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

IN THE MATTER OF: **CASE NO. A-2025-0300**

I.Win Aesthetics LLC DBA Peace Love Tox **License No. 02-64000610**
c/o Ilene Winick, APRN
13 W Orange St.
Chagrin Falls, OH 44022-2757

-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: 10/1/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

October 1, 2025

Dear I.Win Aesthetics, LLC DBA Peace Love Tox and Ilene Winick, APRN:

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 Peace Love Tox'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 Peace Love Tox's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Peace Love Tox'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. 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 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. I.Win Aesthetics, LLC DBA Peace Love Tox, located at 13 W Orange St., Chagrin Falls, Ohio 44022-2757, is a licensed TDDD under license number 02-64000610 and lists owner Ilene Winick, APRN [Ohio Nursing Board license number APRN.CNP.023153] as the Responsible Person.

ALLEGATIONS

1. On or about September 24, 2025, the Board conducted an inspection at Peace Love Tox ("the clinic"), a prescriber clinic licensed by the Board (TDDD 02-64000610). Responsible person, owner, and sole employee Ilene Winick, APRN, was present during the inspection.

2. During the inspection, vials labeled Zen Labs "S", containing purported semaglutide, were located in the active drug stock.

    a. APRN Winick stated the vials of semaglutide were obtained from Zen Labs. Winick stated Olympia was not offering compounded products she needed and with the help of a drug representative, she located Zen Labs and began purchasing drugs from them. NOTE: Zen Labs is an entity that 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.

    b. APRN Winick purchased six vials of Zen Labs "S" on July 23, 2025, and placed a second order for six vials on September 24, 2025. The September 24, 2025 order was canceled during the Board's inspection.

        i. One unopened Zen Labs "S" vial in the medication cabinet contained white powder, purported to be semaglutide. Another Zen Labs "S" vial in the medication refrigerator contained liquid, which was compounded by APRN Winick using the white powder and bacteriostatic water.

        ii. Three empty Zen Labs "S" vials that had been administered to patients were on site.

        iii. When asked about the sixth vial from the initial Zen Labs order, APRN Winick could not produce it and stated she believed she put it in the sharps container.

3. Multiple warnings requiring written responses were issued for violations, including the following:

    a. Dangerous drugs were purchased from unlicensed sources.

        i. The clinic had not conducted a query to confirm organizations they purchase drugs from are licensed with the Ohio Board of Pharmacy. See Allegation #2.

ii. Two large vials of purported “medical-grade” drugs, used topically as chemical peel labeled “The Perfect Derma,” and two small vials labeled “The Perfect Derma Plus,” were located in the active drug stock. These substances are described by the seller, Bella Medical, as “prescription only” and were purchased from Bella Medical, an entity not licensed by the Board.

iii. One unopened vial labeled AnteAGE MDX Brightening Diluent HA+TXA, labeled “for professional use,” was located in the active drug stock. APRN Winick advised a medical representative gave her the sample and no documentation was provided. The date the vial was obtained, and the distributor is unknown.

b. Adulterated drugs.

i. The clinic was in possession of adulterated drugs obtained from unlicensed and/or unknown sources. See Allegations #2 and #3.

ii. Expired dangerous drugs and fillers were comingled in the active drug stock. During the inspection, APRN Winick began removing topicals and drugs from the drug stock cabinet and placing them in a plastic bag. When questioned what she was doing, Winick stated she was cleaning out the cabinet because she knew she had expired and unused drugs in the drug stock cabinet.

iii. The clinic used bacteriostatic water that had expired May 1, 2025, to compound a vial of Zen Labs “S” purported semaglutide powder, which was then administered to a patient on September 24, 2025, prior to the Board’s inspection.

c. Compounding.

i. The clinic is not equipped to adhere to USP <797> guidelines for compounding drug product. The clinic engaged in compounding when following directions accompanying the “S” vials of purported semaglutide, instructing the clinic to “reconstitute” the white powder with bacteriostatic water.

d. Multi-dose vials were not properly labeled.

i. The clinic’s active drug stock contained numerous open multi-dose vials, none of which were labeled with an open date or beyond use date.

e. The clinic was operating as a pick-up station but did not meet the requirements of a pick-up station.

i. The clinic was in possession of patient specific tirzepatide from Boudreaux's New Drug Store.

ii. APRN Winick stated the medication is typically sent to the patient's residence and the only medications stored in the clinic are for patients who do not want to self-administer medication.

iii. The clinic did not meet the requirements of a pick-up station as there was no clear and convincing evidence that delivery of the prescription to the patient would result in danger to the public health or safety or result in danger to the patient, as required by rule to act as a pick-up station.

f. Record keeping.

i. The clinic did not have records of administration for clinic drug stock that was administered to the responsible person, APRN Winick.

