BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES FORSYTHE, MD, HMD,** **Certificate of Registration No. CS05385,** **Respondent.**	**CASE NO. 19-144-CS-N** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

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

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent James Forsythe, MD, HMD, held a Nevada controlled substance registration, Certificate No. CS105385, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 17, 2019, Board staff investigated Respondent's practice at Forsythe Cancer Care Center a/k/a Century Wellness Center located at 521 Hammill Lane, Reno NV. The investigation revealed that Respondent failed to properly label, segregate and/or dispose of adulterated and/or expired dangerous drugs, including open multi-dose containers.

3. The following expired drugs were discovered in the infusion room cabinets:

- One 25-count box of Potassium Chloride Concentrate for injection, 40mEq/20ml Expiration date 2 /1/18.
- One unopened multi-dose vial of Magnesium Chloride Injection, 200 mg/ml Expiration date 12/18.
- One partial multi-dose vial of Magnesium Chloride Injection, 200 mg/ml, no opening date. Expiration date 12/17.
- Two unopened bottles of L-Lysine HCL Injection, 100 mg/ml, 30mL MDV in clear plastic bag, prescribed to Dorothy P. Expiration date 12/17/18. Compounded at McGliff Compounding Pharmacy, Santa Ana, California.

- Two unopened bottles of L-Lysine HCL Injection, 100 mg/ml, 30 mL MDV in clear plastic bag, prescribed for Gloria W. Expiration date 12/17/2018. Compounded at McGliff Compounding Pharmacy, Santa Ana, California.
- One unopened bottle of L-Lysine HCL Injection, 100 mg/ml, 30 mL MDV prescribed to Traci M. Expiration date 10/27/2018.
- One unopened bottle of Dexpanthenol 250 mg/mL 30 mL MDV prescribed to Kevin P. Expiration date 11/11/2018.
- One unopened 5-count box of Dexpanthenol Injection 250mg/ml 10mL SDV prescribed to Kim H. Expiration date 1/20/2019.
- One unopened 5-count box of Dexpanthenol Injection 250mg/ml 10mL SDV prescribed to Dorothy P. Expiration date 1/20/2019
- One opened 30 ml multi-dose vial of Methylcobalamin Injection, 1000 mcg/mL. Expiration date 1/23/19.
- One unopened 30 ml multi-dose vial of L-Lysine HCL Injection 100 mg/ml. Expiration date 12/17/18.
- Two unopened 30 ml multidose vials of Pyridoxine HCL Injection 100 mg/ml Solution. Expiration date 5/29/2019.
- One unopened 50 mL preservative-free multidose vial of Ascorbic Acid Injection 500 mg/mL. Expiration date 1/05/2018.
- One unopened 50 mL multidose vial of Lysine HCL Injection 100 mg/ml Solution. Expiration date 12/13/2018.
- One opened 50 mL multidose vial of Lysine HCL Injection 100 mg/ml Solution with no opening date. Expiration date 12/13/2018.
- Three unopened 10 mL multidose vials of Folic Acid Injection 10 mg/ml Solution. Expiration date 6/25/2019.
- One opened 10 mL multidose vial of Folic Acid Injection 10 mg/ml Solution with no opening date. Expiration date 6/25/2019.
- Three 30 mL multidose vials of L-Lysine HCL Injection 100 mg/ml Solution. Expiration date 12/17/2018.
- Six unopened 10 mL preservative-free multidose vials of Pyridoxine Hydrochloride Injection 100 mg/ml. Expiration date 12/05/2018.
- One opened 10 mL multidose vial of Mesna 1gram/10 ml (100 mg/ml) with no opening date. Expiration date 11/18.
- Anfinitor 5mg tablets, #7. Expiration date 2/19
- Creon Capsules #84. Expiration date 10/18 and 11/18.
- Votrient 200 mg tablets. #60. Expiration date 1/18.

4. The following expired drugs were discovered on the store room shelves:

- Four unopened 12 count boxes of 1000 mL Lactated Ringers (Braun). Expiration 6/18.
- One opened 12 count box of 1000 mL 0.9% Sodium Chloride Injection with 4 IV bags missing (Braun). Expiration 9/16.
- One unopened 24 count box of 500 mL Lactated Ringers Injection (Baxter). Expiration 11/18.
- One partially opened box of 36 count 250 mL Lactated Ringers Injection (Baxter). Expiration 10/18.
- One open box of 36 count 250 mL Lactated Ringers Injection (Baxter). Expiration 3/19.
- One unopened box of 36 count 250 mL Lactated Ringers Injection (Baxter). Expiration 4/18.
- Two unopened boxes of 20 count 500 mL 0.9% Sodium Chloride Injection (Baxter). Expiration 3/19.

5. The investigation also revealed that Respondent possessed in his inventory Veterinary 0.9% Sodium Chloride labeled "For Veterinary Use Only."

APPLICABLE LAW

6. It is unlawful to purchase, access, store, possess, administer, furnish and/or dispense a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.221, NRS 454.311, NRS 454.316.

7. It is unlawful for any person to have in his or her possession, or under his or her control, for the purpose of resale, or to sell or offer to sell or dispense or give away, any pharmaceutical preparation, drug or chemical which . . . is no longer safe or effective for use, as indicated by the expiration date appearing on its label. NRS 639.282(1)(d); *see also* 21 CFR § 211.137.

8. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier. NAC 639.601(1).

9. The breach of the seal of a multi-dose container must be documented and the contents used within 28 days. NAC 639.67057(2).

10. It is unlawful to sell or dispense any medications that are intended for animals for human consumption. 21 CFR § 201.105.

11. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

12. Violating any provision of the Federal Food, Drug and Cosmetic Act or any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11) and (12).

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

FIRST CAUSE OF ACTION
Violations of Law - Failure to Properly Label, Store and Secure Drugs

14. By failing to properly label, segregate and/or dispose of adulterated and/or expired dangerous drugs to ensure they could not be administered to patients, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 211.137, NRS 639.282(1)(d), NAC 639.601(1), and/or NAC 639.67057(2), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) and (12).

SECOND CAUSE OF ACTION
Unlawful Possession of Veterinary Drugs

15. By possessing in his drug inventory Veterinary 0.9% Sodium Chloride labeled "For Veterinary Use Only" for administration to patients, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 201.105, NRS 454.221, NRS 454.311 and/or NRS 454.316, and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) and (12).

THIRD CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By his actions as alleged herein, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By his actions as alleged herein, Respondent has committed an act that would render his Nevada controlled substance registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

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

DATED this 4th day of October, 2021.

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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES FORSYTHE, MD, HMD,** **Certificate of Registration No. CS05385,** **Respondent.**	**CASE NO. 19-144-CS-N** **AMENDED FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, January 12, 2022. Brett Kandt, Esq., prosecuted the case before the Board. Respondent James Forsythe, MD, HMD, Certificate or Registration No. CS05385, appeared with counsel, Marie Mirch, Esq. The Board heard the case and, based on the evidence presented, the Board entered Findings of Fact, Conclusions of Law and Order dated January 12, 2022. Upon Respondent's petition for judicial review and subsequent appeal to the Nevada Supreme Court, the Board makes the following amended Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. At the time of the events set forth herein, Respondent James Forsythe, MD, HMD, held a Nevada controlled substance registration, Certificate of Registration No. CS05385, issued by the Board.

2. On or about September 17, 2019, Board staff investigated Respondent's practice at Forsythe Cancer Care Center a/k/a Century Wellness Center located at 521 Hammill Lane, Reno NV. The investigation revealed that Respondent failed to properly label, segregate and/or

dispose of adulterated and/or expired dangerous drugs, including open multi-dose containers. None of the drugs in question were controlled substances.

3. The following expired drugs were discovered in the infusion room cabinets:

A. One 25-count box of Potassium Chloride Concentrate for injection, 40mEq/20ml Expiration date 2 /1/18.

B. One unopened multi-dose vial of Magnesium Chloride Injection, 200 mg/ml Expiration date 12/18.

C. One partial multi-dose vial of Magnesium Chloride Injection, 200 mg/ml, no opening date. Expiration date 12/17.

D. Two unopened bottles of L-Lysine HCL Injection, 100 mg/ml, 30mL MDV in clear plastic bag, prescribed to Dorothy P. Expiration date 12/1 7/18. Compounded at McGliff Compounding Pharmacy, Santa Ana, California.

E. Two unopened bottles of L-Lysine HCL Injection, 100 mg/ml, 30 mL MDV in clear plastic bag, prescribed for Gloria W. Expiration date 12/17/2018. Compounded at McGliff Compounding Pharmacy, Santa Ana, California.

F. One unopened bottle of L-Lysine HCL Injection, 100 mg/ml, 30 mL MDV prescribed to Traci M. Expiration date 10/27/2018.

G. One unopened bottle of Dexpanthenol 250 mg/mL 30 mL MDV prescribed to Kevin P. Expiration date 11/11/2018.

H. One unopened 5-count box of Dexpanthenol Injection 250mg/ml 10mL SDV prescribed to Kim H. Expiration date 1/20/2019.

I. One unopened 5-count box of Dexpanthenol Injection 250mg/ml 10mL SDV prescribed to Dorothy P. Expiration date 01 /20/2019

J. One opened 30 ml multi-dose vial of Methylcobalamin Injection, 1000 mcg/mL. Expiration date 1/23/19.

K. One unopened 30 ml multi-dose vial of L-Lysine HCL Injection 100 mg/ml. Expiration date 12/17/18.

L. Two unopened 30 ml multidose vials of Pyridoxine HCL Injection 100 mg/ml Solution. Expiration date 5/29/2019.

M. One unopened 50 mL preservative-free multidose vial of Ascorbic Acid Injection 500 mg/mL. Expiration date 1/05/2018.

N. One unopened 50 mL multidose vial of Lysine HCL Injection 100 mg/ml Solution. Expiration date 12/13/2018.

O. One opened 50 mL multidose vial of Lysine HCL Injection 100 mg/ml Solution with no opening date. Expiration date 12/13/2018.

P. Three unopened 10 mL multidose vials of Folic Acid Injection 10 mg/ml Solution. Expiration date 6/25/2019.

Q. One opened 10 mL multidose vials of Folic Acid Injection 10 mg/ml Solution with no opening date. Expiration date 6/25/2019.

R. Three 30 mL multidose vials of L-Lysine HCL Injection 100 mg/ml Solution. Expiration date 12/17/2018.

S. Six unopened 10 mL preservative-free multidose vials of Pyridoxine Hydrochloride Injection 100 mg/ml. Expiration date 12/05/2018.

T. One opened 10 mL multidose vial of Mesna lgram/10 ml (100 mg/ml) with no opening date. Expiration date 11/18.

U. Anfinitor 5mg tablets, #7. Expiration date 2/19.

V. Creon Capsules #84. Expiration date 10/18 and 11/18.

W. Votrient 200 mg tablets. #60. Expiration date 1/18.

4. The following expired drugs were discovered on the storeroom shelves:

A. Four unopened 12 count boxes of 1000 mL Lactated Ringers (Braun). Expiration 6/18.

B. One opened 12 count box of 1000 mL 0.9% Sodium Chloride Injection with 4 IV bags missing (Braun). Expiration 9/16.

C. One unopened 24 count box 0 500 mL Lactated Ringers Injection (Baxter). Expiration 11/18.

D. One partially opened box of 36 count 250 mL Lactated Ringers Injection (Baxter). Expiration 10/18.

E. One open box of 36 count 250 mL Lactated Ringers Injection (Baxter). Expiration 3/19.

F. One unopened box of 36 count 250 mL Lactated Ringers Injection (Baxter). Expiration 4/18.

G. Two unopened boxes of 20 count 500 mL 0.9% Sodium Chloride Injection (Baxter). Expiration 3/19.

5. The investigation also revealed that Respondent possessed in his inventory Veterinary 0.9% Sodium Chloride labeled "For Veterinary Use Only."

6. Board staff incurred at least $2384.08 in attorney's fees and recoverable costs investigating and prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Respondent pursuant to NRS 454.291.

2. The applicable law in this matter is as follows:

A. It is unlawful to administer, furnish and/or dispense a dangerous drug in Nevada that cannot be lawfully prescribed. NRS 454.221(1).

B. It is unlawful for any person to have in his or her possession, or under his or her control, for the purpose of resale, or to sell or offer to sell or dispense or give away, any pharmaceutical preparation, drug or chemical which . . . is no longer safe or effective for use, as indicated by the expiration date appearing on its label. NRS 639.282(1)(d).

C. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier. NAC 639.601(1).

D. Federal law prohibits dispensing any veterinary medications that are intended for animals to human patients.

E. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for discipline of any license or registration issued by the Board. NRS 639.210(4).

F. Violating any provision of the Federal Food, Drug and Cosmetic Act or any law or regulation relating to drugs is grounds for discipline of any license or registration issued by the Board. NRS 639.210(11) and (12).

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

3. By failing to properly segregate and/or dispose of adulterated and/or expired dangerous drugs to ensure they could not be administered to patients, Respondent violated and/or attempted to violate NRS 639.282(1)(d) and/or NAC 639.601(1), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(12).

4. By possessing in his drug inventory Veterinary 0.9% Sodium Chloride labeled "For Veterinary Use Only" that could not be lawfully prescribed or dispensed to human patients, Respondent violated and/or attempted to violate federal law and/or NRS 454.221(1), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) and (12).

5. By his actions as set forth herein, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.255.

6. By his actions as set forth herein, Respondent has committed an act that would render his Nevada controlled substance registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 639.255.

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. For the violations set forth above, Respondent James Forsythe, MD, HMD, Certificate of Registration No. CS05385, shall accept this Amended Order as a public reprimand regarding his duties and responsibilities as a practitioner when maintaining an inventory of dangerous drugs.

2. In compliance with the January 12, 2022, Order Respondent timely submitted to an inspection of Respondent's practice at Forsythe Cancer Care Center a/k/a Century Wellness Center.

3. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), in compliance with the January 12, 2022, Order Respondent timely paid a fine of Five Thousand Dollars ($5000.00) for

4. Pursuant to NRS 622.400, in compliance with the January 12 ,2022, Order Respondent timely paid Two Thousand Three Hundred Eighty-Four and 8/100 Dollars ($2384.08) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter.

5. Any failure by Respondent to comply with the terms of this Amended 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 Amended Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

6. This Amended Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5) and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

7. This Amended Order is effective immediately.

IT IS SO ORDERED.

Entered this 30th day of May, 2024.

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