		Zip
Description of Duties		Number of Employed Hours	
Business Name		From - To (MM/YY - MM/YY)	
Business Address		City	State
Phone	Title		Zip
Description of Duties		Number of Employed Hours	

Continue on next page if additional space is needed.

N/A

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History		Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?			✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?			✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.			✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. **A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # N/A. Provide all the following where applicable:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Jeremy Wayne Bullock, certify that as the MDEG Administrator for

that I (initial that you have read and meet the following requirements):

1. JWB Have a high school diploma or its equivalent;
2. JWB Have
 - a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
 - b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JWB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JWB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeremy Wayne Bullock

Print Name (First, Last)

Jeremy Wayne Bullock
Original Signature (electronic, copies or stamps not accepted)

11 OCT 2023
Date

Board Use Only

Date Received: _____

14

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Facility for Treatment with Narcotics Application

Non-Refundable \$80 fee

Rev (01/05/2024)

This application cannot be returned by fax or email. An original signature and fee are required to process.

NAC 449.1542 “Facility for treatment with narcotics” defined. (NRS 449.0302, 449.0303) “Facility for treatment with narcotics” means any person or any public or private facility that provides a narcotic treatment program described in 42 C.F.R. Part 8.

42 C.F.R. § 8.2. “Opioid agonist treatment medication” means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

NRS 639.0065 “Dispense” defined.

1. “Dispense” means to deliver a controlled substance or dangerous drug to an ultimate user, patient, or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, 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.

NRS 453.021 “Administer” defined. “Administer” means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

1. A practitioner or, in the practitioner’s presence, by the practitioner’s authorized agent; or
2. The patient or research subject at the direction and in the presence of the practitioner.

A person or public or private facility may apply to the Board for a license to administer opioid agonist treatment medication by submitting an application to the Board. An applicant for a license must meet all of the following criteria:

1. Be certified by the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services pursuant to 42 C.F.R. § 8.11;
2. Hold a license issued by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NAC 449.154 to 449.15485, inclusive, to operate a facility for treatment with narcotics;
3. Be certified by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NRS 458.025;
4. Ensure that each practitioner who administer opioid agonist treatment medication at the facility is registered with the Board pursuant to NRS 453.231 and the Drug Enforcement Administration (DEA) of the United States Department of Justice to dispense controlled substances; AND
5. Be registered with the Drug Enforcement Administration (DEA) [Opioid Treatment Program \(OTP\) - How to Become Certified? | SAMHSA](https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program) (<https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program>), [eCFR :: 42 CFR 8.11 -- Opioid treatment program certification](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.11). (<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.11>).

Complete and mail the application that is **attached** to these instructions to the address indicated above with the required **non-refundable fee of \$80.00**. Fees can be paid by credit card, debit card, personal check, cashier’s check, or money order made payable to the **Nevada State Board of Pharmacy**. Credit and debit card payments are charged a **5% processing fee**.

Upon approval of the application, a pre-opening inspection will be required. Information regarding the pre-opening inspection will be provided to you after the approval of your application.

Once an application is approved, the facility receives a satisfactory pre-opening inspection and all other requirements of the board have been completed, a license will be issued.

A Facility for Treatment with Narcotics license expires OCTOBER 31, OF EVEN NUMBERED YEARS, despite when the registration is issued.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Facility for Treatment with Narcotics Application

Non-Refundable \$80 fee

Rev (01/05/2024)

Section 1: Your Information

First: _____ Middle: _____ Last: _____

Date of Birth: _____ SSN or ITIN: _____ Sex: ☐ M ☐ F ☐ X

Home Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

If the owner of the facility is a practitioner, include the following:

Practitioner License #: _____ Specialty: _____

Controlled Substance (CS) Registration #: _____ DEA #: _____

Section 2: Facility Information (A practice address is required for processing of your application.)

Practice Name (if any): _____

Practice Address: _____ Suite #: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____ Email: _____

Please indicate if opioid agonist treatment medication(s) will be administered or administered and dispensed at the facility:

☐ The facility will **ONLY BE** administering opioid agonist treatment medications.

☐ The facility will be administering **AND** dispensing opioid agonist treatment medications. (Each practitioner who intends to dispense opioid treatment medications must also obtain a dispensing registration with the Board (NAC 639.742).

Section 3: List the names of the practitioners that will be administering/dispensing opioid agonist treatment medications from the facility. (Use a separate piece of paper if additional space is needed.)

Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____
Name: _____	CS Registration #: _____

Section 4: Provide the following documents with your application:

1. The facility certification by the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services pursuant to 42 C.F.R. § 8.11;
2. The facility license issued by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NAC 449.154 to 449.15485, inclusive, to operate a facility for treatment with narcotics;
3. The facility certification by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NRS 458.025; AND

I certify under penalty of perjury that the information contained in this application is accurate, true, and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Print Name (First, Last)

Date

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: _____ Amount: _____



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • (800) 364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

Applicant Name: _____

Payment: Pay application fee by providing your credit or debit card information below, or by submitting a check made payable to **Nevada State Board of Pharmacy**.

Credit cards are charged a 5% processing fee.

Credit Type: ☐ Visa ☐ MasterCard ☐ Discover ☐ American Express	Credit Card #: _____	
Expiration Date: ____/____ (MM/YY)	CVV (3 digits on back of card): _____	Amount: \$ _____
Name on Card: _____		
Billing Address: _____ _____ _____		

15

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Change in Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Application Non-Refundable \$50.00 Fee

Rev (05/17/2023)

Section 1: Pharmacy Information			
Pharmacy Name:	Humboldt County General Hospital Pharmacy		License #: PH04461
Physical Address:	118 E Haskell St		
City:	Winnemucca	State:	NV Zip: 89445
Mailing Address (if different from physical address):	n/a		
City:	n/a	State:	n/a Zip: n/a
Telephone:	775.623.5222 x1550	Toll Free # (NAC 639.708, NRS 639.23286):	n/a
Fax:	775.625.8559	Contact Email:	simonsenj@hghospital.org

Section 2: Previous Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Information	
Pharmacist Name:	Janie Bright NV Pharmacist Registration #: 18028
State and End Date of the Managing Pharmacist/PIC/Supervising Pharmacist:	12/28/2022 to 12/26/2023

Section 3: New Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Information	
Pharmacist Name:	Joseph T. Simonsen NV Pharmacist Registration #: 20645
State Date as the Managing Pharmacist/PIC/Supervising Pharmacist:	TBD, pending Board approval, ideally 1/18/24

Personal and Professional History for the New Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist					Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?						✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?						✓
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?						✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?						✓
If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u> . Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.						
Board Administrative Action:		State:	Date:	Case #:		
Criminal Action:	State:	Date:	Case #:	County:	Court:	

Section 4: New Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Acknowledgement

Managing Pharmacist Name: Joseph T. Simonsen Pharmacist Registration #: 20645
Pharmacy Name: Humboldt County General Hospital Pharmacy Pharmacy License #: PH04461

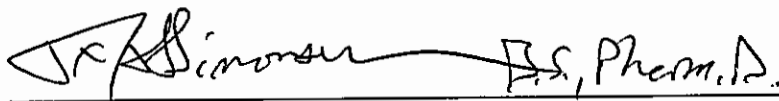
Initial each statement below to indicate you have read and agree with the following:

- JTS  I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.
- JTS  I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.
- JTS  I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.
- JTS  I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).
- JTS  I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Tyler Simonsen

Print Name of New Managing Pharmacist

 J.T. Simonsen, Pharm.D.

Original signature of New Managing Pharmacist (copies or stamps not accepted)

28 Dec 2023
28 December 2023

Date

Board Use Only

Date Received: 1/3/24

Amount: \$50.00

20A - Financial Report

SFY24 MONTHLY BUDGET REPORT
NEVADA STATE BOARD OF PHARMACY
CURRENT MONTH: Dec 23

REVENUES	APPROVED BUDGET	BUDGET AMENDMENTS	REVISED BUDGET	CURRENT MONTH REVENUE/EXPENSE	PRIOR MONTH(S) REVENUE/EXPENSE	PROJECTIONS THROUGH 6/30/2024	TOTAL REVENUE/EXPENSE SFY24	DIFFERENCE
Beginning Balance	\$ 6,232,358		\$ 6,232,358	\$ -	\$ -	\$ 6,232,358	\$ 6,232,358	\$ -
Renewal Fees	\$ 1,795,552		\$ 1,795,552	\$ 2,800	\$ 1,862,410	\$ 14,000	\$ 1,879,210	\$ 83,658
Registration Fees	\$ 1,561,460		\$ 1,561,460	\$ 83,040	\$ 535,520	\$ 942,900	\$ 1,561,460	\$ -
Recovered Costs	\$ 30,000		\$ 30,000	\$ -	\$ 500	\$ 29,500	\$ 30,000	\$ -
CC Processing Fees	\$ 175,000		\$ 175,000	\$ 2,405	\$ 106,186	\$ 66,410	\$ 175,000	\$ -
Change MGR RPh	\$ 22,800		\$ 22,800	\$ 1,000	\$ 5,900	\$ 15,900	\$ 22,800	\$ -
Inspections	\$ 5,000		\$ 5,000	\$ 75	\$ 3,110	\$ 1,815	\$ 5,000	\$ -
Interest Income	\$ 30,000		\$ 30,000	\$ 11,256	\$ -	\$ 18,744	\$ 30,000	\$ -
Late Fees	\$ 15,000		\$ 15,000	\$ 2,000	\$ 10,891	\$ 2,109	\$ 15,000	\$ -
Total Revenues	\$ 9,867,170	\$ -	\$ 9,867,170	\$ 102,576	\$ 2,524,517	\$ 7,323,736	\$ 9,950,828	\$ 83,658

EXPENSES	APPROVED BUDGET	BUDGET AMENDMENTS	REVISED BUDGET	CURRENT MONTH REVENUE/EXPENSE	PRIOR MONTH(S) REVENUE/EXPENSE	PROJECTIONS THROUGH 6/30/2024	TOTAL REVENUE/EXPENSE SFY24	DIFFERENCE
Payroll	\$ 4,142,479		\$ 4,142,479	\$ 282,711	\$ 1,539,335	\$ 2,320,433	\$ 4,142,479	\$ -
Operating	\$ 1,146,199		\$ 1,146,199	\$ 86,402	\$ 391,818	\$ 667,979	\$ 1,146,199	\$ -
Equipment	\$ 25,000		\$ 25,000	\$ 2,906	\$ -	\$ 22,094	\$ 25,000	\$ -
In-State Travel	\$ 110,000		\$ 110,000	\$ 6,546	\$ 36,520	\$ 66,933	\$ 110,000	\$ -
Out-of-State Travel	\$ 65,000		\$ 65,000	\$ 3,424	\$ 8,089	\$ 53,487	\$ 65,000	\$ -
DAG Cost	\$ 40,000		\$ 40,000	\$ 864	\$ 1,581	\$ 37,556	\$ 40,000	\$ -
Reserve	\$ 4,338,492	\$ -	\$ 4,338,492	\$ -	\$ -	\$ -	\$ 4,422,150	\$ 83,658
Total Expenses	\$ 9,867,170	\$ -	\$ 9,867,170	\$ 382,853	\$ 1,977,344	\$ 3,168,481	\$ 9,950,828	\$ 83,658
Balance	\$ -	\$ -	\$ -				\$ -	\$ -