IN THE MATTER OF: **CASE NO. A-2025-0197**

Smooth Line Aesthetics by Bonnie **License No. 02-64000663**
6571 Wilson Mills Rd.
Mayfield, OH 44143

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Smooth Line Aesthetics by Bonnie (Smooth Line) for the purpose of resolving all issues between the parties relating to the Board investigation of Smooth Line's possession of a non-FDA approved "Research Use Only" drug, obtained from an unlicensed source. Together, the Board and Smooth Line 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. Smooth Line is a licensed Terminal Distributor of Dangerous Drugs under license number 02-64000663.

FACTS

1. The Board initiated an investigation of Smooth Line, Terminal Distributor of Dangerous Drugs license number 02-64000663, related to Smooth Line's possession of a non-FDA approved "Research Use Only" drug, obtained from an unlicensed source.

2. On or about July 10, 2025, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Smooth Line, 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 July 15, 2025, Smooth Line, through owner Bonnie Kitchen, APRN, timely requested an administrative hearing, which was subsequently scheduled for October 7, 2025.

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. Smooth Line admits the allegations stated in the Summary Suspension/Notice of Opportunity for Hearing letter dated July 10, 2025, and the Board 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 Smooth Line's TDDD license number 02-64000663 and reinstate the license immediately upon the effective date of this Agreement.

4. Smooth Line agrees to pay to the Board a monetary penalty in the amount of $25,000. This fine will be attached to your license record.

    a. $5,000 of the fine must be paid no later than twelve (12) months from the effective date of this Agreement.
    b. $20,000 of the fine is stayed, subject to successful completion of Term #6, payment of the $5,000 fine as stated in Term #4a, and contingent upon no additional violations by Smooth Line in twelve (12) months from the effective date of this Agreement.
    c. To pay this fine you must login to www.elicense.ohio.gov and process the items in the cart of the Responsible Person.

5. The Board hereby imposes a written reprimand on Smooth Line's TDDD license, number 02-64000663.

6. Smooth Line agrees that Bonnie Kitchen or the current 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 (6) months from the effective date of this Agreement. Copies of completed CEs must be e-mailed to legal@pharmacy.ohio.gov.

7. Smooth Line 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. Smooth Line 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 Smooth Line 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 Smooth Line by the Board and will NOT discharge Smooth Line from any obligation under the terms of this Agreement.

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

10. Smooth Line 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 Smooth Line will operate.

12. Smooth Line 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:

Bonnie S. Kitchen CP — 9-11-2025

Bonnie Kitchen, on behalf of,
Smooth Line Aesthetics by Bonnie, Respondent — Date of Signature

Jeana M. Singleton — 09/16/2025

Jeana Singleton, Attorney for Respondent — Date of Signature

09.16.2025

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: **CASE NO. A-2025-0197**

Smooth Line Aesthetics by Bonnie **License No. 02-64000663**
c/o Bonnie Sue Kitchen, APRN-CNP
6571 Wilson Mills Rd.
Mayfield, OH 44143

July 10, 2025

Dear Smooth Line Aesthetics by Bonnie and Bonnie Sue Kitchen, APRN-CNP:

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 Smooth Line Aesthetics by Bonnie'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 Smooth Line Aesthetics by Bonnie's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Smooth Line Aesthetics by Bonnie'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. Smooth Line Aesthetics by Bonnie located at 6571 Wilson Mills Rd., Mayfield, OH 44143, is a licensed TDDD under license number 02-64000663 and lists Bonnie Sue Kitchen [Ohio Board of Nursing Board license number RN.330107 / APRN.CNP.18995] as the Responsible Person (RP) and owner.

ALLEGATIONS

1. On or about June 16, 2025, the Board conducted an inspection at Smooth Line Aesthetics by Bonnie (Smooth Line) (TDDD 02-64000663), located at 6571 Wilson Mills Rd., Mayfield, Ohio. The Responsible Person and owner, Bonnie S. Kitchen, APRN-CNP, was present.

2. The inspection revealed Smooth Line was in possession of illegal drugs. Two (2) vials of a substance labeled as "AOD 9604 5mg," "Laboratory or Research Use Only, Not for Human or Animal Consumption" were observed. [*NOTE: Research Use Only drugs are not approved by the Food and Drug Administration (FDA). They are drugs specifically designed and labeled for use in scientific research and not for clinical or diagnostic purposes*.] The vials of AOD 9604 were purchased from an online website, BiotechPeptides.com, which is an illegitimate 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.

3. During the June 16, 2025 inspection, CNP Kitchen provided the following information:

    a. The TDDD was applied for in April 2024 at CNP Kitchen's home address. She only ordered neurotoxins to start and in January 2025, she started with GLP-1s.

    b. The clinic at the Wilson Mills Road location opened mid-March 2025 and is open Saturday, Monday and by appointment. CNP Kitchen has about 40 patients and she is the only employee.

    c. CNP Kitchen ordered two vials of the AOD 9604 from Biotech Peptides on 4/12/25 and had them shipped to her home address. She stated the peptides are to aid with fat loss in conjunction with other drugs. She found out about the drug "through research" and the "peptide world." She stated she had not used them and claimed she did not intend to administer them to patients.

    d. CNP Kitchen stated the vials were at the clinic because all of her supplies are located there. If she was going to try the AOD 9604, she would try it at the clinic.

    e. CNP Kitchen stated if a patient expressed interest in trying the AOD 9604 labeled for Research Use Only, she would not have used it because she had not tried it herself and she tries everything first before offering it to patients.

f. When asked if she ever gets "nervous" about some of these products, CNP Kitchen stated all the products she offers, your body makes. She stated she tries all of them and sees the benefit of them (e.g., GLPs).

4. The inspection conducted on June 16, 2025, resulted in warnings and warnings requiring written responses for violations including the following:

a. Two vials of AOD 9604 Research Use Only products were purchased from Biotech Peptides with an intent to self-inject. The products were shipped to CNP Kitchen's home and brought to the clinic where they were stored with the clinic's active drug stock. Biotech Peptides is not an Ohio Board of Pharmacy licensed drug distributor and CNP Kitchen did not verify if Biotech Peptides was licensed with the Board prior to the purchase of AOD 9604.

b. Clinic was operating as a pick-up station for one patient specific prescription for NAD500. The patient's RX number and name were removed from the vial.

c. Open multi-dose vials were not dated.

d. Punctured sodium chloride vials were stored in the refrigerator. The vials are labeled to be stored at room temperature.

e. The clinic failed to maintain employee administration records for medications from the clinic that Kitchen has self-injected.

f. The clinic was personally furnishing MICC (a compounded dangerous drug that contains methionine 25mg/ml, inositol 50mg/ml, choline 50mg/ml, and cyanocobalamin 0.33mg/ml) to patients in pre-drawn syringes. The clinic labeled the bag containing the pre-drawn syringes with the medication name, administration instructions, and the statement "keep refrigerated." The label contained handwritten dates for the date filled and expiration date. The date filled on the label was 6/17/2025, while the current date was 6/16/2025 and the assigned expiration date was 9/28/25 instead of the permitted 6 hours for immediate use, non-hazardous sterile compounding rules.

g. No drug disposal records were kept.

h. A request for address change was submitted to the Board on June 11, 2025. At the time of inspection, the current address for the TDDD was listed as 1431 Richmond Rd. Lyndhurst, OH 44124, which is Kitchen's home address. The clinic moved March 2025 and is currently located at 6571 Wilson Mills Rd. Mayfield, OH 44143.

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

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[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. * * *
5. 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
6. 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:
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).

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, 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

      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).

3. 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.

4. 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.

5. 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).

6. 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); and/or

    d. 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).

7. Such conduct as set forth in the 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, Personally furnishing dangerous drugs, 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).

8. 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 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

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 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

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).

9. Such conduct as set forth in paragraphs (1)(g) of 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. 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. If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces, OAC Rule 4729:7-3-04(B)(3); and/or

ii. 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

iii. If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely disposed. Records of disposal shall be maintained in accordance with rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(B)(5); and/or

iv. 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

v. 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).

10. 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).

11. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-03 of the OAC, Change in description of a terminal distributor of dangerous drugs, as effective October 1, 2024, each punishable by a maximum penalty of $1,000:

    a. Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires an application and required fee. The application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address, OAC Rule 4729:5-2-03(A).

12. 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. 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

    e. 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).

13. 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. 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

    e. 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

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