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

IN THE MATTER OF: **CASE NOS. A-2025-0306**

Ageless Medica, LLC **License No. 02-64000579**
c/o Shri K. Rao, MD
4872 Socialville-Foster Road
Mason, Ohio 45040

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 10/8/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

October 8, 2025

Dear Dr. Shri Rao and Ageless Medica, LLC:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Ageless Medica LLC'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 Ageless Medica's method used to possess or distribute dangerous drugs, and the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor. As such, the Board summarily suspends Ageless Medica LLC's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) 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. Further, pursuant to Section 4729.55(E), the Board shall refuse to issue a future license to an applicant for a TDDD if the applicant, or any agent (including any owner or responsible person) or employee of the applicant, has been found to have violated any of the specified laws identified therein or any rule of the board, absent proof of adequate safeguards assuring prevention of a recurrence of the violation. Additionally, Section 4729.57 of the 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. Ageless Medica, LLC, located at 4872 Socialville-Foster Road, Mason, Ohio, is a licensed TDDD under license number 02-64000579 and lists Shri K. Rao, [Ohio Medical Board license number 35.085099] as the Responsible Person and owner.

ALLEGATIONS

1. On or about September 30, 2025 a Board Inspector and Agent of the Board (Board inspectors) conducted an inspection at Ageless Medica, LLC, located at 4872 Socialville-Foster Road, Mason, Ohio. The Responsible Person, Shri Rao, MD and Angela Miracle, Office Manager, were present.

2. During the inspection, the following illegal dangerous drugs were discovered by the Board inspectors:

    a. One vial of (compounded) liquid labeled "ULTRABURN injection USP 30ml Vial."

        i. This vial was purchased from Zion Clinical Pharmacy, an entity located in Florida that is not licensed by the Board.

    b. One vial of (compounded) liquid labeled "GLP-1R 24mg/vial."

        i. This vial contained retatrutide and was purchased from Alpha BioMed.

            1. Retatrutide is not an FDA-approved drug and not allowed to be purchased or administered in the United States.
            2. Alpha BioMed is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration. Dangerous Drugs purchased from Alpha BioMed are misbranded.

    c. One vial of white powder labeled "DSIP 99%+ 5mg," "Immune Support Research," and "Longevity Research Peptide."

        i. The vial was labeled with a notice stating, ""This product is sold as a pure compound for research purposes only and is not intended as a dietary supplement."

        ii. DSIP is not an FDA-approved drug and is not allowed to be purchased or administered in the United States.

iii. This vial was purchased from Limitless Biotech, an entity located in Florida that is not licensed with the Board.

1. Limitless Biotech's website states the following, "All products on this site are for Research, Development use only. . *[sic]* The statements made within this website have not been evaluated by the US Food and Drug Administration. The statements and the products of this company are not intended to diagnose, treat, cure or prevent any disease. Limitless Biotech is a chemical supplier. Limitless Biotech is not a compounding pharmacy or chemical compounding facility as defined under 503A of the Federal Food, Drug, and Cosmetic act."

3. The inspection conducted on September 30, 2025, resulted in 10 warnings requiring written responses, including but not limited to:

a. Controlled substances were not stored pursuant to rule.

i. All clinic staff, including non-licensed healthcare professionals, i.e. the office manager and medical assistants, had access to the cabinet where the controlled substances were stored.

b. Purchases of dangerous drugs from unlicensed entities.

i. Ageless Medica purchased dangerous drugs from multiple unlicensed manufacturers including Alpha Biomed, Zion Clinical Pharmacy and Limitless BioTech.

ii. The clinic did not complete an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale.

c. Refrigerators used for storage of drugs and devices did not record temperatures daily.

i. The refrigerator had a thermometer. There was no continuous monitoring or temperature logs and no way for clinic staff to know if an excursion occurred during days the clinic was closed.

d. Multi-dose vials were not properly labeled.

i. Observed eight multi-dose vials that were not labeled with the initial date of puncture and/or the beyond use date (BUD).

e. Adulterated drugs and expired drugs were stored with the active drug stock.
i. Research Use Only drugs and drugs from unlicensed entities, listed above, were comingled with the active drug stock.

ii. The following expired dangerous drugs were comingled with the active drug stock:

1. Two punctured vials of unlabeled compounded Methylcobalamin
2. One vial of compounded tirzepatide - exp. 1/1/2025
3. One punctured vial of compounded Tri-Immune Boost - exp. 12/16/2024
4. One punctured vial of lidocaine 1% 10mg/mL - exp. 7/1/2025

f. Order or protocol for drugs administered by a (non-prescriber) health care professional was incomplete.

i. Observed order for patient “SP” which stated "Weekly B12 injections for 8 weeks."

1. The order did not give a specific dose to be administered. It was unclear how medical assistant(s) knew how much medication to administer.

g. Records of in-office drug administration were not compliant.

i. Records for administration for controlled substances did not include positive identification of the administrator.

h. Personally furnished drugs were not properly labeled and documented.

i. Clinic personally furnished one vial of DSIP 99% +5mg, labeled for research purposes only. The vial was personally furnished without proper labeling.

1. Ms. Miracle stated the vial found at the clinic was going to be for the same patient.

ii. Records indicating the prescriber performed the final check of personally furnished drugs were missing (no positive identification of the prescriber).

i. Drug disposal records for drugs destroyed on-site were not maintained by the clinic.

i. Disposal records were not maintained; the office manager stated drugs were disposed of by using the Sharps container.

ii. The clinic did not maintain DEA Form 41 for controlled substances that were disposed of.

j. Inventory records for controlled substances were not maintained.

i. The clinic completed monthly controlled substance inventories but did not complete an annual controlled substance inventory, in accordance with 21 CFR 1304.11 and the OAC.

4. Administration records showed Ageless Medica administered "GLP-1R", a drug purported to be retatrutide, to patients 70 times between April 2025 and September 2025. Ms. Miracle stated the drug rep who pushed GLP-1R advised the clinic not to promote the drug as retatrutide.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52 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

    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); and/or

    e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5).

2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, 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, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 2925.09(A) of the ORC, 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, each a felony of the fifth degree, punishable by a maximum penalty of $7,500 if committed by an organization.

[1] ORC Section 3715.63: When a drug or device is adulterated
[2] ORC Section 3715.64: Misbranded drug or device

4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, 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, each violation is a misdemeanor of the first degree, each violation 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, constitutes a violation of Section 4729.60(B) of the ORC, 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.

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, 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).

8. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.291(A) of the ORC, Drugs personally furnished by prescriber- Except when provided under section 4731.97 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted

pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

9. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022, each violation 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).

10. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements, each violation punishable by a maximum penalty of $1,000:

    a. A… licensed health professional authorized to prescribe drugs… will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or

    b. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

11. 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or

e. 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

f. 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

g. 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).

12. 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); and/or

e. 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

f. 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

g. 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

h. 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).

13. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, each violation punishable by a maximum penalty of $1,000:

    a. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and/or

    b. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

        i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

        ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and/or

    c. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

        i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and/or

        ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and/or

        iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and/or

        iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and/or

        v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and/or

        vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and/or

        vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and/or

        viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and/or

        ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9); and/or

    d. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and/or

e. All the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and/or
2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and/or
3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and/or
4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and/or
5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and/or
6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and/or
7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4).

14. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021, each violation punishable by a maximum penalty of $1,000:

a. The responsible person shall maintain the following records relating to the compounding of dangerous drugs:

i. All drug orders and records, including logs, relating to the compounding of drugs. Such drug orders and records may be retained by any process providing an exact duplicate of the original order or prescription, OAC Rule 4729:7-3-06(A)(1); and/or

ii. Records of each drug compounded shall, at a minimum, include all the following:

1. The full name of the patient, unless compounded in accordance with paragraph (G)(2) of rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-06(A)(3)(a); and
2. Name, strength, and dosage form of the compounded drug, Rule 4729:7-3-06(A)(3)(b); and
3. Name and quantity of each ingredient, Rule 4729:7-3-06(A)(3)(c); and
4. If a controlled substance, the disposition of unused drug(s) and amount, Rule 4729:7-3-06(A)(3)(d); and
5. Date and time of preparation, Rule 4729:7-3-06(A)(3)(e); and
6. Beyond-use date of the compounded drug, Rule 4729:7-3-06(A)(3)(f); and

7. The positive identification of the personnel responsible for compounding the drug, Rule 4729:7-3-06(A)(3)(g); and
8. The positive identification of either of the following:

    a. Person or persons performing medication validation prior to the compounded drug being administered, Rule 4729:7-3-06(A)(3)(h)(i); and/or

    b. The prescriber personally furnishing the compounded drug, Rule 4729:7-3-06(A)(3)(h)(ii); and

b. Records of disposal of compounded drugs, 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, the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:7-3-06(B); and/or

c. All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.

    i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:7-3-06(E)(1).

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

16. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to: 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).

17. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

    a. A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall affix to the container a label showing:

        i. The name and address of the prescriber; OAC Rule 4729:5-19-02(A)(1); and/or

ii. The name of the patient for whom the drug is intended; OAC Rule 4729:5-19-02(A)(2); and/or

iii. Name and strength of the drug; OAC Rule 4729:5-19-02(A)(3); and/or

iv. Directions for use; OAC Rule 4729:5-19-02(A)(4); and/or

v. Date furnished; OAC Rule 4729:5-19-02(A)(5); and/or

vi. If a compounded drug, the statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label, OAC Rule 4729:5-19-02(A)(6); and/or

b. Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1).

18. 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, each violation punishable by a maximum penalty of $1,000:

a. All records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access, OAC Rule 4729:5-19-03(J); 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. 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).

19. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, 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 personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver, OAC Rule 4729:5-19-04(D); and/or

    e. 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:

        i. For controlled substance dangerous drugs: the positive identification of the health care professional administering the drug, OAC Rule 4729:5-19-04(E)(1)(b); and/or

ii. Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification, OAC Rule 4729:5-19-04(E)(3); 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); and/or

g. Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code, OAC Rule 4729:5-19-04(G); and/or

h. 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.

i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:5-19-04(J)(1); and/or

ii. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-04(J)(2).

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 <u>not</u> 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/alg/rlj

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