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

   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 4729.51(F) of the ORC, effective 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.

[1] ORC Section 3715.63 – When drug or device is adulterated.
[2] ORC Section 3715.64 – Misbranded drug or device.

3. 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.

4. 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).

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, Prescription pick-up station, as effective December 1, 2020, each violation punishable by a maximum penalty of $1,000: The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

    a. Danger to the public health or safety, OAC Rule 4729:5-5-14(C)(1); or

    b. Danger to the patient, OAC Rule 4729:5-5-14(C)(2).

6. 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 March 1, 2019, 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 Rule 4729:5-3-06; and/or

b. 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 . . .. 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).

7. 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. 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

   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).

8. 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 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).

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

ii. 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

d. 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).

e. 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).

10. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, Prescription pick-up station, as effective December 1, 2020, each violation punishable by a maximum penalty of $1,000: The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

a. Danger to the public health or safety, OAC Rule 4729:5-5-14(C)(1); or

b. Danger to the patient, OAC Rule 4729:5-5-14(C)(2).

11. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, Non-Hazardous Drugs Compounded by a Prescriber, 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).

12. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, Immediate-use, sterile non-hazardous drugs compounded by a prescriber, each violation punishable by a maximum penalty of $1,000:

a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and/or

iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and/or

iv. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and/or

v. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and/or

b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

i. The beyond-use date for an immediate-use compounded drug preparation is as follows:

1. Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(a); and/or

ii. Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

1. Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name, OAC Rule 4729:7-3-04(B)(6)(a); and/or

2. The name and quantity of each ingredient, OAC Rule 4729:7-3-04(B)(6)(b); and/or

3. The beyond-use date and time prepared, OAC Rule 4729:7-3-04(B)(6)(c); and/or

4. The name or initials of the person who prepared the compounded drug preparation, OAC Rule 4729:7-3-04(B)(6)(d); and/or

iii. Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber, OAC Rule 4729:7-3-04(B)(7); and/or

c. Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins, OAC Rule 4729:7-3-04(C); and/or

d. Preparations that are deemed category two, medium-risk level, or high-risk level compounded drug preparations as defined in United States pharmacopeia chapter <797> shall not be prepared as immediate-use, OAC Rule 4729:7-3-04(D); and/or

e. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and/or

f. Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(H); and/or

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

    i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and/or

    ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and/or

h. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

    i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

    ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and/or

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

    i. Verify the accuracy of:

        1. Drug name, OAC Rule 4729:7-3-04(N)(3)(a); and

        2. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

        3. Drug volume, OAC Rule 4729:7-3-04(N)(3)(c); and

        4. Rate of administration, OAC Rule 4729:7-3-04(N)(3)(d); and

        5. Route of administration, OAC Rule 4729:7-3-04(N)(3)(e); and

6. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and

7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4).

13. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021, Record Keeping, 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/or

2. Name, strength, and dosage form of the compounded drug, OAC Rule 4729:7-3-06(A)(3)(b); and/or

3. Name and quantity of each ingredient, OAC Rule 4729:7-3-06(A)(3)(c); and/or

4. If a controlled substance, the disposition of unused drug(s) and amount, OAC Rule 4729:7-3-06(A)(3)(d); and/or

5. Date and time of preparation, OAC Rule 4729:7-3-06(A)(3)(e); and/or

6. Beyond-use date of the compounded drug, OAC Rule 4729:7-3-06(A)(3)(f); and/or

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

8. The positive identification of either of the following:

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

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

14. 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).

15. 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. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or

    b. 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

    c. 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).

16. 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. 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).

17. 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).

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/zas/rlj

cc: David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov