IN THE MATTER OF: **CASE NO. A-2025-0157**

Rejuvize DBA JuviveMD **License No. 02-60002980**
c/o Dr. Rajmony Pannu
4466 Morse Rd.
Columbus, OH 43230

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and JuviveMD for the purpose of resolving all issues between the parties relating to the Board investigation of JuviveMD's possession of non-FDA approved South Korean liporase, and "Research Use Only" drugs, both obtained from unlicensed sources. Together, the Board and JuviveMD are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. JuviveMD is a licensed Terminal Distributor of Dangerous Drugs under license number 02-60002980.

FACTS

1. The Board initiated an investigation of JuviveMD, Terminal Distributor of Dangerous Drugs license number 02-60002980, related to JuviveMD's possession of non-FDA approved South Korean liporase, and "Research Use Only" drugs, both obtained from unlicensed sources.

2. On or about June 5, 2025, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to JuviveMD, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. On or about June 19, 2025, JuviveMD, through counsel Todd Newkirk, timely requested an administrative hearing, which was subsequently scheduled for August 6, 2025, but was continued at counsel's request. WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. JuviveMD neither admits nor denies the allegations stated in the Summary Suspension/Notice of Opportunity for Hearing letter dated June 5, 2025; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. The Board will lift the summary suspension imposed on JuviveMD's TDDD license number 02-60002980 and reinstate the license immediately upon the effective date of this Agreement.

4. JuviveMD agrees to pay to the Board a monetary penalty the amount of $25,000. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

5. The Board hereby imposes a written reprimand on JuviveMD's TDDD license, number 02-60002980.

6. JuviveMD agrees that the Responsible Person will (1) attend and successfully complete the Board sponsored Responsible Person 101 Roundtable (one hour) and (2) obtain six hours professional continuing education, to be pre-approved by the Board and which may not also be used for license renewal, and must be in the following topic areas: drug storage and handling, regulatory compliance and/or law/ethics. The continuing education must be completed within six months from the effective date of this Agreement. Copies of completed CEs must be e-mailed to legal@pharmacy.ohio.gov.

7. JuviveMD agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

8. JuviveMD agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by JuviveMD of the terms of one or more federal or state requirements may constitute sufficient grounds for further

enforcement action related to any licenses granted to JuviveMD by the Board and will NOT discharge JuviveMD from any obligation under the terms of this Agreement.

9. JuviveMD agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

10. JuviveMD understands that it has the right to be represented by counsel for review and execution of this agreement.

11. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom JuviveMD will operate.

12. JuviveMD explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

13. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

14. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

15. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

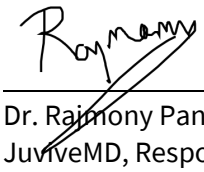
16. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

17. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:



Aug 11, 2025

Dr. Raimony Pannu, on behalf of,
JuviveMD, Respondent

Date of Signature

August 11, 2025

Todd Newkirk, Attorney for Respondent

Date of Signature

8/12/2025

Jeff Huston, RPh, President,
Ohio Board of Pharmacy

Date of Signature

SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF:

RejuvizeMD DBA JuviveMD
c/o Dr. Rajmony Pannu
4466 Morse Road
Columbus, OH 43230

CASE NO. A-2025-0157

License No. 02-60002980

June 5, 2025

Dear RejuvizeMD DBA JuviveMD and Dr. Rajmony Pannu:

You are hereby notified, in accordance with Section 119.07 of the Ohio Revised Code (ORC), the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS RejuvizeMD DBA JuviveMD's license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Sections 4729.57 and 4729.571 of the Ohio Revised Code.

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to RejuvizeMD DBA JuviveMD's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends RejuvizeMD DBA JuviveMD's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the ORC.

2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs.

3. RejuvizeMD DBA JuviveMD ("JuviveMD"), located at 4466 Morse Road, Columbus, Ohio 43230, is a licensed TDDD under license number 02-0002980 and lists Dr. Rajmony Pannu [Ohio Medical Board license number 35.121853] as the Responsible Person (RP) and owner.

ALLEGATIONS

1. On or about May 22, 2025, the Board conducted an inspection at JuviveMd, a prescriber clinic licensed by the Board (TDDD 02-60002980), located at 4466 Morse Road, Columbus, OH 43230. During the inspection, a Board Specialist found in the clinic's refrigerator with the clinic's active drug stock the following dangerous drugs:

    a. Eight (8) vials of Liporase (hyaluronidase) 1500 unit vials in a ten (10)-pack box. Labeling and manufacturer indicate the product is of South Korean origin;

        i. NOTE: Liporase is not a Food and Drug Administration (FDA) approved product.

    b. One (1) partial and one (1) full vial of tesamorelin, CJC-1295, ipamorelin 12 mg labeled as "Research Use Only," dispensed from PeptideSciences.com and billed and shipped to the clinic's address;

        i. NOTE: Research Use Only drugs are not approved by the FDA. They are drugs specifically designed and labeled for use in scientific research and not for clinical or diagnostic purposes.

        ii. NOTE: Investigation revealed PeptideSciences.com is not a licensed wholesale distributor of dangerous drugs in Ohio.

2. During the May 22, 2025 inspection, Dr. Pannu provided the following information:

    a. He was offered the Liporase from a colleague. His intention was to offer them to patients but he has not administered any. He was not able to speak to the disposition of the two vials missing from the packaging.

    b. Tesamorelin, CJC-1295, ipamorelin 12 mg labeled as "Research Use Only" was ordered from PeptideSciences.com. He stated that it was for self-administration only.

3. The inspection conducted on May 22, 2025, resulted in warnings requiring written responses for the following:

    a. Research Use Only products and foreign language products, including foreign language liporase, were present within the active drug stock.

    b. There was no documentation of eLicense query of wholesale drug distributors.

    c. Observed standing water and damp cardboard within the clinic refrigerator containing dangerous drugs.

d. There was no temperature monitoring documentation. Temperatures were reportedly spot checked but not recorded.

e. Observed several multi dose vials without opening date or beyond use date stored and comingled in the refrigerator with the active drug stock.

f. Observed several vials which had exceeded the beyond use date stored and comingled in the refrigerator with the active drug stock.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52(A) of the ORC, Prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization: The following acts and causing them are prohibited:

   a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and/or

[1] ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and/or

d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4).

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.65(A) of the ORC, Application for new drug required, each a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization:

   a. No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 2925.09(A) of the ORC, Unapproved drugs, No person shall administer, dispense, distribute, manufacture, possess, sell, or use any drug, other than a controlled substance, that is not approved by the United States food and drug administration, or the United States department of agriculture, a felony of the fifth degree, each violation punishable by a maximum penalty of $2,500 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, Storage of adulterated drugs, each violation punishable by a maximum penalty of $1,000:

   a. To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, OAC 4729:5-3-06; and/or

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a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

i. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC 4729:5-3-06(A); and/or

ii. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective October 3, 2023 and April 9, 2025, Selling, purchasing, distributing, or delivering dangerous or investigational drugs – No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, punishable by a maximum penalty of $5,000 if committed by an organization.

6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(G) of the ORC, effective October 3, 2023, Selling, purchasing, distributing, or delivering dangerous or investigational drugs – No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Verification of license prior to transactions – Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, Verification of licensure prior to sale or purchase, each violation punishable by a maximum penalty of $1,000:

   a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the

board's website: www.pharmacy.ohio.gov) to confirm any of the following:

i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or

b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

9. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021, Security, control and storage of dangerous drugs, each violation punishable by a maximum penalty of $1,000:

a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and/or

b. All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

i. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

1. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-19-03(K)(1)(a); or

2. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-19-03(K)(1)(b); and/or

ii. The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs, OAC Rule 4729:5-19- 03(K)(2); and/or

c. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and/or

d. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M); and/or

e. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(O).

10. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, General security requirements, each violation punishable by a maximum penalty of $1,000:

    a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to:

        i. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or

        ii. Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

11. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, Record Keeping, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

    a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and/or

    b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or

    c. Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-19-03 of the Administrative Code shall include any of the following:

        i. For temperature logs, either:

            1. The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(a); and/or

2. For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(b); and/or

ii. For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion, OAC Rule 4729:5-19-04(C)(2); and/or

d. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration and either: (a) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug. * * *, OAC Rule 4729:5-19-04(E)(1); and/or

e. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and/or

f. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F).

g. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years, OAC Rule 4729:5-19-04(J).

12. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible person – terminal distributor, as effective April 25, 2022, each punishable by a maximum penalty of $1,000:

a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or

b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).

13. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of $1,000:

    a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or

    b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or

    d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(B)(6); and/or

    e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or

    f. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

14. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of $1,000:

    a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

    b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or

    d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or

    e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or

    f. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person’s professional practice, OAC Rule 4729:5-4-01(B)(18); and/or

g. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/zas/jrn

cc: Melinda Snyder, State Medical Board of Ohio, at: melinda.snyder@med.ohio.gov