October 2024 Board Meeting Handouts

5L. Robert Feingold

5K. Cristy O'Connell

5l. Sam Zand

6A. OxyGO – Exhibits

NV Board of Pharmacy 2025 Calendar

20A. Financial Report

7. American Wellness Pharmacy

11F. Omniscript Pharmacy, LLC

16. Audit – Fiscal Year Ending June 30, 2024

5L

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROBERT FEINGOLD, MD,** **Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, PD27479,** **Respondent.**	**Case No. 23-118-CS-PD-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through General Counsel Brett Kandt, and Respondent Robert Feingold, MD, Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, and PD27479, by and through counsel, Craig K. Perry, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about February 9, 2024, 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. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

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

4. 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 him 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 Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. By unlawfully issuing prescriptions as alleged, Respondent violated 21 U.S.C. § 353(b)(1), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), CFR § 1306.04(a) and (b), NRS 454.223, NRS 454.311(1), NRS 453.321(1)(a), NRS 453.331(1) (d) and (i), NRS 453.401(l)(a), NRS 639.2353, NRS 639.268(1)(a), NRS 639.281(1), NRS 639.2813(1), NAC 453.430(1), and/or NAC 453.440, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

B. By failing to put into practice all necessary policies and procedures to maintain the security of the drug inventory in the course of operating Advanced Medical, to ensure that all drugs were possessed, administered, furnished and/or dispensed to patients with direct practitioner supervision and a bona fide therapeutic relationship, and to ensure that no prescription was dispensed unless Respondent was on-site at the facility, as alleged, Respondent violated 21 CFR § 1301.71, NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS 453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.23505; NAC 453.400, NAC 453.410, NAC 639.742 and/or NAC 639.745(1)(c), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

C. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all controlled substances and dangerous drugs as alleged, Respondent violated 21 U.S.C. § 842(a)(5), 21 CFR § 1304.04 21 CFR § 1304.21; NRS 453.246, NRS 453.251, NRS 453.326(1)(a), NRS 454.286, NAC 453.410(1) and/or NAC 639.745(1) and (3), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

D. By failing to query the PMP database both prior to issuing and upon dispensing controlled substance prescriptions and to review for accuracy his MyRx prescriber activity as required, as alleged, Respondent violated NRS 453.163, NRS 453.164(7) and NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

E. By his acts as alleged, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945 and committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and/or NRS 639.255.

8. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The certificates of registration of Respondent Robert Feingold, MD, Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, and PD27479, are revoked pursuant to NRS 453.241(1)(b). The revocations are stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a practitioner under NRS Chapters 453 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of One Thousand Dollars ($1,000.00) for each of the thirteen counts in the Accusation, for

a total of Thirteen Thousand Dollars ($13,000.00), by personal, business, certified or cashier's 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, due and payable by December 1, 2024;

C. Pursuant to NRS 622.400, Respondent shall pay Three Thousand Dollars ($3,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "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, due and payable by December 1, 2024; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, and PD27479 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately revoke Respondent's Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, and PD27479, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 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 October 16, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

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 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

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

13. 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 knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 7 day of October 2024

ID AnksKo5DJuK5ucbSnjQKg6aJ

ROBERT FEINGOLD, MD
Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, PD27479

Signed this ___ day of _____ 2024

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

APPROVED AS TO FORM AND CONTENT
this 07 day of October 2024

Craig K. Perry
ID d2kAufE1TVLKhdWYMWpeo8ap

CRAIG K. PERRY, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Robert Feingold, MD, Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741, and PD27479, in Case No. 23-118-CS-PD-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2024.

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

eSignature Details

Signer ID:	**AnksKo5DJuK5ucbSnjQKg6aJ**
Signed by:	Robert Feingold
Sent to email:	rfein007@yahoo.com
IP Address:	172.56.208.222
Signed at:	Oct 7 2024, 4:50 pm PDT

Signer ID:	**d2kAufE1TVLKhdWYMWpeo8ap**
Signed by:	Craig Perry
Sent to email:	cperry@craigperry.com
IP Address:	74.211.37.70
Signed at:	Oct 7 2024, 6:18 pm PDT

5K

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CRISTY O'CONNELL, APRN** **Certificate of Registration No. CS25857,** **Respondent.**	**CASE NO. 23-090-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 General Counsel Brett Kandt, and Respondent Cristy O'Connell, APRN, Certificate of Registration No. CS25857 (Respondent), by and through counsel, J. Malcolm DeVoy, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about August 27, 2024, 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. On or about September 27, 2024, Respondent filed an Objection, Answer and Notice of Defense to the Accusation.

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 her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

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 her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be

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accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent issued prescriptions for compounded semaglutide under the names of specific patients to Meta Pharmacy, which ultimately were administered by injection to multiple patients, and issued prescriptions for compounded testosterone cypionate in grapeseed oil, a schedule III controlled substance, under the names of specific patients to Olympia Pharmacy, which ultimately were administered by injection to multiple patients, conduct that Respondent represents she discontinued prior to the filing of the Accusation in this case; and

B. Such conduct, if proven, could be found by the Board to constitute a violation of 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 U.S.C. 841 21 U.S.C. 842(a), 21 U.S.C. 846, 21 CFR § 1306.03(a)(1), 21 CFR 1306.04, 21 CFR 1306.05, NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.331(1)(d) and (i), NRS 453.377, NRS 453.381(1), NAC 453.430(1), NAC 453.440, NRS 639.2353, NRS 639.268(1)(a) and/or NAC 639.757(4) and (5), could be found by the Board to constitute unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h) and (i), and could be found by the Board to constitute acts that render registration inconsistent with the public interest pursuant to NRS 453.231(1):

8. Those violations alleged in the Accusation are pled with particularity in the Accusation and grounds for action pursuant to NRS 453.236(1), NRS 639.210, NRS 639.255, NAC 639.955 and NRS 622.400.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. Respondent Cristy O'Connell, APRN, Certificate of Registration No. CS25857, is placed on probation pursuant to NRS 639.255(1)(b) for a period of one (1) year subject to the following conditions:

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A. Respondent shall accept this Stipulation and Order as a public reprimand regarding her duties and responsibilities as a practitioner under NRS Chapters 453, 454 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations alleged in the Accusation, by personal, business, certified or cashier's 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, due and payable by December 1, 2024;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "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, due and payable by December 1, 2024;

D. Respondent's practice at Health Xpress Medical Center LLC shall be subject to quarterly inspections by Board staff at Respondent's expense, not to exceed $500 per inspection; and

E. Respondent shall materially comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.

Upon successful completion of probation by discharge of items 9(A) through (E) above, Respondent's Certificate of Registration No. CS25857 will be fully restored and any limitations thereto imposed by the Board released with no further action by the Board or Respondent required at such time.

10. Any failure by Respondent to comply with the terms of this Order may, in the Board's discretion, result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order

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by Respondent, the Board may impose additional discipline upon Respondent based upon the act constituting a violation of this Order that is not inconsistent with the provisions of NRS Chapters 453 and 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 16, 2024. Respondent's counsel shall appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from or related to 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.

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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 knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 18th day of October 2024

CRISTY O'CONNELL, APRN
Certificate of Registration No. CS25857

Signed this ___ day of _____ 2024

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

APPROVED AS TO FORM AND CONTENT
this 11th day of October 2024

J. MALCOLM DEVOY, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Cristy O'Connell, APRN, Certificate of Registration No. CS25857, in Case No. 23-090-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2024.

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

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LAS VEGAS, NV 89134

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAM ZAND, MD,** **Certificate of Registration No. CS22466,** **Respondent.**	**Case No. 21-229-CS-A-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through General Counsel Brett Kandt, and Respondent Sam Zand, MD, Certificate of Registration No. CS22466, by and through counsel, Maria Nutile, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about February 27, 2024, 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. On or about May 31, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

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 him 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 his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. By permitting unauthorized persons to access the Prescription Monitoring Program (PMP) database and Protected Health Information (PHI) using Respondent's credentials, and by failing to review for accuracy his MyRx prescriber activity, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. §1320d-6, 45 C.F.R. Part 160 and Part 164, Subparts A and E, NRS 453.164(7) and (8), NRS 453.321(1)(a), NRS 453.552(2), NRS 639.100(1) and/or NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b); and

B. By permitting unauthorized persons to access the PMP database and PHI using Respondent's credentials, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h) and (i), has committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(c), NRS 453.241(1) and/or NRS 639.210(4).

The Board does not allege that prescriptions were not issued for a legitimate medical purpose and does not allege patient harm.

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and/or NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. Respondent Sam Zand, MD, Certificate of Registration No. CS22466, is placed on probation for a period of one (1) year pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a practitioner under NRS Chapters 453 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, by personal, business, certified or cashier's 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, due and payable by December 1, 2024;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "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, due and payable by December 1, 2024; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS22466 will be fully restored.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately suspend Respondent's Certificate of Registration No. CS22466

and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 16, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

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

AGREED:

Signed this 16th day of September 2024

SAM ZAND, MD
Certificate of Registration No. CS22466

Signed this ___ day of _____ 2024

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

APPROVED AS TO FORM AND CONTENT
this 16th day of September 2024

MARIA NUTILE, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Sam Zand, MD, Certificate of Registration No. CS22466, in Case No. 21-229-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2024.

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

6A

EXHIBIT 1

NVBOP v. OxyGo
24-057-O

24-057-WH-O

Packing Slip

#IF50511

2/9/2024

Ship To
A+ Oxygen & DME
A+ Oxygen & DME
940 MATLEY LN
STE 14
Reno NV 89502-2139
United States
LIFT GATE NEEDED:

Date	Tracking #	Ship Via	Fulfillment of
2/9/2024	270800666130 270801392065 270800667136 270801391676 270801392786 270801392694 270800667607 270800666861	FedEx - FedEx Ground	Sales Order #SO242970

PO#
02072024Derek

	Shipped
1400-5100 OxyHome™ Stationary 0-5 LPM Concentrator Three year warranty for concentrator, including all components and sieve beds.	4

1400-5100 Serial Numbers:

11544 11542 11539 11543

OxyGo
2200 Principal Row
Orlando FL 32837
United States

P: 888-327-7301 F: 440-871-9964
Email: ar@oxygo.life

https://oxygo.life

CONSIGNEE DELIVERY RECEIPT

Freight Bill Number: 270800666130 R0 **TNBR Number:** **DATE:** 02/09/2024

Consignee
A+ OXYGEN AND DME
940 MATLEY LN
RENO
NV 89502-2139 US

Trailer # 232390

Shipper
OXYGO EAST
28825 RANNEY PKWY
WESTLAKE
OH 44145-1173 US

FedEx Freight Economy

PIECES	PKG	H/U	HM	DESCRIPTION	WGT(LBS)	NMFC	PCF	CLASS	RATE	TOTAL CHARGES
				: REDELIVERY CHARGE COLL : LIFTGATE DELIVERY-COLL 0355 CUBIC FEET FUEL SURCHG LTL SHPT31.70% 0000440 DEFICIT WT=LOWER CHARGES RATED AS..... 489737253-114-0-27 020 EARNED DISCOUNT 489737253-114-0-33 *FXF EZONE01/01/24 LS 13137	440 5000					
96		4		PREPAID - WILL INVOICE SHIPPER	4560					

BY ACCEPTING THE SHIPMENT, YOU AGREE TO BE FULLY RESPONSIBLE FOR ANY ADDITIONAL APPLICABLE CHARGES FOR DELIVERY SERVICES RENDERED INCLUDING BUT NOT LIMITED TO DETENTION.
** CHARGES SUBJECT TO CHANGE **

Delv. Driver & #:

Date:	Arrive:	Depart:
# of Skids:	# of Pcs:	OS&D #:

Shipment received in apparent good order with wrap intact unless otherwise noted.

Received by: _____

☐ Over ☐ Damage Exceptions:
☐ Short ☐ Wrap Broken

Bill of Lading Number SH75232360 1083.00

P.O. Number 02072024Derek

FedEx Freight

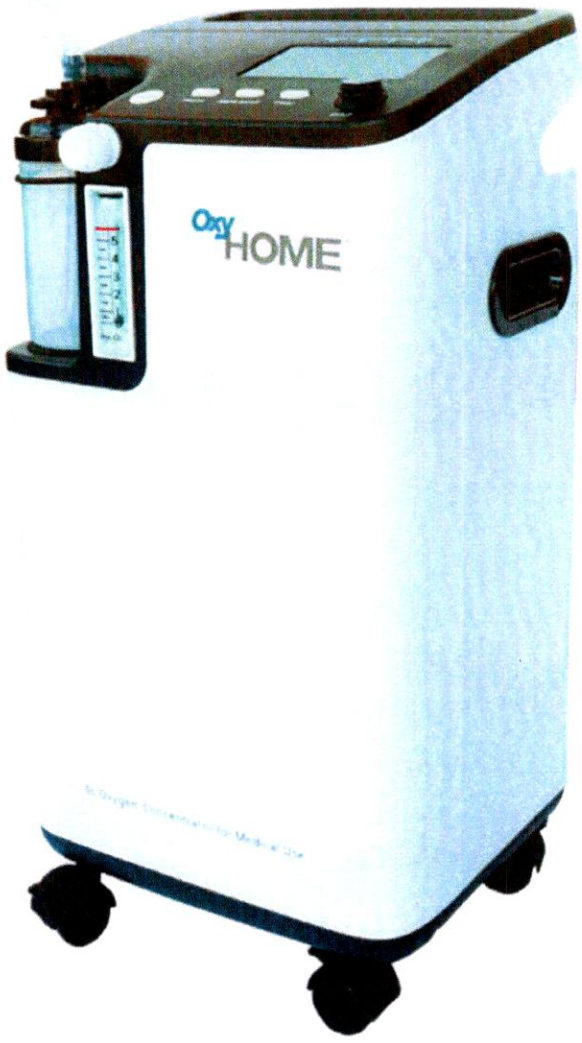
P.O. BOX 840
HARRISON, AR 72602-0840
fedex.com 1.866.393.4585

fedex.com/fastfreight

EXHIBIT 2

NVBOP v. OxyGo
24-057-O

Sale!



(https://www.oxygenparts.com/wp-content/uploads/2023/04/OxyHome-Stationary-Oxygen-Concentrator.png)

OxyHome Stationary Oxygen Concentrator

SKU: **1400-5100** Category: **Stationary oxygen concentrators (https://www.oxygenparts.com/product-category/oxygen-concentrators/stationary-oxygen-concentrators/)** Tag: **Rx required (https://www.oxygenparts.com/product-tag/rx-required/)**

~~$895.00~~ **$795.00**

3-YEAR WARRANTY

- Quiet operation
- Small footprint
- Purity check by percentage
- Alarm indicators: No flow, Low/high pressure, purity, power
- Twin blower cooling design
- Contemporary design
- 3-year replacement warranty

This item requires a doctor's prescription

CLICK HERE TO SUBMIT YOUR RX (HTTPS://HIPAA.JOTFORM.COM/213134592156150)

SKU: **1400-5100** Category: **Stationary oxygen concentrators (https://www.oxygenparts.com/product-category/oxygen-concentrators/stationary-oxygen-concentrators/)** Tag: **Rx required (https://www.oxygenparts.com/product-tag/rx-required/)**

Have questions?

Email us (https://oxygenparts.com/contact)

Call us (tel:18333602155)

Customer service hours are Mon–Fri 9AM–5PM Central Time.

Description

Additional information

User manuals

Product downloads

Device listing and declarations

Reviews (0)

Description

The new OxyHome 5L Stationary Concentrator by OxyGo has a sleek, modern look with the reliability you need in a stationary unit.

The OxyHome stationary oxygen concentrator features:

- Quiet operation
- Small footprint
- Purity check by percentage
- Alarm indicators: No flow, Low/high pressure, purity, power
- Twin blower cooling design
- Contemporary design

Warranty:

- 3-Year Replacement Warranty

Technical specifications:

- Flow Specifications: 0 – 5 LPM
- Oxygen Concentration 93% (+3%, -3%)
- Oxygen Output Pressure 8 (+2%, -2%) psi
- Rated Voltage/Frequency 120 VAC ±10% 60Hz
- Power Consumption 350 Watts
- Sound ≤ 45 dB(A)

Weight & dimensions:

- **Height:** 25.6 in (65 cm)
- **Width:** 13.4 in (34 cm)
- **Depth:** 11.8 in (30 cm)
- **Weight:** 41.8 lbs (19 kg)

Related products

NVBOP 2025 Calendar

2025
Nevada Board of Pharmacy Calendar

January

Su	M	Tu	W	Th	F	Sa
			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	29	30	31	

February

Su	M	Tu	W	Th	F	Sa
						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	

March

Su	M	Tu	W	Th	F	Sa
						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	29
30	31					

April

Su	M	Tu	W	Th	F	Sa
		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	29	30			

May

Su	M	Tu	W	Th	F	Sa
				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	29	30	31

June

Su	M	Tu	W	Th	F	Sa
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
29	30					

July

Su	M	Tu	W	Th	F	Sa
		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	29	30	31		

August

Su	M	Tu	W	Th	F	Sa
					1	2
3	4	5	6	7	8	9
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17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

September

Su	M	Tu	W	Th	F	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
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28	29	30				

October

Su	M	Tu	W	Th	F	Sa
			1	2	3	4
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12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

November

Su	M	Tu	W	Th	F	Sa
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23	24	25	26	27	28	29
30						

December

Su	M	Tu	W	Th	F	Sa
	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	29	30	31			

BOARD MEETING DATES	
Jan 15-16	Las Vegas, NV
March 5-6	Las Vegas, NV
April 16-17	Reno, NV
June 4-5	Las Vegas, NV
July 16-17	Las Vegas, NV
Sep 3-4	Reno, NV
Oct 15-16	Las Vegas, NV
Dec 3-4	Las Vegas, NV

OBSERVED STATE HOLIDAYS	
Jan 01	New Years Day
Jan 20	Martin Luther King, Jr.'s Birthday
Feb 17	Washington's Birthday
May 26	Memorial Day
Jun 19	Juneteenth Day
Jul 04	Independence Day
Sept 1	Labor Day
Oct 31	Nevada Day
Nov 11	Veterans' Day
Nov 27	Thanksgiving Day
Nov 28	Family Day
Dec 25	Christimas Day

ANNUAL MEETINGS	
APhA Annual	March 21-24 (Nashville, TN)
NACDS Annual	April 26-29 (Palm Beach, FL)
NABP Annual	May 13-16 (Fort Lauderdale, FL)
ASHP Summer	June 7-11 (Charlotte, NC)
NASCSA Annual	October 20-23 (New Orleans, Louisiana)
ASHP Mid Year	December 7-11 (Las Vegas, NV)
NABP District 8	TBD

20A

SFY25 MONTHLY BUDGET REPORT
NEVADA STATE BOARD OF PHARMACY
Sep-24

REVENUES	APPROVED BUDGET	BUDGET AMENDMENTS	REVISED BUDGET	CURRENT MONTH REVENUE/EXPENSE	PRIOR MONTH(s) REVENUE/EXPENSE	PROJECTIONS THROUGH 6/30/2025	TOTAL REVENUE/EXPENSE SFY25	DIFFERENCE
Beginning Balance	$ 4,663,661		$ 4,663,661	$ -	$ -	$ 4,663,661	$ 4,663,661	$ -
Renewal Fees	$ 6,106,426		$ 6,106,426	$ 3,529,770	$ 200	$ 2,576,456	$ 6,106,426	$ -
Registration Fees	$ 1,297,680		$ 1,297,680	$ 101,130	$ 224,500	$ 972,050	$ 1,297,680	$ -
Recovered Costs	$ 30,000		$ 30,000	$ 8,000	$ 25,818	$ (3,818)	$ 30,000	$ -
CC Processing Fees	$ 300,000		$ 300,000	$ 178,600	$ 5,946	$ 115,455	$ 300,000	$ -
Change MGR RPh	$ 22,800		$ 22,800	$ 900	$ 2,250	$ 19,650	$ 22,800	$ -
Inspections	$ 5,000		$ 5,000	$ 825	$ 7,929	$ (3,754)	$ 5,000	$ -
Interest Income	$ 30,000		$ 30,000	$ 19,176	$ 13,321	$ (2,497)	$ 30,000	$ -
Late Fees	$ 15,000		$ 15,000	$ -	$ 200	$ 14,800	$ 15,000	$ -
Total Revenues	**$ 12,470,567**	$ -	**$ 12,470,567**	**$ 3,838,400**	**$ 280,164**	**$ 8,352,003**	**$ 12,470,567**	**$ -**

EXPENSES								
Payroll	$ 4,139,230		$ 4,139,230	$ 304,199	$ 611,793	$ 3,223,238	$ 4,139,230	$ -
Operating	$ 1,382,732		$ 1,382,732	$ 666,688	$ 179,605	$ 536,439	$ 1,382,732	$ -
Equipment	$ 25,000		$ 25,000	$ 400	$ -	$ 24,600	$ 25,000	$ -
In-State Travel	$ 110,000		$ 110,000	$ 6,557	$ 8,611	$ 94,832	$ 110,000	$ -
Out-of-State Travel	$ 65,000		$ 65,000	$ -	$ 2,191	$ 62,809	$ 65,000	$ -
DAG Cost	$ 40,000		$ 40,000	$ -	$ 415	$ 39,585	$ 40,000	$ -
Reserve	$ 6,708,605	$ -	$ 6,708,605	$ -	$ -		$ 6,708,605	$ -
Total Expenses	**$ 12,470,567**	$ -	**$ 12,470,567**	**$ 977,843**	**$ 802,615**	**$ 3,981,503**	**$ 12,470,567**	**$ -**
Balance	$ -	$ -	$ -				$ -	$ -

7

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY,** **Pharmacy License No. PH02705,** **Respondent.**	**CASE NOS. 23-063-PH-N**

REQUEST FOR SPECIAL / EMERGENCY MEETING

Comes now, Kimberly Maxson-Rushton, Esquire on behalf of Respondent / Applicant, American Wellness Pharmacy ("American Wellness") and respectfully submits this request to for a special / emergency meeting of the Nevada State Board of Pharmacy ("Board") to consider Respondent's Application for Reconsideration. This Request is filed pursuant to the authority set forth in Nevada Revised Statute ("NRS") 241.020 (public meeting standards; standard for emergency meeting) and 241.023 (requirements for holding meeting via remote technology).

All notices, pleading documents and correspondence pertaining to this proceeding should be directed to the following individual:

Kimberly Maxson-Rushton, Esq.
Cooper Levenson, Attorneys at Law
3016 W. Charleston Boulevard, Suite 195
Las Vegas, NV 89102
krushton@cooperlevenson.com

I.

Procedural History

On September 4, 2024, the Board entered a Settlement and Order whereby Respondent, American Wellness was suspended from compound sterile drug products. On September 10, 2024, American Wellness received the Board Settlement and Order and learned, for the first time, that it had been suspended from operating.

Shortly thereafter, on September 20, 2024, Respondent filed an Application for Reconsideration pursuant to NRS 639.252 (Rehearing) and reinstatement of Respondent's ability to compound sterile drug product. *See*, NRS 639.2565 (Reinstatement of suspended certificate).

Petitioner filed a Response to Respondent's Application on September 23, 2024, and on September 26, 2024, Respondent filed a Reply in Support of the Application for Reconsideration and Reinstatement.

On September 27, 2024, the Board noticed American Wellness that the Application for Reconsideration would be considered at the Board's regularly scheduled October Board Meeting.

As a result of the suspension, American Wellness, and most importantly, its patients have suffered due to the immediate and unsuspected suspension of operation that went into effect on September 4, 2024. Considering the irreparable harm Respondent is facing, operational coupled with their patient's needs, American Wellness respectfully submits this request for a special / emergency meeting of the Board to vacate and modify the September 4, 2024, Settlement and Order. NRS 622A.390.

II.

Legal Authority to Convene Special / Emergency Meeting

Pursuant to Nevada's Open Meeting Law, a public body (administrative board) must provide public notice of any scheduled meeting at least three (3) days in advance of the meeting date. NRS 241.020. In response to the Covid pandemic, Nevada's public bodies may hold a meeting using remote technology (for example, Zoom). NRS 241.023. However, when unforeseen circumstances (i.e. suspension) could potentially impact the health and safety of the public, a public body may convene an emergency meeting, with less than three (3) days' notice. NRS 241.020(12). In this instance, the public health and safety of American Wellness's patients is in jeopardy due to the inability to access their medication.

Presently, the Board is scheduled to meet on October 16, 2024. If this Request is *not granted*, and an emergency meeting is not held, Respondent's patients will be forced to wait an additional two weeks for their medications. The potential for harm to said patients could be significant, thereby justifying the need for special consideration of Respondent's Application for reconsideration and reinstatement. Clearly, this is what the Nevada Legislature contemplated when passing NRS 241.020(12), the standard for convening an emergency public meeting.

> "[E]mergency" means an unforeseen circumstance which requires immediate action and includes, but is not limited to:
> (a) Disasters caused by fire, flood, earthquake or other natural causes; or
> (b) *Any impairment of the health and safety of the public.*
>
> (emphasis added)

This is also consistent with the Board's Legislative declaration, which "declares the practice of pharmacy to be a learned profession, affecting public safety and welfare and charged with the public interest, and is therefore subject to protection and regulation by the State." NRS 639.213.

Equally important for the Board's consideration is the corrective actions American Wellness has undertaken since the November 2023 inspection and, most recently, in response to the suspension. Please see attached Exhibits A through F. The intent is submitting these for the Board's consideration is to provide the Board and Respondent's patients with the assurance that reinstating American Wellness's act of compounding sterile drugs will not, in any way, threaten the safety of the public.

III.

Conclusion

Based on the arguments set forth herein, coupled with the pleadings and papers currently on file, American Wellness respectfully requests that a special / emergency meeting of the State Board of Pharmacy be held immediately to reconsider the terms of the Settlement and Order and to lift the

suspension imposed on Respondent.

COOPER LEVENSON, P.A.

By _____

Kimberly Maxson-Rushton, Esq.
Nevada Bar No. 5065
3016 West Charleston Boulevard - #195
Las Vegas, Nevada, 89102
Attorneys for American Wellness Pharmacy

CERTIFICATE OF SERVICE

I CERTIFY that on September 30, 2024, I served the, **REPLY IN SUPPORT OF APPLICATION FOR RECONSIDERATION AND REQUEST FOR REINSTATEMENT,** by depositing a copy in the United State Mail, postage prepaid, to the address listed below and by electronic mail to the following:

I declare under penalty of perjury und the law of the State of Nevada that the foregoing is true and correct.

BRETT KANDT, ESQ.
Nevada Bar No. 5384
General Counsel
NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy., Suite 206
Reno, Nevada 89521
bkandt@pharmacy.nv.gov

DATED this 30 day of September, 2024.

COOPER LEVENSON, P.A.

By Gayle B Battaglia
An Employee at Cooper Levenson, P.A.

American Wellness Pharmacy Statement

At American Wellness Pharmacy, patient safety is our foremost priority. We deeply understand that maintaining the highest standards of patient safety is critical. We acknowledge that recent concerns have highlighted areas where improvement is necessary. This document aims to provide transparency regarding the comprehensive measures we have already taken, our current efforts to enhance our healthcare facility, and our strategic roadmap for ongoing improvements.

I. Completed Safety Enhancements

Over the past year, we have made significant strides in improving our safety protocols and facility conditions. Key updates include:

- Immediate changes implemented following our November 2023 Sterile Inspection (EXHIBIT A); please refer to EXHIBIT B for more detail:
  - All sterile compounds are accurately labeled with the appropriate Beyond-Use Dates (BUDs) in compliance with USP <797> guidelines
  - All compounds with an extended BUD in excess of USP <797> guidelines have the appropriate testing measures
- In November 2023, following our annual board inspection (EXHIBIT A), we received notice regarding the updated FDA Category 2 list, which had been revised on September 29, 2023 (EXHIBIT C). In compliance with the interim policy (EXHIBIT D), we began gradually ceasing production of Category 2 compounds, ensuring patient therapy was not interrupted and working to identify alternative compounds where available. This measured approach allowed time for patients to transition safely and for providers to adjust treatment plans accordingly (EXHIBIT E). By September 2024; we fully ceased all compounding of medications containing substances from the Category 2 list, ensuring a smooth transition for both patients and providers.

II. Current Initiatives

To build on our progress, we are actively engaged in several ongoing initiatives aimed at further enhancing safety and operational excellence, which include:

- **Rewriting our Standard Operating Procedures for non-sterile and sterile compounding:** This comprehensive update aims to incorporate the latest 2023 updates from USP <795>, USP <797> and USP <800> guidelines, while refining our procedures to ensure greater efficiency and compliance. Key areas of focus

include streamlining procedures, implementing best practices, and enhancing training and support.

- Please refer to the Timeline of all changes and activities for improvements regarding the Pharmacy thus far (EXHIBIT F)

III. Roadmap for Future Improvements

Looking ahead, we are committed to a strategic plan to further enhance safety and operational efficiency. Our roadmap includes:

- New facility
  - A room with negative pressure for non sterile hazardous compounding
  - A fancy cleanroom with negative pressure for sterile HDs :)
- Live CE courses, hands on training for sterile pharmacists and technicians

Our commitment to patient safety is resolute at American Wellness Pharmacy. Through our recent updates, ongoing initiatives, and future plans, we strive to provide the highest standards of care and safety for all our patients. We deeply value the trust placed in us and are committed to continuous improvement.

Sincerely,

American Wellness Pharmacy

EXHIBIT A

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Sterile Compounding

Section 1: General Information	
Inspection Date:	11/16/23
Pharmacy Name:	American Wellness Pharmacy
Pharmacy Address:	2775 S. Jones Blvd Ste 100A
Pharmacy Phone:	702-405-9500
Pharmacy License #:	PHC02705
Managing Pharmacist:	Thomas Schotik
Managing Pharmacist License #:	08312
E-mail to be utilized for inspection f/u:	tom@americanwellnesspharmacy.com
Name of Certification Company:	CEM
Name of Pharmacist present for Inspection:	Thomas Schotik
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. PIC very well prepared for inspection with all paperwork available for review during inspection process.	☒	☐
2.	List of sterile compounding personnel available for review with associated risk level. Comments: Completed prior to inspection. Inspector added additional two staff members to list during inspection.	☒	☐
3.	Pharmacy compounds high risk sterile products. Comments: All compounding performed at location is high risk sterile compounding.	☒	☐
4.	Most recent ISO classified area certification report available for review. Comments: Reviewed most recent report dated 9/28/23. Particle count data for ISO-7 and ISO-8 rooms were well below established guidelines. Compounding room 2 was listed as inactive on the report and was not certified. Air exchanges per hour in the buffer room was 41.7. Location has BSC that is used to compound non-hazardous sterile compounded products located in buffer room. BSC passed all certification tests. Reviewed viable air sampling results. All results were below thresholds. No action required. Reviewed viable surface sampling results. All results were below thresholds. No action required. HEPA filter leak flow tests performed. No issues identified. CEM stated that certification was performed under dynamic conditions.	☒	☐
5.	Glove finger-tip results complete and accurate.	☐	☒

	Comments: Reviewed documentation provided by PIC. The only 2 personnel who completed GFT testing in the past 6 months are Rebekah Molina and Thomas Schotik. Mayhlee Kahmvongsa was due on 11/9/23 and there are no results for Magdalena Cybulska for 2023. PIC is aware that these two employees are not able to compound high risk sterile products until they pass this test. Reviewed testing form and meets all requirements.		
6.	Media fill results complete and accurate. Comments: Reviewed documentation provided by PIC. The only 2 personnel who completed Media testing in the past 6 months are Rebekah Molina and Thomas Schotik. Mayhlee Kahmvongsa was due on 11/9/23 and there are no results for Magdalena Cybulska for 2023. PIC is aware that these two employees are not able to compound high risk sterile products until they pass this test. Reviewed testing form and meets all requirements.	☐	☒
7.	Cleaning log completed and available for review for ISO classified areas. Comments: Location has separate log for ISO Class 5 area and remaining sterile compounding areas. Log contains name and dwell time for cleaning agents. Name of person performing cleaning is listed on document. Cleaning is performed on all days that the pharmacy is open and performing compounding.	☒	☐
8.	Compounding record is signed by both technician performing compounding and pharmacist who performs final verification. Comments: Both technician and pharmacist performing verification sign compounding record. Document is uploaded into software system.	☒	☐
9.	Annual competency documentation complete and accurate. Comments: Reviewed documentation for both compounding technicians. Documentation is complete and accurate.	☒	☐
10.	Pharmacy assigns beyond use dates in excess of USP-797 guidelines. Comments: Please see comments below.	☒	☐
11.	Bubble point testing results complete and accurate if applicable. Comments: Reviewed process with Rebekah Molina. She was able to appropriately describe the bubble point testing process. Filter required and PSI threshold is listed on formula for each product. If filter fails the bubble point test then pharmacy re-filters product and performs retesting. Test is documented on the compounding record. Picture of filter is placed in permanent record.	☒	☐
12.	Biological indicator results complete and accurate if applicable. Comments: Pharmacy is using autoclave for nandrolone and testosterone. Reviewed process with Rebekah Molina. She was able to appropriately describe the utilization of the biological indicator. Test is documented on the compounding record.	☒	☐
13.	Sterility, Potency, and Endotoxin results available for any products requiring such documentation. Comments: Please see comments below. Firm has folder available for review but based on NVBOP inspectors assessment many items are missing this information.	☐	☒
14.	Pharmacy performs hazardous sterile drug compounding. Comments: Hormones	☒	☐

15.	Hazardous compounding is performed in a BSC or CACI. Comments: Only ISO Class 5 hood at location is BSC.	☒	☐
16.	Documentation of initial and ongoing training for hazardous compounding staff is available for review. Comments: Location has employees sign hazardous risk assessment. Issue reviewed with PIC for need of specific hazardous compounding training. Will be addressed with USP-800.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
All Pharmacists will check that they have documentation to support BUD for high risk sterile compounded products prior to dispensing any products.	**ASAP**
PIC to provide the following documentation to NVBOP inspector: List of all high risk sterile products, BUD assigned by pharmacy, storage conditions assigned by pharmacy, sterility and potency data to support any extended BUD.	**12/16/23**

Additional Comments:
Semaglutide 1.2mg/ml 30ml vials for office use located in refrigerator during inspection. Lot was batched on 11/13/23. Expiration date listed on vial was 12/28/23. When pharmacist was asked for potency data to establish extended BUD he stated that the product was given a 45 day BUD for the frozen state. I advised PIC that since the product was being stored in the refrigerator the BUD is 3 days (high risk sterile compounding) and that the product would need to be destroyed after 11/16/23. Product vial states to refrigerate and the product has a 45 day BUD date listed on the vial. PIC was advised that under refrigeration the product BUD must be 3 days. PIC states that there are no studies on file to support an extended BUD.
Myers cocktail 50ml vials for office use located in refrigerator during inspection. Lot was batched on 10/25/23 and given a BUD of 45 days. PIC stated that product is only stored in the refrigerator and the product is labeled as refrigerate. PIC stated they have no potency or sterility testing for extended BUD. PIC advised that they must not use a BUD greater than allowed by USP unless potency, sterility, and endotoxin tests have been completed to support BUD.
Glutathione 200mg/ml 10ml vial located in refrigerator and labeled as refrigerate. Lot batched on 11/15/23 and given 90 day BUD. PIC unable to provide documentation to support BUD.
Pressure gradients are documented on all days in which pharmacy is open. All documented pressures are well above 0.02.
Discussed updated USP-797, USP-795, and USP-800 guidelines.
Discussed that office use regulation will be changing in the near future and that FDA currently doesn't allow for office use compounding. Location is currently providing a significant amount of products for office use.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

Luis Curras – lcurras@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov

Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

EXHIBIT B

STERILE INSPECTIONS 2023 CORRECTIVE ACTIONS:

1. (IN REFERENCE TO: SECTION 2 INSPECTION REPORT: # 5 AND #6):
   Glove finger-tip and Media Fill testing is completed and documented periodically (every 6 months) for all employees trained in sterile compounding. Only trained individuals have access to the sterile room. All sterile compounders are current in their fingertip and media fill tests. Any personnel without current fingertips and media fill completed testing is prohibited to participate in sterile compounding.

2. (IN REFERENCE TO: SECTION 2 INSPECTION REPORT: # 13)
   The pharmacy is currently working on extending BUD to address the new regulation of endotoxin testing in addition to the previous regulation of sterility and potency. During the transition, the pharmacy strictly follows USP 45 day frozen BUD, and has informed all clinics and patients on "3 day use after thaw" BUD. The pharmacy bulk vendors are all FDA approved and have sterility, potency and endotoxin tests as indicated per their COA.

(NUMBERS 3-5: IS IN REFERENCE TO: ADDITIONAL COMMENTS ON THE INSPECTION REPORT)

3. Semaglutide 1.2mg/ml
   a. Lot batched on 11/13/23 was wasted following the inspector's instructions.
   b. All frozen compounds were clearly labeled with "use within 3 days after thaw date"
   c. Semaglutide testing for potency, sterility, and endotoxin is currently in progress, by an accredited third party facility, to extend future BUD date.

4. Myers cocktail
   a. Lot batched on 10/25/23 was wasted following the inspector's instructions.
   b. Myers cocktail is compounded to order and clearly labeled with "use within 3 days after thaw date"

5. Glutathione 200mg/ml
   a. All frozen compounds were clearly labeled with "use within 3 days after thaw date"
   b. Pior testing of potency and sterility for glutathione had been completed. Additional testing for endotoxins is in progress at an accredited third party facility.

LIST OF ALL HIGH RISK STERILE PRODUCTS WITH STORAGE AND BEYOND USE DATES FOR AMERICAN WELLNESS PHARMACY

12/07/2023

ASCORBIC ACID 500 MG/ML FROZEN 45 DAYS

ALPROSTADIL 1000 MCG/ML REFRIGERATED 90 DAYS

BREMELANOTIDE (PT-141) 10 MG/ML FROZEN 45 DAYS

CARNITINE-L 250 MG/ML FROZEN 45 DAYS

GAC (GLUTAMINE/ARGININE/CARNITINE 50/50/100 MG/ML) FROZEN 45 DAYS

GLUTATHIONE 200 MG/ML FROZEN 45 DAYS

GONADORELIN 2 MG/ML FROZEN 45 DAYS

KETAMINE HCL 50 MG/ML REFRIGERATED 3 DAYS

KETAMINE HCL 100 MG/ML REFRIGERATED 3 DAYS

LIDOCAINE HCL 1% FROZEN 45 DAYS

LIDOCAINE 2% FROZEN 45 DAYS

LIDOCAINE 1% W/ EPINEPHERINE 1:100000 FROZEN 45 DAYS

LIDOCAINE 2% W/ EPINEPHERINE 1:100000 FROZEN 45 DAYS

LIPO V 10ML VIAL INJ (CARNITINE 250MG/ML, CHOLINE 100MG/ML, INOSITOL 50MG/ML, METHIONINE 15MG/ML, CYANOCOBALAMIN 0.5MG/ML) FROZEN 45 DAYS

LIRAGLUTIDE 2.5 MG/ML FROZEN 45 DAYS

LONG R3-IGF-1 200 MCG/ML FROZEN 45 DAYS

MIC FROZEN 45 DAYS

MIC-B12 FROZEN 45 DAYS

MYERS COCKTAIL FROZEN 45 DAYS

NAD+ 25 MG/ML FROZEN 45 DAYS

NANDROLONE DECANOATE 200 MG/ML ROOM TEMPERATURE 180 DAYS

PAPAVERINE 30 MG/ML REFRIGERATED 90 DAYS

PENTOSAN POLYSULFATE SODIUM 250 MG/ML FROZEN 45 DAYS

PGE ALPROSTADIL 20 MCG/ML FROZEN 45 DAYS

PGE ALPROSTADIL 80 MCG/ML FROZEN 45 DAYS

PGE ALPROSTADIL 100 MCG/ML FROZEN 45 DAYS

PGE ALPROSTADIL 150 MCG/ML FROZEN 45 DAYS

PHENTOLAMINE 30 MG/ML REFRIGERATED 90 DAYS

SEMAGLUTIDE 1.2 MG/ML FROZEN 45 DAYS

SERMORELIN 2 MG/ML 5ML FROZEN 45 DAYS

TESTOSTERONE CYPIONATE 200 MG/ML ROOM TEMPERATURE 180 DAYS

TESTOSTERONE PROPIONATE 100 MG/ML ROOM TEMPERATURE 50 DAYS

TIRZEPATIDE 12 MG/ML FROZEN 45 DAYS

TRIMIX #1 FROZEN 45 DAYS

TRIMIX #2 FROZEN 45 DAYS

TRIMIX #3 REFRIGERATED 60 DAYS

TRIMIX #8 FROZEN 45 DAYS

TRIMIX #9 REFRIGERATED 60 DAYS

TRIMIX CUSTOM FROZEN 45 DAYS

VITAMIN A 100,000U/ML ROOM TEMPERATURE 1 DAY

VITAMIN B COMPLEX FROZEN 45 DAYS

VITAMIN B COMPLEX W/B12 FROZEN 45 DAYS

VITAMIN B6 110 MG/ML FROZEN 45 DAYS

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 484496-01
LOT #: 08/07/2018 9:33:09AM
DESCRIPTION: ALPROSTADIL 1000UG/ML
DATE RECEIVED: 08/08/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (8 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Alprostadil Specifications = 90.0% - 115.0%	1000	µg/mL	1021.0635	102.1%	HPLC	11/9/2018

Time = 3 Months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

11/09/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452677-01
LOT #: 02/22/2018 1:56:56PM
DESCRIPTION: NANDROLONE DECANOATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials w/2 mL each in brown bags (14 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	08/23/2018

Time = 6 months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Jessica Pagan - Microbiologist

09/10/2018
Date Reported

Sterility – 18 day sterility report. In accordance with the test methodology, the sample was incubated for a minimum of 18 days.

Fungal – 18 day fungal report. In accordance with the test methodology, the sample was incubated for a minimum of 18 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
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Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452677-01
LOT #: 02/22/2018 1:56:56PM
DESCRIPTION: NANDROLONE DECANOATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials w/2 mL each in brown bags (14 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Nandrolone Decanoate Specifications = 90.0% - 110.0%	200	mg/mL	196.7838	98.4%	HPLC	8/24/2018

Time = 6 months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

08/24/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452677-01
LOT #: 02/22/2018 1:56:56PM
DESCRIPTION: NANDROLONE DECANOATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials w/2 mL each in brown bags (14 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-144	08/23/2018

Time = 6 months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

09/06/2018

Jessica Pagan - Microbiologist — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 365308-01
LOT #: 08162016G10
DESCRIPTION: Papaverine 30 mg/mL Inj
DATE RECEIVED: 08/17/2016
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Three 5 mL amber vials w/3 mL each in clear bags (8 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	01/12/2017

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
Time = 5 months of testing at pre-defined timepoints.

Maurice Rogers - Microbiologist

01/26/2017
Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA

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Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 365308-01
LOT #: 08162016G10
DESCRIPTION: Papaverine 30 mg/mL Inj
DATE RECEIVED: 08/17/2016
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Three 5 mL amber vials w/3 mL each in clear bags (8 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Papaverine HCl Specifications = 95% - 105%	30	mg/mL	30.438	101.5%	HPLC	1/16/2017

The analyses referenced in this report are for non-cGMP purpose only. The method(s) used for testing are not validated. Specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.
Time = 5 months of testing at pre-defined timepoints.

Wen Yang - Chemist

01/16/2017
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 484511-01
LOT #: 08/07/2018 9:33:46AM
DESCRIPTION: PHENTOLAMINE 30MG/ML
DATE RECEIVED: 08/08/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (8 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	11/08/2018

Time = 3 Months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Kerri Hirst - Microbiologist III — 11/26/2018 Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 484511-01
LOT #: 08/07/2018 9:33:46AM
DESCRIPTION: PHENTOLAMINE 30MG/ML
DATE RECEIVED: 08/08/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (8 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Phentolamine Mesylate Specifications = 90.0% - 110.0%	30	mg/mL	31.2159	104.1%	HPLC	11/9/2018

Time = 3 Months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

11/12/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

Certificate of Analysis

CLIENT : Precision Specialty Pharmacy
DESCRIPTION : TESTOSTERONE CYPIONATE 50mg/ml
LOT # : 11/4/2022 9:45:12 PM
ARL # : 879409
FORMULATION ID : TESTOSTERONE CYPIONATE 50MG/ML

DATE RECEIVED : 11/08/2022
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Endotoxin	MBI-145	Report Value	<10.00 EU / mL	01/10/2023
Sterility - (PRELIMINARY)	MBI-144	Sterile	No Growth at 3 Days	01/09/2023

Notes

Sterility: MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Time = Day 60 of testing at pre-defined timepoints.

Megan Adler - Microbiologist I

01/12/2023
Date

ARL BIO PHARMA

Certificate of Analysis

CLIENT : Precision Specialty Pharmacy
DESCRIPTION : TESTOSTERONE CYPIONATE
LOT # : 11/4/2022 9:45:12 PM
ARL # : 879169
FORMULATION ID : TESTOSTERONE CYPIONATE 50MG/ML

DATE RECEIVED : 11/08/2022
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Assay - Testosterone Cypionate	HPLC / AMIF-1874	90.0% - 110.0%	97.2% (48.6148mg / 1mL)	11/08/2022

Notes

Assay: The referenced method (AMIF) used for testing was validated for non-cGMP analysis of the stated analyte(s). The client should verify the specifications and analyte(s) reported are correct for the compounded formulation.

Katie Coats - Senior Chemist

11/11/2022
Date

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452686-01
LOT #: 02/22/2018 1:56:43PM
DESCRIPTION: TESTOSTERONE CYPIONATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each In brown bags (14 Total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Testosterone Cypionate Specifications = 90.0% - 110.0%	200	mg/mL	199.5923	99.8%	HPLC	8/24/2018

Time = 6 months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katherine Coats - Chemist II

08/24/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 452686-01
LOT #: 02/22/2018 1:56:43PM
DESCRIPTION: TESTOSTERONE CYPIONATE 200MG/ML GRAPESEED
DATE RECEIVED: 02/23/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in brown bags (14 Total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-144	08/28/2018

Time = 6 months of testing at pre-defined timepoints.
MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

09/11/2018

Jessica Pagan - Microbiologist — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA

Certificate of Analysis

CLIENT : American Wellness Pharmacy
DESCRIPTION : Testosterone propionate 100mg/mL
LOT # : 3/27/2023 10:32:18 AM
ARL # : 923120
FORMULATION ID : 3/27/2023 10:32:18 AM

DATE RECEIVED : 05/01/2023
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Assay - Testosterone Propionate	HPLC / AMIF-1874	88.0% - 112.0%	97.0% (97.0259mg / 1mL)	05/18/2023

Notes

Assay: The referenced method (AMIF) used for testing was validated for non-cGMP analysis of the stated analyte(s). The client should verify the specifications and analyte(s) reported are correct for the compounded formulation.

Amber Fisher

Amber Fisher - Data Review Chemist I

05/19/2023

Date

ARL BIO PHARMA

Certificate of Analysis

CLIENT : American Wellness Pharmacy
DESCRIPTION : Testosterone propionate 100mg/mL
LOT # : 3/27/2023 10:32:18 AM
ARL # : 923120
FORMULATION ID : 3/27/2023 10:32:18 AM

DATE RECEIVED : 05/01/2023
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Endotoxin	MBI-145	Report Value	<10.00 EU / mL	05/18/2023
Sterility - (PRELIMINARY)	MBI-144	Sterile	No Growth at 5 Days	05/17/2023

Notes

Sterility: MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

MA

05/22/2023

Megan Adler - Microbiologist I — Date

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
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Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 541635-01
LOT #: 06/17/2019 9:08:23AM
DESCRIPTION: TRIMIX #3: ALPROSTADIL 25UG/ML PHENTOLAMINE 1MG/ML PAPAVERIN
DATE RECEIVED: 06/18/2019
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL clear vials w/2.5 mL each in clear bags (12 total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Alprostadil Specifications = 90.0% - 115.0%	25	mcg/mL	23.1760	92.7%	AMIF-1867	8/19/2019
Papaverine HCl Specifications = 95.0% - 105.0%	28.2	mg/mL	28.6775	101.7%	AMIF-1868	8/20/2019
Phentolamine Mesylate Specifications = 90.0% - 110.0%	1.0	mg/mL	0.9371	93.7%	AMIF-1868	8/20/2019

Time = Day 60 of testing at pre-defined timepoints.

The referenced method (AMIF) used for testing was validated for non-cGMP analysis of the stated analyte(s). The client should verify the specifications and analyte(s) reported are correct for the compounded formulation.

Katherine Coats - Chemist II

08/21/2019
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
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Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 541635-01
LOT #: 06/17/2019 9:08:23AM
DESCRIPTION: TRIMIX #3 ALPROSTADIL 25UG/ML PHENTOLAMINE 1MG/ML PAPAVERIN
DATE RECEIVED: 06/18/2019
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL clear vials w/2.5 mL each in clear bags (12 total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	MBI-144	08/16/2019

Time = Day 60 of testing at pre-defined timepoints.

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Madeline Kennedy

Madeline Kennedy - Microbiologist II

08/19/2019
Date Reported

ARL Form QUF-078-V6 11/26/2012

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
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FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460869-01
LOT #: 04/05/2018 11:16:08
DESCRIPTION: TRIMIX #9 ALPROSTADIL 50UG/ML PHENTOLAMINE 1.5MG/ML PAPAVERI
DATE RECEIVED: 04/06/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL amber vials w/2 mL each in clear bags (12 total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	MBI-144	06/06/2018

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.
Time = 2 months of testing at pre-defined timepoints.

Kerri Hirst

Kerri Hirst - Microbiologist II

06/20/2018
Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

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Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460869-01
LOT #: 04/05/2018 11:16:08
DESCRIPTION: TRIMIX #9 ALPROSTADIL 50UG/ML PHENTOLAMINE 1.5MG/ML PAPAVERI
DATE RECEIVED: 04/06/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Four 5 mL amber vials w/2 mL each in clear bags (12 total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Alprostadil Specifications = 90.0% - 115.0%	50	µg/mL	47.7501	95.5%	HPLC	6/9/2018
Papaverine HCl Specifications = 95.0% - 105.0%	27	mg/mL	28.1841	104.4%	HPLC	6/7/2018
Phentolamine Mesylate Specifications = 90.0% - 110.0%	1.5	mg/mL	1.5650	104.3%	HPLC	6/7/2018

Time = 2 months of testing at pre-defined timepoints.

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Wen Yang - Chemist

06/11/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460887-01
LOT #: 04/05/2018 11:30:17
DESCRIPTION: VITAMIN D3 100,000 UNITS/ML
DATE RECEIVED: 04/06/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in clear bags (6 total)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-144	06/06/2018

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Time = 2 months of testing at pre-defined timepoints.

* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

Kerri Hirst

06/20/2018

Kerri Hirst - Microbiologist II — Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: Precision Specialty Pharmacy
2775 S. Jones Blvd., #100A
Las Vegas, NV 89146

ARL #: 460887-01
LOT #: 04/05/2018 11:30:17
DESCRIPTION: VITAMIN D3 100,000 UNITS/ML
DATE RECEIVED: 04/06/2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials w/2 mL each in clear bags (6 total)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Vitamin D3 (Cholecalciferol) Specifications = 90.0% - 120.0%	100000	Units/mL	108454	108.5%	HPLC	6/8/2018

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Time = 2 months of testing at pre-defined timepoints.

Wen Yang - Chemist

06/08/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

EXHIBIT C

Updated July 1, 2020

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Includes three categories of bulk drug substances:

- Category 1: Bulk Drug Substances Under Evaluation
- Category 2: Bulk Drug Substances that Raise Significant Safety Concerns
- Category 3: Bulk Drug Substances Nominated Without Adequate Support

Updates to Section 503A Categories

- Removal from category 3
    - Artesunate – This bulk drug substance is a component of an FDA-approved drug product (NDA 213036) and compounded drug products containing this substance may be eligible for the exemptions under section 503A of the FD&C Act pursuant to section 503A(b)(1)(A)(i)(II). This change will be effective immediately and will not have a waiting period.

For more information, please see the Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A and the final rule on bulk drug substances that can be used for compounding under section 503A, which became effective on March 21, 2019.

Updated July 1, 2020

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

- Cesium Chloride
- Domperidone
- Quinacrine Hydrochloride for Intrauterine administration
- Germanium Sesquioxide

Updated November 2, 2021

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Includes three categories of bulk drug substances:

- Category 1: Bulk Drug Substances Under Evaluation
- Category 2: Bulk Drug Substances that Raise Significant Safety Concerns
- Category 3: Bulk Drug Substances Nominated Without Adequate Support

Notice of Updates to Section 503A Categories

Additions to category 1

- Ammonium Tetrathiomolybdate – This bulk drug substance was nominated with sufficient supporting information to permit FDA to evaluate it and may be eligible for inclusion on the 503A Bulks List
- Enclomiphene Citrate-This bulk drug substance was nominated with sufficient supporting information to permit FDA to evaluate it and may be eligible for inclusion on the 503A Bulks List

For more information, please see the Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A and the final rule on bulk drug substances that can be used for compounding under section 503A, which became effective on March 21, 2019.

Updated November 2, 2021

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

- Cesium Chloride
- Domperidone
- Quinacrine Hydrochloride for intrauterine administration
- Germanium Sesquioxide

Updated September 29, 2023

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Includes three categories of bulk drug substances:

- Category 1: Bulk Drug Substances Under Evaluation
- Category 2: Bulk Drug Substances that Raise Significant Safety Concerns
- Category 3: Bulk Drug Substances Nominated Without Adequate Support

Notice of Updates to Section 503A Categories

- Additions to Category 1
  - **GHK-Cu (except for injectable routes of administration)** - This bulk drug substance was nominated with sufficient supporting information to permit FDA to evaluate it and may be eligible for inclusion on the 503A Bulks List. FDA will add GHK-Cu for injectable routes of administration to Category 2 due to significant safety risks associated with its use in compounding.
  - **L-Theanine** - This bulk drug substance was nominated with sufficient supporting information to permit FDA to evaluate it and may be eligible for inclusion on the 503A Bulks List.
- Additions to Category 2

  The following substances will be added to Category 2 because FDA has identified significant safety risks with these substances:

  - AOD 9604
  - BPC-157
  - Cathelicidin LL-37
  - CJC-1295
  - Dihexa Acetate
  - Emideltide (DSIP)
  - Epitalon
  - GHK-Cu (for injectable routes of administration)
  - Ibutamoren Mesylate
  - Ipamorelin Acetate
  - Kisspeptin-10
  - KPV
  - Melanotan II
  - Mechano Growth Factor, Pegylated (PEG-MGF)
  - MOTs-C
  - Selank Acetate (TP-7)
  - Semax (heptapeptide)
  - Thymosin Alpha-1 (Ta1)
  - Thymosin Beta-4, Fragment (LKKTETQ)

Updated September 29, 2023

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

- AOD-9604
- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- CJC-1295
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Ipamorelin Acetate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Selank acetate (TP-7)
- Semax (heptapeptide)
- Thymosin-Alpha 1 (Ta1)
- Thymosin Beta-4, Fragment (LKKTETQ)

Updated May 20, 2024

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Includes three categories of bulk drug substances:

- Category 1: Bulk Drug Substances Under Evaluation
- Category 2: Bulk Drug Substances that Raise Significant Safety Concerns
- Category 3: Bulk Drug Substances Nominated Without Adequate Support

Notice of Updates to Section 503A Categories

Additions to category 3: The substances listed below will be placed in category 3 because they were nominated with insufficient supporting information for FDA to evaluate them:

- DL-Phenylalanine
- L-Ornithine Hydrochloride
- Sodium Hydroxide 1N
- Verapamil

Revisions to category 3:

- "Racephpedrine Hydrochloride" will be corrected to "racephedrine hydrochloride" to correct a spelling error.
- "Tartrate" will be corrected to "Tartrate (acid or salt) to correct an error.
- "Bichloroacetic acid" will be corrected to "Bichloroacetic acid/Dichloroacetic acid" since they are the same substance but were initially listed separately.
- "Mercuric Sulfide" will be corrected to "Mercuric Sulfide, red/Mercury Sulfide" since they are the same substance but were initially listed separately.

Removals from category 3:

- "Psyllium" will be removed because it was originally added to category 3 in error.

Visit Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A[1] and the final rule on bulk drug substances that can be used for compounding under section 503A, which became effective on March 21, 2019, for more information.

[1] The draft guidance for industry "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act – Revision 2," was published on December 7, 2023. The guidance, if finalized as written, would end the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of the final guidance. Visit https://www.fda.gov/media/174456/download.

Updated May 20, 2024

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

Visit Safety Risks Associated with Certain Bulk Drug Substances Nominated for Use in Compounding for a summary of the identified safety risks for bulk drug substances in category 2.

- AOD-9604
- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- CJC-1295
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Ipamorelin Acetate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Selank acetate (TP-7)
- Semax (heptapeptide)
- Thymosin-Alpha 1 (Ta1)
- Thymosin Beta-4, Fragment (LKKTETQ)

Updated September 20, 2024

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Includes three categories of bulk drug substances:

- Category 1: Bulk Drug Substances Under Evaluation
- Category 2: Bulk Drug Substances that Raise Significant Safety Concerns
- Category 3: Bulk Drug Substances Nominated Without Adequate Support

Notice of Updates to Section 503A Categories

- Removals from Category 2 – Consistent with the interim policy guidance, FDA is providing notice to the public before removing the following bulk drug substances from category 2:
    - "AOD-9604" will be removed from Category 2 after 7 calendar days because the nominations were withdrawn by the nominators. However, please note that FDA has announced that it will consult the Pharmacy Compounding Advisory Committee (PCAC) on December 4, 2024 regarding the potential inclusion of AOD-9604-related bulk drug substances (AOD-9406 acetate and AOD-9604 (free base)) on the 503A bulks list.
    - "CJC-1295" will be removed from Category 2 after 7 calendar days because the nominations were withdrawn by the nominators. However, please note that FDA has announced that it will consult the PCAC on December 4, 2024 regarding the potential inclusion of CJC-1295-related bulk drug substances (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate)) on the 503A bulks list.
    - "Ipamorelin acetate" will be removed from Category 2 after 7 calendar days because the nominations were withdrawn by the nominators. However, please note that FDA has announced that it will consult the PCAC on October 29, 2024 regarding the potential inclusion of Ipamorelin-related bulk drug substances (Ipamorelin acetate and Ipamorelin (free base)) on the 503A bulks list.
    - "Thymosin alpha-1 (Ta1)" will be removed from Category 2 after 7 calendar days because the nomination was withdrawn by the nominator. However, please note that FDA has announced that it will consult the PCAC on December 4, 2024 regarding the potential inclusion of Thymosin alpha-1-related bulk drug substances (Thymosin alpha-1 acetate and Thymosin alpha-1 (free base)) on the 503A bulks list.
    - "Selank acetate (TP-7)" will be removed from Category 2 after 7 days because this bulk drug substance was nominated in error. FDA received additional information from the nominator indicating that it intended to nominate a different bulk drug substance.

- Visit Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A[1] and the final rule on bulk drug substances that can be used for compounding under section 503A.

[1] The draft guidance for industry "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act – Revision 2," was published on December 7, 2023. The guidance, if finalized as written, would end the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of the final guidance. See https://www.fda.gov/media/174456/download.

Updated September 20, 2024

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

Visit Safety Risks Associated with Certain Bulk Drug Substances for Use in Compounding for a summary of the identified safety risks for bulk drug substances in category 2.

- AOD-9604
- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- CJC-1295
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Ipamorelin Acetate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Selank acetate (TP-7)
- Semax (heptapeptide)
- Thymosin-Alpha 1 (Ta1)
- Thymosin Beta-4, Fragment (LKKTETQ)

Updated September 27, 2024

Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Includes three categories of bulk drug substances:

- Category 1: Bulk Drug Substances Under Evaluation
- Category 2: Bulk Drug Substances that Raise Significant Safety Concerns
- Category 3: Bulk Drug Substances Nominated Without Adequate Support

Updates to Categories of Substances Nominated for the 503A Bulk Drug Substances List

FDA has removed the following bulk drug substances from Category 2 for the reasons provided below:

- "AOD-9604" has been removed from Category 2 because the nominations were withdrawn by the nominators. However, please note that FDA has announced that it will consult the Pharmacy Compounding Advisory Committee (PCAC) on December 4, 2024, regarding the potential inclusion of AOD-9604-related bulk drug substances (AOD-9406 acetate and AOD-9604 (free base)) on the 503A bulks list.
- "CJC-1295" has been removed from Category 2 because the nominations were withdrawn by the nominators. However, please note that FDA has announced that it will consult the PCAC on December 4, 2024, regarding the potential inclusion of CJC-1295-related bulk drug substances (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate)) on the 503A bulks list.
- "Ipamorelin acetate" has been removed from Category 2 because the nominations were withdrawn by the nominators. However, please note that FDA has announced that it will consult the PCAC on October 29, 2024, regarding the potential inclusion of Ipamorelin-related bulk drug substances (Ipamorelin acetate and Ipamorelin (free base)) on the 503A bulks list.
- "Thymosin alpha-1 (Ta1)" has been removed from Category 2 because the nomination was withdrawn by the nominator. However, please note that FDA has announced that it will consult the PCAC on December 4, 2024, regarding the potential inclusion of Thymosin alpha-1-related bulk drug substances (Thymosin alpha-1 acetate and Thymosin alpha-1 (free base)) on the 503A bulks list.
- "Selank acetate (TP-7)" has been removed from Category 2 because FDA received additional information from the nominator indicating that they intended to nominate a different bulk drug substance.

Visit Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A[1] and the final rule on bulk drug substances that can be used for compounding under section 503A.

[1] The draft guidance for industry "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act – Revision 2," was published on December 7, 2023. The guidance, if finalized as written, would end the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of the final guidance. Visit https://www.fda.gov/media/174456/download.

Updated September 27, 2024

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

Visit Safety Risks Associated with Certain Bulk Drug Substances for Use in Compounding for a summary of the identified safety risks for bulk drug substances in Category 2, as well as other bulk drug substances that may present significant safety risks.

- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Semax (heptapeptide)
- Thymosin Beta-4, Fragment (LKKTETQ)

EXHIBIT D

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2017
Compounding and Related Documents
Revision 1

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2017
Compounding and Related Documents
Revision 1

Contains Nonbinding Recommendations

TABLE OF CONTENTS

Contains Nonbinding Recommendations

Guidance for Industry[1]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's (FDA or Agency) interim regulatory policy concerning compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act). Section 503A of the FD&C Act includes certain restrictions on the bulk drug substances that can be used in compounding and directs FDA to develop a list of bulk drug substances that can be used in compounding under that section. FDA is developing this list of bulk drug substances (the 503A bulks list), and this guidance describes FDA's interim regulatory policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for licensed physicians that compound human drug products using bulk drug substances while the list is being developed.[2,3]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded from bulk drug substances for use in animals. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA's draft guidance, *Compounding Animal Drugs from Bulk Drug Substances.*

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[3] FDA is developing a separate list of bulk drug substances that can be used in compounding under section 503B of the FD&C Act. Because section 503B contains different criteria for that list and provides for a different process for its development, the section 503B bulks list is covered under a separate guidance (see guidance for industry, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*).

II. BACKGROUND

A. Compounding From Bulk Drug Substances Under Section 503A of the Act

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and section 501(a)(2)(B) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist, or licensed physician compounds the drug product using bulk drug substances that:

1. Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
3. If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.[4]

A bulk drug substance is defined as meaning "the same as active pharmaceutical ingredient as defined in 21 CFR 207.1(b)." See 21 CFR 207.3. Active pharmaceutical ingredient is defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body," but the term "does not include intermediates used in the synthesis of the substance" (see section 503A(b)(1)(A) and 21 CFR 207.3).[5,6] FDA has interpreted "an applicable USP or NF

[4] See Section 503A(b)(1)(A)(i) of the FD&C Act.

[5] Section 503A references the definition of bulk drug substances in FDA's drug establishment registration and listing regulations, which was codified at 21 CFR 207.3(a)(4) when section 503A was enacted. On August 31, 2016, FDA published a final rule in the Federal Register to update its registration and listing regulations in Part 207, which made minor changes to the definition of bulk drug substance and moved the definition to 21 CFR 207.3 *See* 81 FR 169 (August 31, 2016). Under the previous definition, bulk drug substance was defined to mean "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances."

[6] Inactive ingredients are not subject to section 503A(b)(1)(A)(i) or the policies described in this guidance because they are not included within the definition of a bulk drug substance. *See* 21 CFR 207.3. Pursuant to section 503A(b)(1)(B), inactive ingredients used in compounding must comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding.

monograph" to mean an official USP or NF **drug substance** monograph. Accordingly, FDA does not consider USP monographs for dietary supplements to be "applicable" USP or NF monographs within the meaning of section 503A(b)(1)(A)(i)(I).

Under section 503A(c)(1), before developing this list through regulation, FDA must convene and consult an advisory committee on compounding unless FDA determines that the issuance of such regulation before consultation with the advisory committee is necessary to protect the public health. FDA must also consult with USP when promulgating the regulations.[7] The criteria for determining which bulk drug substances should appear on the section 503A bulks list "shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify."[8]

Bulk drug substances used in compounding under section 503A must also meet certain other requirements, including: (1) the bulk drug substance must be manufactured by an establishment registered under section 510 of the FD&C Act and (2) the bulk drug substance must be accompanied by a valid certificate of analysis (COA).[9]

In July 2014, FDA issued a guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, that states:

> Until a bulk drug substances list is published in the *Federal Register* as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.[10]

FDA has received comments that this policy could be causing unnecessary and inappropriate disruptions in patient care because there are patients receiving drugs compounded with bulk drug substances that are not components of FDA-approved drugs, or the subject of an applicable USP or NF monograph, but that may ultimately be included on the 503A bulks list, and those patients' care should not be disrupted while the list is under development. After considering this issue, FDA has decided to use this guidance to describe its interim policy concerning compounding with bulk drug substances while the 503A bulks list is being developed. FDA has revised the July 2014 guidance to state:

> FDA's interim policy concerning bulk drug substances that are not components of drugs approved under section 505 of the FD&C Act or that are not the subject of applicable USP or NF monographs can be found in the guidance, *Interim Policy on*

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[7] See section 503A(c)(2) of the FD&C Act.

[8] See section 503A(c)(2) of the FD&C Act.

[9] See section 503A(b)(1)(A) of the FD&C Act.

[10] See page 5 of the guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*

Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act.

FDA seeks to avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them and promulgates the regulations required under section 503A. Therefore, as described further below, FDA is issuing this interim guidance stating that it does not intend to take regulatory action for compounding drug products under section 503A using a bulk drug substance when an applicable USP or NF monograph for the substance does not exist and the substance is not a component of an FDA-approved product if, among other conditions, FDA has determined that the nomination for the bulk drug substance included adequate information for FDA to evaluate the substance and at this time, the substance does not appear to present significant safety risks.

B. Efforts to Develop the List of Bulk Drug Substances under Section 503A

1. Section 503A Bulks List — Early History

Section 503A was enacted in 1997 as part of the Food and Drug Administration Modernization Act. In the *Federal Register* of April 7, 1998 (63 FR 17011), FDA invited all interested persons to nominate bulk drug substances for inclusion on the list of bulk drug substances that can be used in compounding under section 503A and received nominations for 41 different drug substances. In November 1998, FDA published a guidance for industry, *Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act.* In this guidance, FDA announced that it would not normally take regulatory action relating to a drug product that had been compounded with a bulk drug substance that had been nominated for inclusion on the bulk drug substances list on or before November 21, 1999, while the substance was being evaluated, as long as the compounding complied with the other effective requirements in section 503A and did not appear to present a significant safety risk.[11]

In January 1999, after evaluating the nominated drug substances and consulting with the Pharmacy Compounding Advisory Committee (PCAC) as required by section 503A, FDA published a proposed rule listing 20 drug substances on the section 503A bulks list (64 FR 996, January 7, 1999). The preamble to the proposed rule indicated that 10 of the 41 nominated substances were the subject of a USP or NF monograph, or components of FDA approved drugs and did not need to be considered for inclusion on the list.[12] The proposed rule also described 10 nominated substances that were still under consideration for the bulk drug substances list and stated that one of the substances was withdrawn by its nominator at the first meeting of the PCAC. The PCAC reconvened in May 1999 to discuss bulk drug substances included in the proposed rule, in addition to other bulk drug substances (64 FR 19791; April 22, 1999).

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[11] The 1998 guidance was withdrawn in the *Federal Register* notice announcing the availability of the draft guidance *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.* See 78 FR 72901 (Dec. 4, 2013). The final guidance was published in July 2014.

[12] See 64 FR 996, at 997 (January 7, 1999).

However, after a 2002 U.S. Supreme Court decision holding that certain provisions of section 503A were unconstitutional,[13] FDA suspended its efforts to develop the bulk drugs list under section 503A.

Because of the amount of time that had passed between the publication of the proposed rule and the enactment of the 2013 Drug Quality and Security Act, which removed the provisions of the FD&C Act that the U.S. Supreme Court held to be unconstitutional in 2002, FDA felt it was necessary to begin again to develop the section 503A bulk drug substance list. In the December 4, 2013, *Federal Register* (78 FR 72841), FDA published a notice withdrawing the 1999 proposed rule and inviting all interested persons to nominate bulk drug substances for inclusion on a list of bulk drug substances that can be used for compounding under section 503A of the FD&C Act.

2. Current Nominations for the 503A Bulks List

In response to the December 2013, *Federal Register* notice, over 2,000 substances were nominated for the 503A bulks list. However, many of the substances nominated for the 503A list were for substances that can be compounded without being on the list because they are the subject of an applicable USP or NF monograph or are a component of an FDA-approved drug. In addition, many of the nominations were not for substances used in compounding as active ingredients, or did not include sufficient information for FDA to evaluate the nominated substances for inclusion on the list. To improve the efficiency of the process for developing the 503A bulks list, FDA reopened the nomination process in July 2014 (79 FR 37742) and provided more detailed information on what it needs to evaluate nominations for the 503A bulks list. FDA stated that bulk drug substances that were previously nominated would not be considered further unless they were re-nominated with adequate support to permit a meaningful evaluation. Substances that were already eligible for use in compounding or that were not adequately supported would not be evaluated for placement on the 503A bulks list.

In response to this request for nominations, approximately 740 unique substances were nominated. Of the nominated substances:

- Approximately 315 substances are already eligible for use in compounding under section 503A.

  These are the subject of an applicable USP or NF monograph or components of an FDA-approved drug product, which can be used in compounding pursuant to sections 503A(b)(1)(A)(i)(I) and (II) and, therefore, can be compounded without being included on the 503A bulks list. To determine if a bulk drug substance is the subject of an applicable USP or NF monograph, see the *USP-NF* available at www.USPNF.com. To determine if a bulk drug substance is a component of an FDA approved drug, see the FDA's *Orange Book:*

[13] For additional legal history of section 503A, see the guidance *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*

Approved Drug Products with Therapeutic Equivalence Evaluations, available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

- At least one[14] of the nominated substances is not a bulk drug substance.

This is a finished drug product that was nominated by its brand name. Finished drug products are not eligible for the 503A bulks list because they do not meet the definition of a bulk drug substance in 21 CFR 207.3.

- At least one of the substances is considered a biological product subject to approval in a biologics license application (BLA) under section 351 of the Public Health Service (PHS) Act when used for the indication proposed in the nomination.

This substance is not eligible for the 503A bulks list because biological products subject to approval in a BLA under section 351 of the PHS Act are not eligible for the exemptions in section 503A of the FD&C Act.[15] No biological products subject to approval in a BLA will be considered for the 503A bulks list.

- At least four of the nominated substances appear on the list published by FDA of substances that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (withdrawn or removed list).[16]

Such substances cannot be used in compounding under section 503A of the FD&C Act and, therefore, are not eligible for inclusion on the 503A bulks list.

- One of the nominated substances has no currently accepted medical use and is included on Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. § 812(c)).[17]

The CSA does not allow possession or distribution of Schedule I substances (21 USC §§ 841(a)(1) and 829), except for research purposes (21 U.S.C. § 823(f)), and these substances will not be considered for the 503A bulk drug substances list at this time. Those desiring to do research on a Schedule I substance can apply to do so under an investigational new drug application (IND).

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[14] The over-the-counter finished drug product Maalox was nominated. Maalox is not a bulk drug substance.

[15] The nominated substance is sodium hexachloroplatinate (IV) hexahydrate. See the revised draft guidance, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* for FDA's proposed policies regarding State-licensed pharmacies, Federal facilities, and outsourcing facilities that mix, dilute, or repackage biological products outside the scope of an approved BLA.

[16] See Section 503A(b)(1)(C) of the FD&C Act. See also 21 CFR 216.24. The four substances are: chloroform reagent, cobalt chloride hexahydrate, cobalt gluconate, and phenacetin.

[17] An extract of cannabidiol (CBD) and tetrahydrocannabinol (THC) derived from marijuana (marihuana) was nominated. Marijuana (marihuana) is a Schedule I substance.

- Of the substances that are not components of an approved drug or the subject of an applicable USP or NF monograph and that are not biological products subject to licensure in a BLA or included on Schedule I of the CSA, and do not appear on the withdrawn or removed list, approximately 350 substances were nominated without sufficient supporting evidence for FDA to evaluate them.

- The remaining substances may be eligible for inclusion on the 503A list and were nominated with sufficient supporting information for FDA to evaluate them. However, FDA has identified significant safety risks relating to the use of some of these bulk drug substances in compounded drug products.

FDA's website identifies the following categories of substances nominated for the 503A bulks list:[18]

503A Category 1 – Substances Nominated for the Bulks List Currently Under Evaluation: These substances may be eligible for inclusion on the 503A bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear on any other list.

503A Category 2 – Substances Nominated for the Bulks List That Raise Significant Safety Risks: These substances were nominated with sufficient supporting information to permit FDA to evaluate them and they may be eligible for inclusion on the 503A bulks list. However, FDA has identified significant safety risks relating to the use of these substances in compounding pending further evaluation, and therefore does not intend to adopt the policy described for the substances in Category 1. If FDA adds a substance to Category 2, it will publish a public communication (e.g., a safety alert) describing the safety risks and will post the communication on FDA's human drug compounding website,[19] advising that the substance has been added to Category 2 and is no longer eligible for the policies that apply to substances in Category 1.

503A Category 3 – Substances Nominated for the Bulks List Without Adequate Support: These substances may be eligible for inclusion on the 503A bulks list, but were

[18] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. As discussed in the July 2014 Federal Register notice requesting nominations for the 503A bulks list (79 FR 37742), nominators were to confirm that all substances nominated for the list are active ingredients that meet the definition of a "bulk drug substance." Inclusion of a substance in any of these categories does not reflect a determination by FDA that the substance is a bulk drug substance. Whether a substance is a bulk drug substance subject to the conditions in section 503A(b)(1)(A) depends on whether it meets the definition of a bulk drug substance in 21 CFR 207.3. If the substance is used in a compounded drug as an inactive ingredient, then it does not meet the definition of a bulk drug substance in 21 CFR 207.3, is not subject to the conditions in section 503A(b)(1)(A), and need not appear on the 503A bulks list to be eligible for use in compounding. Instead, when used as an inactive ingredient, the substance is subject to the conditions in section 503A(b)(1)(B), which applies to ingredients other than bulk drug substances used in compounded drugs.

[19] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm. FDA also encourages compounding facilities to subscribe to FDA's list serve to receive updates at: http://service.govdelivery.com/service/subscribe.html?code=USFDA_429.

nominated with insufficient supporting information for FDA to evaluate them. These substances can be re-nominated with sufficient supporting information through a docket that FDA has established, as discussed below in section III.B.

3. Process for Developing the 503A List

FDA is currently evaluating the substances that were nominated for the 503A bulks list with sufficient information to permit evaluation. FDA is considering a number of factors in prioritizing the order in which it reviews the nominated bulk drug substances, including but not limited to the following:

- Safety concerns about use of the bulk drug substance in compounding
- Whether the bulk drug substance was nominated by multiple parties or identified as necessary by medical professional organizations
- The efficiency with which the evaluation can be completed, based on ease of acquiring the necessary information to conduct the review, available resources, and other logistical issues

FDA may also group some nominated drug substances to facilitate efficient review and discussion. These include drugs that raise similar issues (e.g., vitamins or botanicals) or have been nominated for the treatment of the same condition (e.g., warts).

In conducting its evaluations, FDA reviews the information provided in support of the nomination and other available information to assess each bulk drug substance according to the following four criteria discussed at the PCAC meeting on February 23, 2015:

- The physical and chemical characterization of the substance
- Any safety issues raised by the use of the substance in compounded drug products
- Historical use of the substance in compounded drug products, including information about the medical condition(s) the substance has been used to treat and any references in peer-reviewed medical literature
- The available evidence of effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists

In evaluating candidates for the 503A bulks list under these criteria, FDA is using a balancing test. No single one of these criteria is dispositive; rather, FDA is considering each criterion in the context of the others and balancing them, on a substance-by-substance basis, to evaluate whether a particular substance is appropriate for inclusion on the list.

Once the evaluation of a substance is complete, FDA will present the results of its review to the PCAC to obtain its advice on whether to include the substance on the list.[20]

[20] See Section 503A(c)(1) of the FD&C Act.

Section 503A requires that FDA create the 503A bulks list by regulation in consultation with the USP. To this end, FDA has been periodically meeting with USP and discussing the list. FDA will publish a notice of proposed rulemaking (NPRM) that identifies substances FDA proposes for placement on the 503A bulks list and the substances FDA has evaluated but is not proposing to include on the 503A bulks list. After publication of the NPRM, the public will have an opportunity to comment on the proposed rule. After considering the comments submitted to the docket, FDA will publish a final rule that establishes the 503A bulks list and identifies the substances that were considered and will not be placed on the list. FDA does not intend to evaluate all of the sufficiently supported nominations before publishing the first NPRM. Instead, after FDA has made a decision on whether to propose a group of substances (e.g., 10 substances) it intends to publish an NPRM with respect to that group of substances and continue to prepare the list on a rolling basis.

A final rule will list the substances that FDA has determined can be used in compounding under section 503A and those substances that have been evaluated and not placed on the 503A bulks list, if any.

After a final rule is published, drug products compounded using the substances on the 503A bulks list will be eligible for the section 503A exemptions provided the drug product is compounded in compliance with the other conditions of section 503A. Those substances that have been evaluated and not placed on the 503A bulks list will not qualify for the policies described for the substances in Category 1.

III. POLICY[21]

A. Compounding from Bulk Drug Substances under Section 503A

Under section 503A of the FD&C Act, a bulk drug substance that is not the subject of an applicable USP or NF monograph or is not a component of an FDA-approved drug cannot be used in compounding unless it appears on a list promulgated as a regulation pursuant to section 503A(b)(1)(A)(i)(III) of the FD&C Act. This list will be codified at 21 CFR part 216 subpart E.

However, until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product and that is not the subject of an applicable USP or NF monograph, provided that the following conditions are met:

1. The bulk drug substance appears in 503A Category 1 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. A Category 1 substance may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for FDA to

[21] See the Appendix for a chart summarizing FDA's interim policy.

evaluate it and has not been identified by FDA as a substance that presents a significant safety risk in compounding prior to the publication of a final rule.

2. The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i)) of the FD&C Act);

3. The bulk drug substance is accompanied by a valid COA; and

4. The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FD&C Act.

Original manufacturer means the entity that originally produced the bulk drug substance and not a subsequent packer, repacker, labeler, or distributor.

This policy does not apply to a licensed pharmacist in a State-licensed pharmacy or Federal facility, or a licensed physician, that compounds a drug using a bulk drug substance that does not meet each of the above conditions, and the bulk drug substance is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug.

B. Substances Not Nominated or Nominated Without Adequate Support

As stated above, one of the categories of bulk drug substances FDA has identified on its website is substances nominated for the 503A bulks list that may be eligible for inclusion on the list, but that FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for FDA to evaluate them (503A Category 3). In the *Federal Register* of October 27, 2015, FDA established a docket (October docket) where these substances can be re-nominated with sufficient supporting information or where nominations for substances that were not previously nominated can be submitted.

After a substance is nominated to the October docket,[22] FDA will determine whether the nomination is supported with sufficient information to allow FDA to evaluate it. After FDA makes that determination, the nominated substance will be placed in one of the three categories described in section II.B.2 above, and the categorization will be published on the FDA website. Once the category of a substance is published, FDA intends to apply the policy described in Section III.A of this guidance to that substance. FDA generally expects to categorize bulk drug substances nominated to the October docket and to publish updated categories on its website on the first business day of each month. Please note that until substances nominated for the October docket have been categorized, the policy does ***not*** apply to those substances.

C. Comments about Nominated Bulk Drug Substances

[22] This includes re-nominations of substances with sufficient supporting information.

If you feel that a substance that you nominated does not appear on the appropriate list or category as described in this guidance you can submit your comment to docket number FDA-2015-N-3534. If you have new information on a previously nominated substance that was placed in Category 3, the substance can be re-nominated with the additional information.

A nominator may also submit a comment to the docket requesting withdrawal of any of its nominations. If the party nominating the substance was the sole nominator, FDA will update the categories described in this guidance to reflect the withdrawn nomination.[23] FDA intends to provide notice to the public before removing any nominated substances from Category 1 or Category 2.

Withdrawal of a nomination upon the nominator's request and the resulting updates to the categories described in this guidance, do not reflect a determination by FDA regarding the validity of the nomination or of any reasons given by the nominator for requesting withdrawal. In addition, FDA may continue to evaluate a substance at its discretion even if the nominator submits a comment requesting withdrawal of the nomination.

[23] If multiple parties nominated the same substance, each party that nominated the substance must withdraw its nomination for the nominated substance to be considered withdrawn and for the categories to be updated to reflect that withdrawal.

APPENDIX: SUMMARY OF POLICY

The following table summarizes the interim policy for bulk drug substances set forth in this guidance:

Category	FDA Policy
The bulk drug substance appears in 503A Category 1 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. Such substances may be eligible for inclusion on the 503A bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear to present a significant safety risk.	FDA does not intend to take action for compounding a drug product from a bulk drug substance in Category 1 that does not meet the conditions of section 503A(b)(1)(A)(i), provided that the bulk drug substance was manufactured by an establishment registered with FDA under section 510 of the FD&C Act and is accompanied by a valid COA from the entity that originally produced the bulk drug substance and provided that the drug compounded from the bulk drug substance is compounded in compliance with the other conditions of section 503A.
The bulk drug substance is a component of an FDA-approved drug and/or the subject of an applicable USP or NF monograph.	The bulk drug substance can be used in compounding under section 503A of the FD&C Act, provided it complies with the standards of the monograph (if one exists) and is compounded in compliance with the other conditions of section 503A.
The bulk drug substance appears on the withdrawn or removed list.	The bulk drug substance cannot be used in compounding under section 503A of the FD&C Act. A drug compounded using the bulk drug substance is subject to regulatory action.
The bulk drug substance appears in 503A Category 2 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. The substance has been identified by FDA as presenting a significant safety risk pending further evaluation.	The bulk drug substance cannot be used in compounding under section 503A of the FD&C Act unless and until FDA publishes a final rule authorizing its use under section 503A.
The bulk drug substance is a biological product subject to approval in a BLA.	The bulk drug substance is not eligible for the 503A bulks list. FDA has issued a separate draft guidance document describing the Agency's proposed policies concerning mixing, diluting, and repackaging biological products subject to approval in a BLA.[24]
The bulk drug substance appears in 503A Category 3 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. The substance may be eligible for inclusion on the 503A bulks list, but was nominated with insufficient supporting information for FDA to evaluate it.	The bulk drug substance cannot be used in compounding under section 503A of the FD&C Act. See section III.B of this guidance for information about re-nominating substances that were previously nominated with insufficient supporting information.

[24] See FDA's revised draft guidance, *Mixing, Diluting, and Repackaging Biological Products Subject to Approval in a Biologics License Application.*

EXHIBIT E

AMERICAN MALE WELLNESS

accounts Wellness Pharmacy <accounts@americanwellnesspharmacy.com>

American Wellness Pharmacy Formulary and Policy Updates

1 message

accounts@americanwellnesspharmacy.com <accounts@americanwellnesspharmacy.com> Thu, Dec 21, 2023 at 10:56 AM
To: balley@americanmalewellness.com

To Our Valued Customers,

First and foremost, I would like to thank you for your business and trust in our quality products for all your patient needs. I would like to take this time to update you on recent FDA regulations and changes in our formulary.

Due to the FDA placing certain peptides on the Category 2 list they have become unavailable to us through our 510C Certification FDA facility. The Category 2 list basically states that the FDA has identified safety risks with these peptides and needs to further investigate their potential for harm to the public. We recognize you have patients on continuing therapy and the cessation of that therapy could be detrimental to your patient's health. However, we would like you to recognize American Wellness Pharmacy has and will always follow all local, state, and federal regulations to provide the best quality and safety for all of our products and services. With that said, we will continue to provide peptides that we have available in stock to accommodate your needs and help you transition into new alternative peptides that will be viable options for your patient's continued medicinal treatments.

American Wellness Pharmacy is well-versed in the knowledge of peptides, and health and wellness treatments. We have a vast database of peptides we feel can better treat your patients without the discontinuation of treatment and allow you to educate yourself and your patients on the medicinal support that is available to provide better patient outcomes. We have identified several alternative peptides that we feel will have the same or better efficacy, which will provide a brief list of in this email, and further information on dosing, indications, and how the peptides will be supplied will follow in additional correspondence to individual clinics/patients upon request.

Please send all inquiries, questions, comments, and/or concerns to our team to further evaluate and provide additional education on our abilities to continue providing proper medicinal peptide support for your patients.

Category 2 List Peptides	Alternative Peptides
BPC-157	*PDA(Pentadeca Arginate)*
AOD 9604	*Hexarelin*
CJC-1295	*Hexarelin*
Dihexa	*Pinealon, FGL*
Epitalon	*Thymogen*
GHK-Cu (injectable route only)	*Hexarelin*
GHRP-2 (injectable and nasal route only).	*Hexarelin*
GHRP-6	*Hexarelin*
Ibutamoren	*Hexarelin*
Kisspeptin	*Gonadorelin*
Mots-C	*Elamipretide (SS-31)*
Selank.	*P-21 Peptide, FGL*
Semax.	*P-21 Peptide, FGL*
Thymosin Alpha 1	*Thymogen*
Thymosin Beta 4	*Thymogen*

Sincerely,
Jessica

Office: (702) 405-9500
Fax: (702) 405-9501

2775 S. Jones Blvd Ste #100A
Las Vegas, NV 89146
Website: https://americanwellnesspharmacy.com/

AMERICAN WELLNESS PHARMACY

EXHIBIT F

AMERICAN WELLNESS PHARMACY TIMELINE

RETAIL

UPCOMING CHANGES

- Extending work counter

HAZARDOUS DRUGS/NIOSH

- 08/21/2024 - Rearranged shelves, removed expired drugs, removed rack
- 09/06/2024 - Rearranged HDs onto their own shelf
- 09/12/2024 - HDs counting and filling station

NON-STERILE

STANDARD OPERATING PROCEDURES MANUAL

- 08/23/2024 - Started writing a new manual to include the updated USP <795> updates and USP <800> updates (in progress)

ROOM REORGANIZATION

- 08/28/2024 - Cabinets relabeled, cleaned, rearranged
- 08/29/2024 - Fridge and freezer removed from non-sterile into point-of-sale room (retail)

HAZARDOUS DRUGS/NIOSH

- 08/06/24 - Began research for a hood for HDs compounding
- 09/10/2024 - Additional capsule trays arrived and labeled for HDs only
- 09/12/2024 - Chemo gowns and gloves arrived

HOOD

- 09/09/24 - Pending quote/purchase from PCCA for the HDs compounding hood
- 09/19/2024 - Email from PCCA, cannot deliver and install hood, finding another installer
- 09/19/2024 - Spoke with LetCo as an alternative option
- 09/20/2024 - Purchased hood from PCCA

STERILE

UPCOMING CHANGES

- Ordered 09/10/24 - Payment Confirmed 9/16/24 - Dry oven
- Ordered 09/10/24 - Payment Confirmed 9/16/24 -2nd Incubator
- Ordered 09/12/24 - NIST Certified Digital Tracking Thermometers

- 09/18/2024 - NIST Certified Thermometers arrived
- Sink - 09/12/2024 - Began research options for touchless faucet
- Ordered 09/27/2024 - Payment Confirmed - Faucet
- Eyewash Station 09/05/2024 - Began research options pending purchase
- Portable shower 09/27/2024- Began research options pending purchase

LYOPHILIZER

- 02/21/2024 - Inquired with Aapptec regarding lyophilizer equipment purchase
- 02/29/2024 - Sent quote for two lyophilizers
- 03/04/2024 - Discussed with ownership funding and timeline
- 07/19/2024 - GSL Electrician inspected space for upgraded circuitry required for equipment
- 08/18/2024 - Received proposal from GSL Electric
- 08/29/2024 - Proposal revised per ownership
- 09/06/2024 - Declined proposal per ownership due to insufficient proposal
- 09/11/2024 - Scheduled inspection with Canyon Electric Company
- 09/13/2024 - Canyon inspected space
- 09/16/2024 - Proposal received from Canyon Electric
- 09/26/2024 - Canyon re-inspected space
- 09/27/2024 - Updated proposal set date of October 4, 2024 for upgrade

ACHC INSPECTION SERVICES PRE-INSPECTION

- 07/31/24 - ACHC Pre-inspection for Florida and Texas
- 08/01/24 - ACHC Report and feedback with suggestions from inspector Mike Annekan, RPh

BUDs

- 11/16/2023 - All improperly stored sterile products were promptly disposed of upon notification by the inspector
- 11/21/2023 - "Date thawed _____. Discard after 3 days" stickers printed and labeled on all frozen sterile compounds
- 12/07/2023 - "High Risk Sterile Products BUD" document created (reorganized version)
- 09/13/2024 - "High Risk Sterile Products BUD" document last revised
- UPCOMING ADDITIONAL TESTING: Sterility testing <71>, method suitability test, and antimicrobial testing <51>

STANDARD OPERATING PROCEDURES MANUAL

- 08/23/2024 - Started outlining new manual to include the updated USP <797> updates and USP <800> updates (in progress)

HAZARDOUS DRUGS/NIOSH

- 09/12/2024 - Chemo gowns and gloves, and new cleaning supplies arrived

MANAGEMENT

STAFF CHANGES

- 07/22/2024 - New Pharmacist In Charge → Nicole Sy #20646
- 09/10/2024 - Thomas Schotik #08312 suspended
- 09/19/2024 - Thomas Schotik #08312 employment separation
- 09/20/2024 - Notified board of staff changes via e-mail (info@, CC: Nicole@)
- 09/20/2024 - Nicole Sy informed employer of resignation #20646

PARAGRAPH 8(c) modifications: Case No. 23-063-PH-S

***MANAGING PHARMACIST TRAINING:** Managing pharmacist shall complete compounding and USP core training courses through accredited vendor PCCA. Said training will take place onsite and online at https://www.pccarx.com/PCCAEducation/Pharmacy. Moreover, in anticipation of the Board Certified Sterile Compounding Pharmacist (BCSCP) certification examination, managing pharmacist shall complete an ACPE-accredited course which consists of 27.5 hours, "Compounded Sterile Preparations Certificate for Pharmacists."

Additionally, all Pharmacists and Pharmaceutical Technicians will complete continuing educations courses on sterile compounding through Critical Point at https://www.criticalpoint-lms.com.

***QUARTERLY INSPECTIONS:** American Wellness shall undergo at least two (2) inspections by the National Association of Board's of Pharmacy (NABP) with all results/findings sent directly to the Board of Pharmacy.

***NOTICE TO PATIENTS:** Pharmacy must generate a list of all dispensing's for products that were mislabeled with inaccurate beyond use dates. All patients must receive written notification that the product they received had a beyond use date listed that was fifteen times what was allowed by law. The letter must a notice that the patient may request a refund of what the patient paid for the mislabeled product. Form of notification subject to approval by Board staff; list must be provided to Board staff.

11F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 01895	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FA2325783 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1 - General Information

Pharmacy Name: OMNISCRIPT PHARMACY LLC

Physical Address: 4045 E BELL RD STE 163

City: PHOENIX State: ARIZONA Zip: 85032

Mailing Address (if different from physical address): THE SAME

City: _____ State: _____ Zip: _____

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Supervising/Managing Pharmacist Name (NRS 639.220): KRISTINE LOWE

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 12361

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Financial Statements

June 30, 2024

Nevada State Board of Pharmacy

Nevada State Board of Pharmacy

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Casey Neilon, Inc.
Accountants and Advisors

Independent Auditor's Report

To the Board of Directors
Nevada State Board of Pharmacy
Carson City, Nevada

Report on the Audit of the Financial Statements

Opinions

We have audited the accompanying financial statements of the governmental activities and the major fund of the Nevada State Board of Pharmacy ("the Board") as of and for the year ended June 30, 2024, and the related notes to the financial statements, which collectively comprise the Board's basic financial statements as listed in the table of contents.

In our opinion, the financial statements referred to above present fairly, in all material respects, the respective financial position of the governmental activities, and the major fund of the Nevada State Board of Pharmacy, and the respective changes in financial position, for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinions

We conducted our audit in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Board and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Board's ability to continue as a going concern for twelve months beyond the financial statement date, including any currently known information that may raise substantial doubt shortly thereafter.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards and *Government Auditing Standards* will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with generally accepted auditing standards and *Government Auditing Standards*, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Board's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Board's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

Required Supplementary Information

Accounting principles generally accepted in the United States of America require that the management's discussion and analysis on pages 5 through 9, pension information – schedule of changes in net pension liability on page 28, pension information – schedule of contributions on page 29, other post-employment benefit information – schedule of changes in net other post-employment benefits liability on page 30, other post-employment benefit information – schedule of contributions on page 31, and the notes to the required supplementary information on page 32, be presented to supplement the basic financial statements. Such information is the responsibility of management and, although not a part of the basic

financial statements, is required by the Governmental Accounting Standards Board, who considers it to be an essential part of financial reporting for placing the basic financial statements in an appropriate operational, economic, or historical context. We have applied certain limited procedures to the required supplementary information in accordance with auditing standards generally accepted in the United States of America, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management's responses to our inquiries, the basic financial statements, and other knowledge we obtained during our audit of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

Supplementary Information

Our audit was conducted for the purpose of forming opinions on the financial statements that collectively comprise the Board's financial statements. The accompanying condensed schedules of net position, condensed schedules of activities and schedule of expenditures of federal awards, as required by Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, are presented for purposes of additional analysis and are not a required part of the basic financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the basic financial statements. The information has been subjected to the auditing procedures applied in the audit of the basic financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the basic financial statements or to the basic financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, condensed schedules of net position, condensed schedules of activities and the schedule of expenditures of federal awards are fairly stated, in all material respects, in relation to the basic financial statements as a whole.

Report on Summarized Comparative Information

Summarized information for the year ended June 30, 2023 is presented for comparative purposes only and was extracted from the financial statements for that year, on which we expressed an unmodified audit opinion on those financial statements. In our opinion, the summarized comparative information presented herein as of and for the year ended June 30, 2023 is consistent, in all material respects, with the audited financial statements from which it has been derived.

Other Reporting Required by Government Auditing Standards

In accordance with *Government Auditing Standards*, we have also issued our report dated October 11, 2024 on our consideration of the Nevada State Board of Pharmacy's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is solely to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the Board's internal control over financial reporting or on compliance.

That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the Board's internal control over financial reporting and compliance.

Reno, Nevada
October 11, 2024

The Board members' and management's discussion and analysis of the Nevada State Board of Pharmacy's (Board) financial condition and activities for the fiscal year ended June 30, 2024 is presented in conjunction with the audited financial statements.

Financial Highlights

- Program revenue for the fiscal year ended June 30, 2024 was approximately $5,200,000 representing a $400,000 increase from the fiscal year ended June 30, 2023.
- The Nevada State Legislative Commission approved a license for Recovery Room with a fee of $500 every even year. The Board mandated inspections of the sites prior to operation. The Board expects a limited number of license applications.
- The Board approved Regulations for both Automated Dispensing Systems (ADS) and Mechanical Devices (MD). The Board mandated inspections of the sites prior to operation. The ADS fee is $500 every even year and the MD fee is $250 every even year. The Board expects a limited number of license applications.
- The Board along with the State of Nevada Department of Health secured a federal grant fund to continue providing an enhancement to the Prescription Drug Monitoring Program (PMP) allowing for integration of PMP data into medical health records throughout the State. This addition was fully funded by grant funding and will cease upon loss of grant funds. These expansions do not represent a commitment of Board funds in future years.

Overview of Annual Financial Report

Management's Discussion and Analysis (MD&A) serves as an introduction to, and should be read in conjunction with, the basic audited financial statements and supplementary information. The MD&A represents the Board members' and management's examination and analysis of the Board's financial condition and performance. Summary financial statement data, key financial and operational indicators used in the Board's strategic plan, budget, and other management tools were used for this analysis.

The Board uses the modified accrual basis of accounting for internal financial statement reporting. The financial statements have been prepared in accordance with generally accepted accounting principles as they apply to governmental units. The financial statements include a balance sheet, a statement of revenue, expenditures, and changes in fund balance, and notes to the financial statements.

The Statement of Net Position and Governmental Fund Balance Sheet present the financial position of the Board on both the modified accrual basis under the general fund and the full accrual basis as net position. This statement provides information on the Board's assets, deferred outflows, liabilities and deferred inflows, with the difference reported as net position/fund balance. Over time, increases and decreases in net position/fund balance are one indicator of whether the financial position of the Board is improving or deteriorating.

The Statement of Net Position and the Governmental Fund Balance Sheet provide information about the nature and number of resources and obligations at year-end. The Statement of Activities and Governmental Fund Revenue, Expenditures and Changes in Fund Balance presents the results of the activities over the course of the fiscal year and information as to how the fund balance and net position changed during the year.

The fund balance changes under the modified accrual method when revenue is received or the expenditure is made, while changes in net assets under the full accrual method are recorded as soon as the underlying event giving rise to the change occurs, regardless of the timing of the related cash flows. This statement also provides certain information about the Board's recovery of its costs.

The notes to financial statements provide required disclosures and other information that are essential to a full understanding of material data provided in the statements. The notes present information about the Board's accounting policies, significant account balances and activities, material risks, obligations, commitments, contingencies and subsequent events, if any.

The financial statements were prepared by the Board's staff from the detailed books and records of the Board. The financial statements were audited during the independent external audit process.

Financial Analysis

The basic financial statements, as well as the required supplementary information, serve as the key financial data for the Board members' and management's monitoring and planning.

Statement of Net Position

The Board's net position remains strong at year-end with adequate liquid assets to fulfill its responsibilities even though the net position is a deficit at year end. The Board members and management believe the current financial condition and staff capabilities are sufficient to meet anticipated operating expenses and operational objectives. During the year ended June 30, 2015, the Board implemented GASB Statements No. 68 and No. 71, *Accounting and Financial Reporting for Pensions and Pension Transitions for Contributions Made Subsequent to the Measurement Date*, respectively. In March 2016, the GASB issued Statement No. 82, *Pension Issues – An Amendment of GASB Statements No. 67, No. 68, and No. 73*, effective for periods beginning after June 15, 2016, or June 15, 2017 when an employer's pension liability is measured on a date other than the employer's most recent fiscal year-end. The objective of this statement is to address certain issues that have been raised with respect to GASB Statements No. 67, No. 68, and No. 73 regarding (1) the presentation of payroll-related measures in required supplementary information, (2) the selection of assumptions and the treatment of deviations from the guidance in an Actuarial Standard of Practice for financial reporting purposes, and (3) the classification of payments made by employers to satisfy employee (plan member) contribution requirements. Management implemented the statement during the year ended June 30, 2018.

During the year ended June 30, 2018, the Board implemented GASB Statement No. 75, *Accounting and Financial Reporting for Post-employment Benefits other than Pensions*, as required. The purpose of the statement is to improve accounting and financial reporting by state and local governments for post-employment benefits other than pensions (other post-employment benefits or OPEB). It also improves information provided by state

and local governmental employers about financial support for OPEB that is provided by other entities. Total OPEB Liability (referred to as the Actuarial Accrued Liability under GASB Statement No. 45) must be determined using the Entry Age Normal actuarial cost method as opposed to the Projected Unit Credit actuarial cost method used under GASB 45. This change in actuarial cost method resulted in a decrease in the Total OPEB Liability.

The impact of the implementation of these standards to the current year is to include certain deferred inflows and outflows of resources and reflect a net pension liability for the PERS retirement program and a net other post-employment liability as it relates to the Board. The financial impact resulted in the net position of the Board being a deficit of $1,995,531 and $2,093,568 at June 30, 2024 and June 30, 2023, respectively.

Statement of Activities

Revenue: The program revenue received by the Board is generated through the registration, renewal and licensure of pharmacies and pharmacists. Total revenue received by the Board for fiscal year ended June 30, 2024 was approximately $6,600,000, representing a $100,000 increase from the fiscal year ended June 30, 2023.

Expenses: Operating expenses for the fiscal year ended June 30, 2024 were approximately $6,500,000, representing a $200,000 decrease from the fiscal year ended June 30, 2023. The decrease primarily relates to decreases in grant expenses, group insurance expenses and bank charges.

General Fund Budgetary Highlights

Total licensing fees received were more than budgeted amounts by approximately $1,800,000, primarily due to increases in renewals and registration fees.

Total expenses were more than the budgeted amounts by approximately $1,000,000, primarily due to increases in committee expenses and pension-related expenses.

Per Board Regulation these funds will be held for Board reserve.

Economic Factors and Next Year's Budget

The Board is charged with, and given statutory authority, to provide public protection through the licensure and regulation of pharmacists, pharmacies, and other businesses and their employees involved in the manufacture, distribution, and dispensation of drugs. The Board provides direction of staff actions toward its mission of public protection through licensure and disciplinary measures.

To this end, the Board has implemented a variety of changes that include continued software development to automate various job functions which provides cost savings in personnel services. Staff has been directed to continue seeking areas in which operating expenses can be reduced without jeopardizing the high level of customer service the licensees and public have come to know.

Through the Board members' and management's review of the annual budget and monthly income and expense statements, it is expected that these tools will continue to provide the Board with sufficient long and short-term planning information.

Following are the condensed statements of net position for the years ended June 30:

	2024 Actual Government-Wide	2023 Actual Government-Wide
Assets		
Cash and cash equivalents	$ 5,138,371	$ 6,473,443
Accounts and grants receivable	85,671	29,375
Prepaid expenses and deposits	41,589	40,392
Capital assets, net of accumulated depreciation	9,025	-
Right of use lease assets, net of accumulated amortization	4,755,496	5,211,526
Total assets	10,030,152	11,754,736
Deferred Outflows of Resources	2,209,726	2,533,680
Total assets and deferred outflows of resources	12,239,878	14,288,416
Liabilities		
Accounts payable and accrued expenses	234,715	263,225
Wholesaler license deposits	325,000	275,000
License fees received in advance	934,580	2,942,830
Lease liabilities	5,045,497	5,367,435
Net other post-employment benefit liability	1,842,876	1,801,318
Net pension liability	5,602,727	5,451,105
Total liabilities	13,985,395	16,100,913
Deferred Inflows of Resources	250,014	281,071
Total liabilities and deferred inflows of resources	14,235,409	16,381,984
Net Position		
Net position		
Invested in capital assets	(280,976)	(155,909)
Unrestricted	(1,714,555)	(1,937,659)
Total Net Position	$ (1,995,531)	$ (2,093,568)

Following are the condensed statements of activities for the years ended June 30:

	2024 Actual Government-Wide	2023 Actual Government-Wide
Expenses		
Operations	$ 1,972,084	$ 2,266,077
Personnel	4,446,503	4,278,355
Travel	91,630	109,173
Total expenses	6,510,217	6,653,605
Program Revenue		
Fees, licensing, and permits (charges for services)	5,199,976	4,847,940
General Revenue		
Grant revenue	1,033,490	1,191,016
Investment income	167,742	101,340
Other income	207,046	398,131
Total general revenue	1,408,278	1,690,487
Total revenue	6,608,254	6,538,427
Change in Net Position	$ 98,037	$ (115,178)

Nevada State Board of Pharmacy
Statement of Net Position and Governmental Fund Balance Sheet
June 30, 2024

	General Fund	Adjustments (Note 10)	Statement of Net Position
Assets			
Cash and investments	$ 5,138,371	$ -	$ 5,138,371
Prepaid expenses	41,589	-	41,589
Accounts receivable	85,671	-	85,671
Capital assets, net of accumulated depreciation	-	9,025	9,025
Right-of-use lease assets, net of amortization	-	4,755,496	4,755,496
Total assets	5,265,631	4,764,521	10,030,152
Deferred Outflows of Resources			
Net other post-employment benefit liability related	-	103,567	103,567
Net pension liability related	-	2,106,159	2,106,159
Total deferred inflows of resources	-	2,209,726	2,209,726
Total assets and deferred outflows of resources	$ 5,265,631	$ 6,974,247	$ 12,239,878
Liabilities			
Accounts payable	$ 35,162	$ -	$ 35,162
Accrued compensated absences			
Due within one year	-	67,000	67,000
Due in more than one year	-	132,553	132,553
Wholesaler license deposits	325,000	-	325,000
Lease liabilities			
Due within one year	-	346,283	346,283
Due in more than one year	-	4,699,214	4,699,214
Licensing fees received in advance	934,580	-	934,580
Net other post-employment benefit liability	-	1,842,876	1,842,876
Net pension liability	-	5,602,727	5,602,727
Total liabilities	1,294,742	12,690,653	13,985,395
Deferred Inflows of Resources			
Net other post-employment benefit liability related	-	152,327	152,327
Net pension liability related	-	97,687	97,687
Total deferred inflows of resources	-	250,014	250,014
Total liabilities and deferred inflows of resources	1,294,742	12,940,667	14,235,409
Fund Balance/Net Position			
Fund balance			
Nonspendable			
Prepaid expenses	41,589	(41,589)	-
Unassigned	3,929,300	(3,929,300)	-
Total fund balances	3,970,889	(3,970,889)	-
Total liabilities and fund balance	$ 5,265,631		
Net position			
Invested in capital assets, net of related debt		(280,976)	(280,976)
Unrestricted		(1,714,555)	(1,714,555)
Total Net Position		$ (1,995,531)	$ (1,995,531)

Nevada State Board of Pharmacy

Statement of Activities and Governmental Fund Revenue, Expenditures, and Changes in Fund Balance

Year Ended June 30, 2024

	General Fund	Adjustments (Note 10)	Statement of Activities
Expenditures/Expenses			
Board operations	$ 5,922,186	$ 588,031	$ 6,510,217
Program Revenue			
Charges for services, licensing revenue	5,199,976	-	5,199,976
Net program revenue	(722,210)	(588,031)	(1,310,241)
General Revenue			
Grant revenue	1,033,490	-	1,033,490
Investment income	167,742	-	167,742
Other income	207,046	-	207,046
	1,408,278	-	1,408,278
Excess (Deficiency) of Revenue over (under) Expenditures	686,068	(686,068)	-
Change in Net Position	-	98,037	98,037
Fund Balance/Net Position			
Beginning of year	3,284,821	(5,378,389)	(2,093,568)
End of Year	$ 3,970,889	$ (5,966,420)	$ (1,995,531)

Note 1 - Reporting Entity and Summary of Significant Accounting Policies

The Nevada State Board of Pharmacy (the Board) was created in 1901. The Board is regulated by the Nevada Revised Statutes, which also specify the authorized activities of the Board. The Board is the licensing and regulatory agency for pharmacists and pharmacies as well as fifteen other license types in the State of Nevada.

The financial statements of the Board have been prepared in accordance with generally accepted accounting principles as applied to governmental units. The Governmental Accounting Standards Board (GASB) is the accepted standard-setting body for establishing governmental accounting and financial reporting principles.

The following is a summary of the more significant accounting policies.

Reporting Entity

Effective July 1, 2001, Chapter 353 of the Nevada Revised Statutes (NRS) was amended to exempt certain professional and occupational boards from the state budget act and the provisions governing the administration of state funding. The provisions of Chapter 353 do not apply to boards created pursuant to chapters 623 to 625A, inclusive, 628, 630 to 640A inclusive, 641 to 644, inclusive, 654 and 656 of the NRS and the officers and employees thereof. Accordingly, the Board's budgeting and accounting practices and procedures have been removed from the oversight of the Department of Administration.

The Board's financial statements are not included in the financial statements of the State of Nevada since the State does not exercise financial or administrative control over the Board. This is in conformance with GASB codification Section 2100, Defining the Government Reporting Entity.

Basis of Presentation

The Board is defined as a single-program special-purpose entity under GASB Statement No. 14, paragraph 131 as amended by GASB Statement No. 39. This classification allows for the preparation of GASB Statement No. 34 financial statements under an optional reporting method which combines the fund and government-wide statements into a single presentation. Under standard GASB Statement No. 34 methodology, the government-wide statement of net position and statement of activities are presented independently from the respective fund balance sheet and statement of revenue, expenditures, and fund balance. A reconciliation of adjustments provided on the modified financial statements demonstrates the changes from the fund financial statements to the government-wide financial statements in order to assist the reader in evaluating these statements. The Board has utilized this optional method of presentation.

Basis of Accounting

The government-wide financial statements are reported using the economic resources measurement focus and the accrual basis of accounting. Revenues are recorded when earned and expenses are recorded when a liability is incurred, regardless of the timing of related cash flows.

Governmental fund financial statements are reported using the current financial resources measurement focus and the modified accrual basis of accounting. Revenue is recognized as soon as it is both measurable and available.

Note 1 - Reporting Entity and Summary of Significant Accounting Policies (Continued)

Basis of Accounting (Continued)

"Measurable" means the amount of the transaction can be determined and "available" means collectable within the current period or soon enough thereafter to pay liabilities of the current period. For this purpose, the government considers revenues to be available if they are collected within 60 days of the end of the current fiscal period. Expenditures generally are recorded when a liability is incurred, as under accrual accounting.

Cash and Investments

Cash is maintained in two commercial banks in Reno, Nevada. The Board participates in the State of Nevada collateralization program to assure that funds deposited are protected.

Cash also consists of time certificates of deposit, which are stated at fair value. The net increase (decrease) in the fair value of the investments is the difference between the cost (if purchased during the fiscal year) or the fair value of the investments at the beginning of the year, and the fair value of the investments at the end of the year. Changes in fair value of the certificates are reflected, together with interest income, as investment income in the accompanying financial statements. The Board's certificates are held in its name and it participates in the State of Nevada collateralization program to assure that funds deposited are protected. By statutes, all cash must be deposited in entities that are located in the State of Nevada.

Capital Assets

Capital assets, which include furniture, fixtures, and equipment, are reported in the net position column in the government-wide financial statements. Capital assets are defined by the Board as assets with an initial, individual cost of $5,000 and an estimated useful life of at least one year. Such assets are recorded at historical cost. Donated assets are recorded at estimated fair market value at the date of donation. The costs of normal maintenance and repairs that do not add to the value of the asset or materially extend asset lives are expensed as incurred. Capital assets are depreciated using the straight-line method over three to twenty years.

Under the modified accrual basis of accounting, acquisitions are considered expenditures in the year purchased.

Compensated Absences

Compensated absences are accounted for in accordance with GASB Statement No. 16, *Accounting for Compensated Absences*, which requires that a liability for compensated absences relating to services already rendered and that are not contingent on a specified event be accrued as an employee earns the rights to the benefits. Compensated absences relating to future services or that are contingent on a specified event will be accounted for in the period those services are rendered, or those events take place. The Board policy permits employees to accumulate earned but unused comp time, vacation and sick benefits subject to certain limitations on hours based on years of service. The sick time paid upon termination is limited to certain payout requirements and has hereby been reflected in the accompanying financial statements based upon these limitations. For the general fund, only the portion of the compensated absences paid from available resources, within 60 days following year-end, are reflected as a liability, if applicable. The full liability is reflected in the government-wide financial statements.

Note 1 - Reporting Entity and Summary of Significant Accounting Policies (Continued)

Wholesaler License Deposits

In accordance with statutes, non-publicly traded companies that are wholesalers of prescription drugs must provide a bond, cash deposit or other form of security. There are two companies that provided cash as security under this statute. The cash and liability are reflected in the accompanying financial statements.

Licensing and Licensing Fees Received in Advance

Licensing revenue includes fees for applications, registration and renewal, fines and penalties for late registration and disciplinary fines and charges for administrative duties performed by the Board.

The Board administers its licensing registration on biennial periods from November through October. Licensing fees received in advance represent revenue from the biennial renewals of licenses and the registration of new licenses and is recognized ratably over the license period.

Deferred Outflows and Inflows of Resources

In addition to assets, a separate section is reported for deferred outflows of resources. This separate financial statement element, deferred outflows of resources, represents a consumption of net position that applies to a future period and will not be recognized as an outflow of resources (expense/expenditure) until then. The differences between expected and actual experience, changes in assumptions, changes in proportion, and differences between employer contributions and proportionate share of contributions as well as contributions made after the measurement period for pensions and other post-employment benefits qualify for reporting in this category.

In addition to liabilities, a separate section is reported for deferred inflows of resources. This separate financial statement element, deferred inflows of resources, represents an acquisition of net position that applies to a future period and will not be recognized as an inflow of resources (revenue) until that time. Differences between expected and actual experience and between projected and actual investment earnings on pension plan investments other post-employment benefits qualify for reporting in this category.

Fund Equity and Net Position

In the governmental fund financial statements, fund balances are classified as follows:

Nonspendable - represents amounts that are either not in a spendable form or are legally or contractually required to remain intact. The Board includes fund balances that have been prepaid for expenses and deposits on hand in this category.

Restricted – represents amounts which can be spent only for specific purposes because of state or federal laws, or externally imposed conditions. The Board has no restricted fund balances.

Committed – represents amounts which can be used only for specific purposes determined by the members of the governing Board’s formal action through a resolution or action. The Board has no committed funds.

Note 1 - Reporting Entity and Summary of Significant Accounting Policies (Continued)

Fund Equity and Net Position (Continued)

Assigned - represents amounts that are intended by the Board for specific purposes but do not require action by the governing Board. The Board has no assigned funds.

Unassigned – represents all amounts not included in spendable classifications.

The Board's policy is to first apply expenditures against restricted, committed, assigned fund balances and then unassigned balances. On an annual basis, assigned fund balances are determined based upon available resources.

In the government-wide financial statements equity is classified as net position and displayed in the three following components, as applicable:

- Net invested in capital assets – consists of capital assets, net of accumulated depreciation, right-of-use assets, net of accumulated amortization, and any related debt as well as lease assets less lease liabilities.
- Restricted net position – consists of net position with constraints placed on their use either by (1) external groups such as creditors, grantors, contributors, or laws and regulations of other governments; or (2) law through constitutional provisions or enabling legislation.
- Unrestricted net position – net position that is neither classified as "invested in capital assets" nor as "restricted."

The Board's policy is to first apply expenditures against restricted net position and then unrestricted balances.

Pensions

For purposes of measuring the net pension liability, deferred outflows of resources, deferred inflows of resources and pension expense, information about the fiduciary net position of the Public Employees' Retirement System of Nevada (PERS) and additions to/deductions from PERS's fiduciary net position have been determined on the same basis as they are reported by PERS. For this purpose, benefit payments (including refunds of employee contributions) are recognized when due and payable in accordance with the benefit terms. Investments are reported at fair value.

Post-employment Benefits Other Than Pensions (OPEB)

For purposes of measuring the net OPEB liability, deferred outflows of resources and deferred inflows of resources related to OPEB, and OPEB expense, information about the fiduciary net position of the Self Insurance Trust Fund, Public Employees' Benefits Program (PEBP) and additions to/deductions from PEBP's fiduciary net position have been determined on the same basis as they are reported by PEBP. For this purpose, PEBP recognizes benefit payments when due and payable in accordance with the benefit terms. PEBP's cash and cash equivalents consist of short-term, highly liquid investments that are both (a) readily convertible to known amounts of cash and (b) so near to materiality that they present insignificant risk of changes in value due to charging interest rates.

Note 1 - Reporting Entity and Summary of Significant Accounting Policies (Continued)

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Subsequent Events

The Board has evaluated subsequent events through October 11, 2024, the date which the financial statements were available to be issued.

Adoption of New Accounting Pronouncements

During the year ended June 30, 2024, the Board implemented the provisions of GASB Statement No. 100, *Accounting Changes and Error Corrections*. Issued in June 2022, the primary objective of this Statement is to enhance accounting and financial reporting requirements for accounting changes and error corrections to provide more understandable, reliable, relevant, consistent, and comparable information for making decisions or assessing accountability. There is no impact to the Board for implementing this standard.

New Accounting Pronouncements (not yet adopted)

The following GASB pronouncements have been issued, but are not effective as of June 30, 2024:

GASB Statement No. 101, *Compensated Absences*. Issued in June 2022, Governments commonly provide benefits to employees in the form of compensated absences. The primary objective of this Statement is to better meet the information needs of financial statement users by updating the recognition and measurement guidance for compensated absences. Statement No. 101 will be effective for the Board for fiscal year ending June 30, 2025.

GASB Statement No. 102, *Certain Risk Disclosures*. Issued in December 2023, the primary objective of this Statement is to enhance the quality and completeness of financial reporting by ensuring that stakeholders are informed about significant risks that could impact the entity's financial position. Statement No. 102 will be effective for the Board for fiscal year ending June 30, 2025.

The Board will implement new GASB pronouncements no later than the required effective date. The Board is currently evaluating whether or not the above listed new GASB pronouncements will have a significant impact on the Board's financial statements.

Note 2 - Compliance with Nevada Revised Statutes and Nevada Administrative Code

The Board conformed to all significant statutory constraints on its financial administration during the fiscal year.

Note 3 - Deposits with Financial Institutions

The Board maintains its checking accounts, certificates of deposit accounts, brokerage account and bond in two commercial banks. The time certificates of deposit are held in the name of the Board. The accounts are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000 in the aggregate per bank for the checking accounts and $250,000 for the time deposits.

The bank balances at June 30, 2024 is covered by the FDIC, and the amount not covered by the FDIC is collateralized with securities held by the Nevada Pooled Collateral program. By provisions of statutes, the Board is required to deposit all money in banks or savings and loan associations located in the State of Nevada.

Note 4 - Capital Assets

The Board has custodial responsibility to the State of Nevada for furniture, fixtures and equipment acquired with resources of the Board. The capital asset activity during the year is as follows:

	June 30, 2023	Increases	Decreases	June 30, 2024
Capital assets, being depreciated				
Office furniture and equipment	$ 755,339	$ 9,500	$ -	$ 764,839
Software	129,060	-	-	129,060
Vehicle	123,225	-	-	123,225
	1,007,624	9,500	-	1,017,124
Less accumulated depreciation				
Office furniture and equipment	(755,339)	-	-	(755,339)
Software	(129,060)	(475)	-	(129,535)
Vehicle	(123,225)	-	-	(123,225)
	(1,007,624)	(475)	-	(1,008,099)
Net capital assets	$ -	$ 9,025	$ -	$ 9,025

Note 5 - Long-Term Obligations

Activity on long-term obligations as provided in the government-wide financial statements is as follows:

	June 30, 2023	Increases	Decreases	June 30, 2024	Current Portion
Licensing fees received in advance	$ 2,942,830	$ 1,869,160	$ (3,877,410)	$ 934,580	$ 934,580
Lease liabilities	5,367,435	-	(321,938)	5,045,497	346,283
Compensated absences	222,666	109,169	(132,282)	199,553	67,000
	$ 8,532,931	$ 1,978,329	$ (4,331,630)	$ 6,179,630	$ 1,347,863

Note 6 - Leases

The Board currently leases office space in Reno and Las Vegas, Nevada. The existing lease in Las Vegas expires February 28, 2027 with monthly payments ranging from $11,001 to $12,382. The existing lease in Reno was amended in May 2022 to expand the office space leased and to extend the term of the lease. The amended lease expires December 31, 2032 and has an option to renew until December 31, 2037. The lease carries monthly payments that range from $27,729 to $37,266 during the initial lease term, and from $38,384 to $43,202 during the option period.

In accordance with GASB Statement No. 87, *Leases,* the lease liability is initially measured at the net present value of the future minimum lease payments expected to be paid. As there was no interest rate stated in any of the leases at the time of initial measurement, the leases were discounted using an incremental borrowing rate equal to the treasury rates that coincide with the length of the leases, as reported by the Wall Street Journal to discount the annual lease payments to recognize the right-to-use lease assets and the lease liabilities as of June 30, 2022.

	June 30, 2023	Increases	Decreases	June 30, 2024
Lease assets:				
Buildings	$ 5,737,887	$ -	$ -	$ 5,737,887
Less: accumulated amortization	(526,361)	(456,030)	-	(982,391)
	$ 5,211,526	$ (456,030)	$ -	$ 4,755,496

	June 30, 2023	Increases	Decreases	June 30, 2024	Current Portion
Lease liabilities:					
Buildings	$ 5,367,435	$ -	$ (321,938)	$ 5,045,497	$ 346,283

Annual requirements to amortize long-term obligations and related interest are as follows:

Year Ending June 30	Principal	Interest
2025	$ 346,283	$ 153,477
2026	371,805	142,946
2027	347,548	131,637
2028	270,469	121,067
2029	290,552	112,840
Thereafter	3,418,840	534,666
	$ 5,045,497	$ 1,196,633

Note 7 - Pensions

General Information About the Pension Plan

Plan Description

PERS (System) administers a cost-sharing, multiple-employer, defined benefit public employees' retirement system which includes both Regular and Police/Fire members. The System was established by the Nevada Legislature in 1947, effective July 1, 1948. The System is administered to provide a reasonable base income to qualified employees who have been employed by a public employer and whose earnings capacities have been removed or substantially impaired by age or disability.

Benefits Provided

Benefits, as required by the Nevada Revised Statutes (NRS or statute), are determined by the number of years of accredited service at time of retirement and the member's highest average compensation in any 36 consecutive months with special provisions for members entering the System on or after January 1, 2010 and for members entering the System on or after July 1, 2015. Benefit payments to which participants or their beneficiaries may be entitled under the plan include pension benefits, disability benefits, and survivor benefits.

Monthly benefit allowances for members are computed as 2.5% of average compensation for each accredited year of service prior to July 1, 2001. For service earned on and after July 1, 2001, this multiplier is 2.67% of average compensation. For members entering the System on or after January 1, 2010, there is a 2.5% service time factor and for regular members entering the System on or after July 1, 2015, there is a 2.25% multiplier. The System offers several alternatives to the unmodified service retirement allowance which, in general, allow the retired employee to accept a reduced service retirement allowance payable monthly during his or her lifetime and various optional monthly payments to a named beneficiary after his or her death.

Post-retirement increases are provided by authority of NRS 286.575 – 286.579.

Vesting

Regular members entering the System prior to January 1, 2010 are eligible for retirement at age 65 with five years of service, at age 60 with 10 years of service, or at any age with thirty years of service. Regular members entering the System on or after January 1, 2010, are eligible for retirement at age 65 with five years of service, or age 62 with 10 years of service, or any age with thirty years of service. Regular members who entered the System on or after July 1, 2015 are eligible for retirement at age 65 with 5 years of service, or at age 62 with 20 years of service, or at age 55 with 30 years of service, or at any age with 33 1/3 years of service.

The normal ceiling limitation on monthly benefits allowances is 75% of average compensation. However, a member who has an effective date of membership before July 1, 1985, is entitled to a benefit of up to 90% of average compensation. Both Regular and Police/Fire members become fully vested as to benefits upon completion of five years of service.

Note 7 - Pensions (Continued)

General Information About the Pension Plan (Continued)

Contributions

The authority for establishing and amending the obligation to make contributions and member contribution rates is set by statute. New hires, in agencies which did not elect the Employer-Pay Contribution (EPC) plan prior to July 1, 1983 have the option of selecting one of two contribution plans. Contributions are shared equally by employer and employee. Employees can take a reduced salary and have contributions made by the employer (EPC) or can make contributions by a payroll deduction matched by the employer.

The System's basic funding policy provides for periodic contributions at a level pattern of cost as a percentage of salary throughout an employee's working lifetime in order to accumulate sufficient assets to pay benefits when due.

The System receives an actuarial valuation on an annual basis indicating the contribution rates required to fund the System on an actuarial reserve basis. Contributions actually made are in accordance with the required rates established by the Nevada Legislature. These statutory rates are increased/decreased pursuant to NRS 286.421 and 286.450.

The actuary funding method used is the Entry Age Actuarial Cost Method. It is intended to meet the funding objective and result in a relatively level long-term contributions requirement as a percentage of salary.

For the fiscal year ended June 30, 2024, the statutory employer/employee matching rate was 17.50% for regular employees. The employer-pay contribution (EPC) rate was 33.50%, June 30, 2024 for regular employees.

Pension Liabilities, Pension Expense, and Deferred Outflows of Resources and Deferred Inflows of Resources Related to Pensions

At June 30, 2024, the Board reported a liability of $5,602,727 for its proportionate share of the net pension liability. The net pension liability was measured as of June 30, 2023, and the total pension liability used to calculate the net pension liability was determined by an actuarial valuation as of that date. The Board’s proportion of the net pension liability was based on total contributions due on wages paid during the measurement period. Each employer's proportion of the net pension liability is based on their combined employer contributions relative to the total combined employer contributions for all employers for the period ended June 30, 2023. At June 30, 2023, the Board’s proportion was .03069% percent, which was an increase of .00050% from its proportion measured at June 30, 2022.

For the years ended June 30, 2024, the Board recognized pension expense of $906,364. Amounts totaling $418,086 resulting from Board contributions subsequent to the measurement date will be recognized as a reduction of the net pension liability in year ended June 30, 2024. For the year ended June 30, 2024, the Board contributed $418,086 under the statute’s requirements based on covered payroll of $2,516,938 which equates to 16.61% overall to the plan.

Note 7 - Pensions (Continued)

General Information About the Pension Plan (Continued)

June 30, 2024, the Board reported deferred outflows of resources and deferred inflows of resources related to pension from the following sources:

	Deferred Outflows of Resources	Deferred Inflows of Resources
Differences between expected and actual experience	$ 730,281	$ -
Changes of assumptions	525,082	-
Net difference between projected and actual investment earnings on pension plan investments	-	52,442
Changes in proportion	432,710	45,245
Contributions subsequent to the measurement date	418,086	-
	$ 2,106,159	$ 97,687

Contributions subsequent to the measurement date are recognized in the following year. Amounts reported as deferred outflows of resources and deferred inflows of resources, without regard to the contributions subsequent to the measurement date, related to pensions will be recognized in pension expense as follows:

Years Ending June 30,	
2025	$ 322,986
2026	270,423
2027	842,465
2028	120,382
2029	34,130
	$ 1,590,386

The net difference between projected and actual investment earnings on pension plan investments will be recognized over five years, all the other above deferred outflow and deferred inflows will be recognized over the average expected remaining services lives, which was 5.63 years for the measurement period.

Reconciliation of the net pension liability at June 30, 2024 is as follows:

Beginning net pension liability	$ 5,451,105
Pension expense	906,364
Employer contributions	(355,339)
Current year net deferred (inflows) and outflows	(399,403)
Ending net pension liability	$ 5,602,727

Note 7 - Pensions (Continued)

Actuarial Assumptions

The System's net pension liability was measured as of June 30, 2023, and the total pension liability used to calculate the net pension liability was determined by an actuarial valuation as of that date. The total pension liability was determined using the following actuarial assumptions, applied to all periods included in the measurement:

Inflation rate	2.50%
Payroll growth	3.50%, including inflation
Investment rate of return	7.25%
Productivity pay increase	0.50%
Projected salary increases	Regular: 4.20% to 9.10%, depending on service. Rates include inflation and productivity increases.
Consumer price index	2.50%
Other assumptions	Same as those used in the June 30, 2023 funding actuarial valuation

Actuarial assumptions used in the June 30, 2023 valuation were based on the results of the experience study covering the period from July 1, 2016, to June 30, 2020.

The discount rate used to measure the total pension liability was 7.25% as of June 30, 2023. The projection of cash flows used to determine the discount rate assumed that employee and employer contributions will be made at the rate specified in statute. Based on that assumption, the pension plan's fiduciary net position at June 30, 2023, was projected to be available to make all projected future benefit payments of current active and inactive employees. Therefore, the long-term expected rate of return on pension plan investments was applied to all periods of projected benefit payments to determine the total pension liability as of June 30, 2023.

Investment Policy

The System's policies which determine the investment portfolio target asset allocation are established by the System. The asset allocation is reviewed annually and is designed to meet the future risk and return needs of the System. The following was the System’s adopted policy target asset allocation as of June 30, 2023:

Asset Class	Target Allocation	Long-Term Geometric Expected Real Rate of Return *
U.S. Stocks	42%	5.50%
International Stocks	18%	5.50%
U.S. Bonds	28%	0.75%
Private Markets	12%	6.65%

*As of June 30, 2023, PERS' long-term inflation assumption was 2.50%.

Note 7 - Pensions (Continued)

Discount Rate and Pension Liability Discount Rate Sensitivity

The following presents the net pension liability of the PERS as of June 30, 2023, calculated using the discount rate of 7.25%, as well as what the PERS net pension liability would be if it were calculated using a discount rate that is 1 percentage-point lower (6.50%) or 1 percentage-point higher (8.50%) than the current discount rate:

	1% Decrease Discount Rate (6.25%)	Discount Rate (7.25%)	1% Increase Discount Rate (8.25%)
Net pension liability	$ 8,717,249	$ 5,602,727	$ 3,030,670

Pension Plan Fiduciary Net Position

Additional information supporting the Schedule of Employer Allocations and the Schedule of Pension Amounts by Employer is located in the PERS Annual Comprehensive Fiscal Report (ACFR) available on the PERS website at www.nvpers.org under Quick Links – Publications.

Note 8 - Other Post-Employment Retirement Benefits (OPEB)

General Information About the OPEB Plan

Plan Description

Employees of the Board are provided with OPEB through the Self Insurance Trust Fund, Public Employees' Benefits Program (PEBP) - a cost-sharing multiple employer defined benefit OPEB plan administered by the Public Employees' Benefits Program Board (PEBP Board) which was created in 1983 by the Nevada Legislature to administer group health, life and disability insurance for covered employees, both active and retired, of the State, and certain other participating public employers within the State of Nevada. PEBP does not provide for refunds of employee contributions. The Self Insurance Trust Fund issues a publicly available financial report that can be obtained at https://pebp.state.nv.us/. The Board is reporting plan information consistently with the PEBP's accounting methods and assumptions as disclosed in the annual report. No information has come to our attention that indicates significant changes to the plan's disclosures.

Benefits Provided

Benefits other than pensions are provided to eligible retirees and their dependents through the payment of subsidies from the State Retirees' Health & Welfare Benefits Fund. The "base" subsidy rates are set by PEBP and approved by the Legislature and vary depending on the number of dependents and the medical plan selected. These subsidy rates are subtracted from the premium to arrive at the "participant premium". The "years of service" subsidy rates are then used to adjust the "participant premium" based on years of service. The current subsidy rates can be found on the PEBP website at www.pebp.state.nv.us.

Note 8 - Other Post-Employment Retirement Benefits (OPEB) (Continued)

Benefits include health, prescription drug, dental and life insurance coverage. As required by statute, benefits are determined by the number of years of service at the time of retirement and the individual's initial date of hire. Officers and employees hired after December 31, 2011 are not eligible to receive subsidies to reduce premiums. The following individuals and their dependents are eligible to receive subsidies from the Retirees' Fund:

Any PEBP covered retiree with State service whose last employer was the State or a participating local government entity and who:

- Was initially hired by the State prior to January 1, 2010 and has at least five years of public service; or
- Was initially hired by the State on or after January 1, 2010, but before January 1, 2012 and has at least fifteen years of public service; or
- Was initially hired by the State on or after January 1, 2010, but before January 1, 2012 and has at least five years of public service and has a disability; or
- Any PEBP covered retiree with State service whose last employer was not the State or a participating local government entity and who has been continuously covered under PEBP as a retiree since November 30, 2008.

State service is defined as employment with any Nevada State agency, the Nevada System of Higher Education and any State Board or Commission. Participating local government entity is defined as a county, school board, municipal corporation, political subdivision, public corporation or other local governmental agency that has an agreement in effect with PEBP to obtain group insurance.

Contributions

Per NRS 287 contribution requirements of the participating entities and covered employees are established and may be amended by the PEBP Board. The Boards' contractually required contribution for the year ended June 30, 2024 was $77,666, actuarially determined as an amount that is expected to finance the costs of benefits earned by employees during the year. Employees are not required to contribute to the OPEB plan.

OPEB Liabilities, OPEB Expense, and Deferred Outflows of Resources and Deferred Inflows of Resources Related to OPEB

At June 30, 2024, the Board reported a liability of $1,842,876 for its proportionate share of the net OPEB liability. The net OPEB liability was measured as of June 30, 2023, and the total OPEB liability used to calculate the net OPEB liability was determined by an actuarial valuation as of that date. The Board's proportion of the net OPEB liability was based on a projection of the Board's long-term share of contributions to the OPEB plan relative to the projected contributions of all participating state agencies, actuarially determined. At June 30, 2023, the Board's proportion was 0.1264%, which was an increase of 0.0015% from its proportion measured at June 30, 2022.

Note 8 - Other Post-Employment Retirement Benefits (OPEB) (Continued)

For the year ended June 30, 2024, the Board recognized OPEB expense of $97,441. At June 30, 2024, the Board reported deferred outflows of resources and deferred inflows of resources related to OPEB from the following sources:

	Deferred Outflows of Resources	Deferred Inflows of Resources
Differences between expected and actual experience	$ -	$ 36,151
Changes of assumptions	25,901	115,641
Asset experience	-	535
Fund contributions subsequent to the measurement date	77,666	-
	$ 103,567	$ 152,327

Contributions subsequent to the measurement date are recognized in the following year. Amounts reported as deferred outflows of resources and deferred inflows of resources, without regard to the contributions subsequent to the measurement date, related to OPEB will be recognized in OPEB expense as follows:

Years Ending June 30,	
2025	$ (52,814)
2026	(61,302)
2027	(5,464)
2028	(5,393)
2029	(1,453)
	$ (126,426)

Actuarial Assumptions

The total OPEB liability in the June 30, 2023 actuarial valuation was determined using the following actuarial assumptions, applied to all periods included in the measurement, unless otherwise specified:

Inflation	2.50 percent
Salary increases	4.20% to 9.10%
Investment rate of return	2.50 percent, same as inflation rate assumption
Discount Rate	3.65 percent
Healthcare cost trend rates	4.80% increase effective 7/1/2023, then 7.25% graded down to 0.25% to ultimate 4.50% over 11 years

Healthy mortality rates were based on the PUB-2010 Public Retirement Plans Safety Mortality Table weighted by Headcount, projected by MP-2020 for officers, and PUB-2010 Public Retirement Plans General Mortality Table weighted by Headcount, projected by MP2020 for civilians. Disabled mortality rates were based on the PUB-2010 Public Retirement Plans Safety Disabled Mortality Table weighted by Headcount, projected by MP-2020 for

Note 8 - Other Post-Employment Retirement Benefits (OPEB) (Continued)

officers, and PUB-2010 Public Retirement Plans General Disabled Mortality Table weighted by Headcount, projected by MP-2020 for civilians. The actuarial assumptions used in the June 30, 2023 valuation were based upon certain demographic and other actuarial assumptions as recommended by the actuary, in conjunction with the State and guidance from the GASB statement.

Discount Rate

The discount rate basis under GASB Statement No. 75 is required to be consistent with a 20-Year Municipal Bond Index. The Bond Buyer General Obligation 20-Bond Municipal Bond Index is used for the determination of the discount rate.

The discount rates as of July 1, 2023 is 3.65%. Additional detail regarding the discount rates as of June 30, 2023, is provided in the "Actuarial Assumptions and Methods" section of the report proved by the PEBP Board.

Sensitivity of the Board's Proportionate Share of the Net OPEB Liability to Changes in the Discount Rate

The following presents the Board's proportionate share of the net OPEB liability, as well as what the Board's proportionate share of the net OPEB liability would be if it were calculated using a discount rate that is 1-percentage-point lower or 1-percentage-point higher than the current discount rate:

	1% Decrease 2.65%	Discount Rate 3.65%	1% Increase 4.65%
Net OPEB liability	$ 2,021,356	$ 1,842,875	$ 1,688,070

Sensitivity of the Board's Proportionate Share of the Net OPEB Liability to Changes in the Healthcare Cost Trend Rates

The following presents the Board's proportionate share of the net OPEB liability, as well as what the Board's proportionate share of the net OPEB liability would be if it were calculated using healthcare cost trend rates that are 1-percentage-point lower or 1-percentage-point higher than the current healthcare cost trend rates:

	Health Care Cost Trend Rates		
	1% Decrease	Trend Rate	1% Increase
Net OPEB liability	$ 1,747,571	$ 1,842,875	$ 1,952,238

OPEB Plan Fiduciary Net Position

Detailed information about the OPEB plan's fiduciary net position is available in the separately issued PEBP financial report.

Note 9 - Commitments, Contingencies and Risk Management

During 2022, the Board was party to a lawsuit that resulted in an adverse judgment against the Board for the costs and attorney's fees of the respondents in the amount of $48,000. By order dated August 5, 2024, the Nevada Supreme Court resolved the lawsuit in favor of the Board. Accordingly, there are no matters that warrant disclosure as of June 30, 2024.

There were no other claims pending or unresolved disputes involving the Board at June 30, 2024.

Note 10 - Conversion to Government-Wide Financial Statements

Adjustments on the face of the financial statements were made to the fund balance sheet in order to reconcile the fund financial statements to the government-wide statements of net position. These adjustments detail the effect of the addition of fixed assets less accumulated depreciation totaling $9,025, right-of-use lease assets, less lease accumulated amortization totaling $4,755,496, amortization expense of $134,092, lease liabilities of $5,045,497, accrued compensated absences of $199,553, net deferred inflows and outflows of $1,959,712, net pension liability of $5,602,727, and the net OPEB liability of $1,842,876. Adjustments on the face of the financial statements were made to the statement of revenue, expenditures, and changes in fund balance in order to reconcile the fund financial statements to the government-wide statements of and activities. These adjustments detail the effects of the capitalization of fixed assets of $9,500 and depreciation expense of $475, the net impact of pension accruals of $488,645 and other post employment benefit accruals of $(2,568), compensated absences of $(23,113) and lease activity of $134,092.

Nevada State Board of Pharmacy

Pension Information - Schedule of Changes in Net Pension Liability

Last Ten Fiscal Years

	2023	2022	2021	2020	2019
Proportion of the net pension liability	0.03069%	0.03019%	0.02905%	0.02553%	0.02649%
Proportionate share of the net liability	$ 5,602,727	$ 5,451,105	$ 2,648,702	$ 3,556,176	$ 3,611,686
Covered payroll	$ 2,441,669	$ 2,292,662	$ 2,104,627	$ 1,845,447	$ 1,835,896
Proportionate share of the net pension liability as a percentage of covered payroll	229.46%	237.76%	125.85%	192.70%	196.73%
Plan fiduciary net position as a percentage of the total pension liability	76.16%	75.12%	86.51%	77.04%	76.46%

	2018	2017	2016	2015	2014
Proportion of the net pension liability	0.02559%	0.02264%	0.01972%	0.01766%	0.01720%
Proportionate share of the net liability	$ 3,490,261	$ 3,010,553	$ 2,654,412	$ 2,024,299	$ 1,793,062
Covered payroll	$ 1,711,106	$ 1,457,180	$ 1,117,746	$ 1,053,952	$ 1,002,366
Proportionate share of the net pension liability as a percentage of covered payroll	203.98%	206.60%	237.48%	192.07%	178.88%
Plan fiduciary net position as a percentage of the total pension liability	75.24%	74.40%	72.20%	75.10%	76.30%

Nevada State Board of Pharmacy

Pension Information - Schedule of Contributions

Last Ten Fiscal Years

Contractually required contributions	$ 418,086	$ 355,706	$ 331,977	$ 304,004	$ 266,075
Contributions in relation to contractually required contributions	(418,086)	(355,706)	(331,977)	(304,004)	(266,075)
Contribution deficiency (excess)	$ -	$ -	$ -	$ -	$ -
Covered payroll	$ 2,516,938	$ 2,441,669	$ 2,292,662	$ 2,104,627	$ 1,845,447
Contributions as a percentage of covered payroll	16.61%	14.57%	14.48%	14.44%	14.42%
	2019	2018	2017	2016	2015
Contractually required contributions	$ 254,976	$ 237,423	$ 184,648	$ 153,565	$ 125,087
Contributions in relation to contractually required contributions	(254,976)	(237,423)	(184,648)	(153,565)	(125,087)
Contribution deficiency (excess)	$ -	$ -	$ -	$ -	$ -
Covered payroll	$ 1,835,986	$ 1,711,106	$ 1,457,180	$ 1,117,745	$ 1,053,952
Contributions as a percentage of covered payroll	13.89%	13.88%	12.67%	13.74%	11.87%

Nevada State Board of Pharmacy

Other Post-Employment Benefit Information - Schedule of Changes in Net Other Post-Employment Benefits Liability

Last Ten Fiscal Years

	2023	2022	2021	2020	2019	2018	2017
Board's Proportion of the Net OPEB Liability	0.1264%	0.1249%	0.1171%	0.0960%	0.0965%	0.1000%	0.0846%
Board's Proportionate Share of the Net OPEB Liability	$ 1,842,875	$ 1,801,317	$ 1,814,540	$ 1,443,826	$ 1,344,606	$ 1,325,428	$ 1,101,166
Board's Covered-Employee Payroll	$ 2,497,012	$ 2,441,669	$ 2,292,662	$ 2,104,627	$ 1,845,447	$ 1,711,106	$ 1,407,868
Board's Proportionate Share of the Net OEPB Liability as a Percentage of its Covered-Employee Payroll	73.80%	73.77%	79.15%	68.60%	72.87%	77.46%	78.30%
Plan Fiduciary Net Position as a Percentage of the Total OPEB Liability	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Note: Only seven years of information is available due to reporting changes with GASB 75 for Fiscal Year 2017.

Nevada State Board of Pharmacy

Other Post-Employment Benefit Information - Schedule of Contributions

Last Ten Fiscal Years

	2024	2023	2022	2021	2020	2019	2018
Contractually Required Contribution	$ 77,666	$ 52,075	$ 49,413	$ 42,134	$ 39,504	$ 39,654	$ 32,195
Contributions in Relation to the Contractually Required Contribution	(77,666)	(52,075)	(49,413)	(42,134)	(39,504)	(39,654)	(32,195)
Contribution Deficiency (Excess)	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Board's Covered-Employee Payroll	$ 2,497,012	$ 2,441,669	$ 2,292,662	$ 2,104,627	$ 1,845,447	$ 1,711,106	$ 1,407,868
Contributions as A Percentage of Covered-Employee Payroll	3.11%	2.13%	2.16%	2.00%	2.14%	2.32%	2.29%

Note: Only seven years of information is available due to reporting changes with GASB 75 for Fiscal Year 2017.

Note 1 - Other Post-Employment Benefit (OPEB)

Changes of Benefit Terms

None.

Changes of Assumptions

The assumed discount rate used by the actuary to determine the post-employment benefits liability at June 30, 2023 was increased to 3.65% from 3.54% at June 30, 2022. The effect of the change would result in an increase in the liability.

Supplementary Information

June 30, 2024

Nevada State Board of Pharmacy

Nevada State Board of Pharmacy
Condensed Schedules of Net Position
Years Ended June 30, 2024 and 2023

	2024 Actual Government-Wide	2023 Actual Government-Wide
Assets		
Cash and cash equivalents	$ 5,138,371	$ 6,473,443
Accounts and grants receivable	85,671	29,375
Prepaid expenses and deposits	41,589	40,392
Capital assets, net of accumulated depreciation	9,025	-
Right of use lease assets, net of accumulated amortization	4,755,496	5,211,526
Total assets	10,030,152	11,754,736
Deferred Outflows of Resources	2,209,726	2,533,680
Total assets and deferred outflows of resources	12,239,878	14,288,416
Liabilities		
Accounts payable and accrued expenses	234,715	263,225
Wholesaler license deposits	325,000	275,000
License fees received in advance	934,580	2,942,830
Lease liabilities	5,045,497	5,367,435
Net other post-employment benefit liability	1,842,876	1,801,318
Net pension liability	5,602,727	5,451,105
Total liabilities	13,985,395	16,100,913
Deferred Inflows of Resources	250,014	281,071
Total liabilities and deferred inflows of resources	14,235,409	16,381,984
Net Position		
Net position		
Invested in capital assets	(280,976)	(155,909)
Unrestricted	(1,714,555)	(1,937,659)
Total Net Position	$ (1,995,531)	$ (2,093,568)

Nevada State Board of Pharmacy
Condensed Schedules of Activities
Years Ended June 30, 2024 and 2023

	2024 Actual Government-Wide	2023 Actual Government-Wide
Expenses		
Operations	$ 1,972,084	$ 2,266,077
Personnel	4,446,503	4,278,355
Travel	91,630	109,173
Total expenses	6,510,217	6,653,605
Program Revenue		
Fees, licensing, and permits (charges for services)	5,199,976	4,847,940
General Revenue		
Grant revenue	1,033,490	1,191,016
Investment income	167,742	101,340
Other income	207,046	398,131
Total general revenue	1,408,278	1,690,487
Total revenue	6,608,254	6,538,427
Change in Net Position	$ 98,037	$ (115,178)

Casey Neilon, Inc.
Accountants and Advisors

Independent Auditor's Report on Internal Control over Financial Reporting and on Compliance and Other Matters Based on an Audit of Financial Statements Performed in Accordance with *Government Auditing Standards*

To the Members of the Board
Nevada State Board of Pharmacy
Reno, Nevada

We have audited, in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of the governmental activities and the major fund of the Nevada State Board of Pharmacy ("the Board"), as of and for the year ended June 30, 2024, and the related notes to the financial statements which collectively comprise the Board's basic financial statements, and have issued our report thereon dated October 11, 2024.

Report on Internal Control over Financial Reporting

In planning and performing our audit of the financial statements, we considered the Board's internal control over financial reporting (internal control) as a basis for designing audit procedures that are appropriate in the circumstances for the purpose of expressing our opinions on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of the Board's internal control. Accordingly, we do not express an opinion on the effectiveness of the Board's internal control.

A *deficiency in internal control* exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A *material weakness* is a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis. A *significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies and therefore, material weaknesses or significant deficiencies may exist that were not identified. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses or significant deficiencies may exist that have not been identified.

Report on Compliance and Other Matters

As part of obtaining reasonable assurance about whether the Board's financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the financial statement. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards.*

Purpose of this Report

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the entity's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the entity's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

Reno, Nevada
October 11, 2024

Independent Auditor's Report on Compliance for the Major Program and on Internal Control over Compliance Required by the Uniform Guidance

To the Members of the Board
Nevada State Board of Pharmacy
Reno, Nevada

Report on Compliance for Each Major Federal Program

Opinion on Each Major Federal Program

We have audited Nevada State Board of Pharmacy's compliance with the types of compliance requirements identified as subject to audit in the *OMB Compliance Supplement* that could have a direct and material effect on Nevada State Board of Pharmacy's major federal program for the year ended June 30, 2024. Nevada State Board of Pharmacy's major federal program is identified in the summary of auditor's results section of the accompanying schedule of findings and questioned costs.

In our opinion, Nevada State Board of Pharmacy complied, in all material respects, with the types of compliance requirements referred to above that could have a direct and material effect on each of its major federal programs for the year ended June 30, 2024.

Basis for Opinion on Each Major Federal Program

We conducted our audit of compliance in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and the audit requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Our responsibilities under those standards and the Uniform Guidance are further described in the Auditor's Responsibilities for the Audit of Compliance section of our report.

We are required to be independent of Nevada State Board of Pharmacy and to meet our other ethical responsibilities, in accordance with relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion on compliance for each major federal program. Our audit does not provide a legal determination of Nevada State Board of Pharmacy's compliance with the compliance requirements referred to above.

Responsibilities of Management for Compliance

Management is responsible for compliance with the requirements referred to above and for the design, implementation, and maintenance of effective internal control over compliance with the requirements of laws, statutes, regulations, rules and the provisions of contracts or grant agreements applicable to Nevada State Board of Pharmacy's federal programs.

Auditor's Responsibilities for the Audit of Compliance

Our objectives are to obtain reasonable assurance about whether material noncompliance with the compliance requirements referred to above occurred, whether due to fraud or error, and express an opinion on Nevada State Board of Pharmacy's compliance based on our audit. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance will always detect material noncompliance when it exists. The risk of not detecting material noncompliance resulting from fraud is higher than for that resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Noncompliance with the compliance requirements referred to above is considered material if there is a substantial likelihood that, individually or in the aggregate, it would influence the judgment made by a reasonable user of the report on compliance about Nevada State Board of Pharmacy's compliance with the requirements of each major federal program as a whole.

In performing an audit in accordance with generally accepted auditing standards, *Government Auditing Standards*, and the Uniform Guidance, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material noncompliance, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding Nevada State Board of Pharmacy's compliance with the compliance requirements referred to above and performing such other procedures as we considered necessary in the circumstances.
- Obtain an understanding of Nevada State Board of Pharmacy's internal control over compliance relevant to the audit in order to design audit procedures that are appropriate in the circumstances and to test and report on internal control over compliance in accordance with the Uniform Guidance, but not for the purpose of expressing an opinion on the effectiveness of Nevada State Board of Pharmacy's internal control over compliance. Accordingly, no such opinion is expressed.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and any significant deficiencies and material weaknesses in internal control over compliance that we identified during the audit.

Report on Internal Control over Compliance

A *deficiency in internal control over compliance* exists when the design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, noncompliance with a type of compliance requirement of a federal program on a timely basis. A *material weakness in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected, on a timely basis. A *significant deficiency in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance with a type of compliance requirement of a federal program that is less severe than a material weakness in internal control over compliance, yet important enough to merit attention by those charged with governance.

Our consideration of internal control over compliance was for the limited purpose described in the Auditor's Responsibilities for the Audit of Compliance section above and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies in internal control over compliance. Given these limitations, during our audit we did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses, as defined above. However, material weaknesses or significant deficiencies in internal control over compliance may exist that were not identified.

Our audit was not designed for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, no such opinion is expressed.

The purpose of this report on internal control over compliance is solely to describe the scope of our testing of internal control over compliance and the results of that testing based on the requirements of the Uniform Guidance. Accordingly, this report is not suitable for any other purpose.

Reno, Nevada
October 11, 2024

Federal Grantor/Pass-Through Grantor/ Program Title	Federal Financial Assistance Listing Number	Pass-through Entity Identifying Number	Expenditures
Department of Health and Human Services			
Pass through the State of Nevada Division of Public and Behavioral Health			
Injury Prevention and Control Research and State and Community Based Programs			
CDC Overdose Data to Action	93.136	NU17CE010224-01	$ 489,047
Injury Prevention and Control Research and State and Community Based Programs			
CDC Overdose Data to Action	93.136	NU17CE925001-03	34,026
Substance Abuse and Mental Health Services Administration (SAMHSA)			
State Opiod Response (SOR) Grant	93.788	5H79TI085762-02	246,500
Total Department of Health and Human Services			769,573
Department of Justice			
Bureau of Justice Assistance			
Harold Rogers Prescription Drug Monitoring Program	16.754	N/A	263,917
Total Department of Justice			263,917
Total Department of Justice			263,917
Total Federal Financial Assistance			$ 1,033,490

Note 1 - Basis of Presentation

The accompanying schedule of expenditures of federal awards (schedule) includes the federal award activity of the Nevada State Board of Pharmacy (Board) under programs of the federal government for the year ended June 30, 2024. The information in this schedule is presented in accordance with the requirements of Title 2 U.S. *Code of Federal Regulations* Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance). Because the schedule presents only a selected portion of the operations of the Nevada State Board of Pharmacy, it is not intended to and does not present the financial position or changes in net position of the Nevada State Board of Pharmacy.

Note 2 - Summary of Significant Accounting Policies

Expenditures reported in the schedule are reported on the modified accrual basis of accounting. When applicable, such expenditures are recognized following the cost principles contained in the Uniform Guidance, wherein certain types of expenditures are not allowable or are limited as to reimbursement. No federal financial assistance has been provided to a subrecipient.

Note 3 - Indirect Cost Rate

The Board has elected to use the 10% de minimis indirect cost rate.

Section I – Summary of Auditor's Results

Financial Statements

Type of auditor's report issued:	Unmodified
Internal control over financial reporting:	
Material weaknesses identified	No
Significant deficiencies identified not considered to be material weaknesses	No
Noncompliance material to financial statements noted?	No

Federal Awards

Internal control over major program:	
Material weaknesses identified	No
Significant deficiencies identified not considered to be material weaknesses	None Reported
Type of auditor's report issued on compliance for major programs	Unmodified
Any audit findings disclosed that are required to be reported in in accordance with Uniform Guidance 2 CFR 200.516	No

Identification of major programs:

Name of Federal Program	CFDA Number
Injury Prevention and Control Research and State and Community Based Programs	93.136

Dollar threshold used to distinguish between Type A and Type B programs:	$750,000
Auditee qualified as low-risk auditee?	No

Section II – Financial Statement Findings

None.

2023-001: Financial Close and Reporting – Significant Deficiency

Criteria:	Management is responsible for establishing and maintaining an effective system of internal control over financial reporting. One of the key components of an effective system of internal control over financial reporting is having the capability to prepare full disclosure financial statements in accordance with generally accepted accounting principles (GAAP).
Condition:	We proposed several audit adjustments for corrections to year-end adjustments. In addition, the year-end reconciliation for deferred revenue was not reviewed, except for a self-review by the preparer. The absence of controls over the reconciliations and year-end adjustments of the financial statements and related financial statement disclosures increases the possibility that a misstatement of the financial statements could occur and not be prevented or detected and corrected in a timely manner.
Cause:	Procedures have not been implemented to ensure final review procedures over the financial statements once all year-end adjustments have been made, including all reconciliations.
Effect:	Financial information prepared by the Board may not comply with generally accepted accounting principles.
Recommendation:	We recommend the Board implement procedures to provide for internal controls over year-end reconciliations and adjustments.
Current Status:	In the current year, corrective actions were taken by management, and a review process is now completed before deferred revenue entries are posted.