IN THE MATTER OF:

CASE NOS. A-2025-0122 & A-2025-0124

Jenerous Hydration, LLC
c/o Jennifer Rummell, CNP
232 W. 3rd Street, Suite 320
Dover, Ohio 44622

License No. 02-62001627

Jenerous Hydration, LLC
c/o Jennifer Rummell, CNP
1518 Sharon Valley Rd. SE
New Philadelphia, Ohio 44663

License No. 02-62000840

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Jenerous Hydration, LLC (Dover) and Jenerous Hydration, LLC (New Philadelphia), collectively "Jenerous Hydration," for the purpose of resolving all issues between the parties relating to the Board investigation of a non-Food and Drug Administration (FDA)-approved medication (retatrutide), discovered during an inspection. Together, the Board and Jenerous Hydration 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. Jenerous Hydration, LLC, located at 232 W. 3rd Street, Suite 320, Dover, Ohio, is a licensed Terminal Distributor of Dangerous Drugs (TDDD) under license number 02-62001627 and lists Jennifer Rummell, CNP [Ohio Board of Nursing license number APRN.CNP.0029553] as the Responsible Person since the license was issued on November 16, 2023.

3. Jenerous Hydration, LLC, located at 1518 Sharon Valley Rd. SE, New Philadelphia, Ohio, is a licensed TDDD under license number 02-62000840 and lists Jennifer Rummell, CNP as the Responsible Person since the license was issued on September 1, 2021.

FACTS

1. The Board initiated an investigation of Jenerous Hydration, Terminal Distributor of Dangerous Drugs license numbers 02-62001627 and 02-62000840, related to Jenerous Hydration's prescribing, purchasing and possession of retatrutide, a non-Food and Drug Administration (FDA)-approved medication.

2. On or about May 12, 2025, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Jenerous Hydration, 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 May 27, 2025, Jenerous Hydration, through counsel Greg Tapocsi, timely requested an administrative hearing, which was subsequently scheduled for July 10, 2025. The parties settled the matter via this Agreement in lieu of hearing.

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. Jenerous Hydration neither admits nor denies the allegations stated in the Summary Suspension/Notice of Opportunity for Hearing letters dated March 25, 2025; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice letters, and hereby adjudicates the same.

3. The Board will lift the summary suspension imposed on Jenerous Hydration's TDDD license numbers 02-62001627 and 02-62000840, and reinstate both licenses immediately upon the effective date of this Agreement.

4. Jenerous Hydration agrees to pay to the Board a monetary penalty the amount of $15,000.00. The monetary penalty will be applied as follows: $7,500.00 will be attached to the license record for license number 02-62001627 and $7,500.00 will be attached to the license record for license number 02-62000840. This fine must be paid no later than 24 months from the effective date of this Agreement. To pay this fine, login to www.elicense.ohio.gov and process the items in each cart.

5. Jenerous Hydration's TDDD licenses are subject to a minimum one-year probationary period beginning the effective date of this Agreement. Jenerous Hydration will remain on probation until the $15,000.00 monetary penalty is paid in full or one year has passed, whichever occurs last.

6. Jenerous Hydration and Jennifer Rummell, CNP agree that Ms. Rummell will notify each patient who was prescribed and/or received retatrutide from Jenerous Hydration of the following: Retatrutide is not an Food and Drug Administration (FDA) approved medication and it is not permitted to be prescribed, purchased, administered or shipped into Ohio.

7. The Board hereby imposes a written reprimand on both of Jenerous Hydration's licenses, TDDD license numbers 02-62001627 and 02-62000840.

8. Jenerous Hydration's owner, Jennifer Rummell, CNP, must obtain ten hours of approved continuing pharmacy education (1.0 CEUs) which may not also be used for the purpose of CNP license renewal. The 1.0 CEUs must be in the topic areas of pharmacy law/compliance and/or Ohio law and must be completed within six months from the effective date of this Agreement. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

9. Jennifer Rummell, CNP agrees to attend a Board-sponsored Responsible Person 101 presentation (one hour) within six months from the effective date of this Agreement.

10. Jenerous Hydration 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.

11. Jenerous Hydration 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 Jenerous Hydration 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 Jenerous Hydration by the Board and will NOT discharge Jenerous Hydration from any obligation under the terms of this Agreement.

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

13. Jenerous Hydration understands that it has the right to be represented by counsel for review and execution of this agreement.

14. 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 Jenerous Hydration will operate.

15. Jenerous Hydration 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.

16. 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.

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

18. 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.

19. 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.

20. 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:

Jennifer Rummell

Jennifer Rummell, on behalf of,
Jenerous Hydration, Respondent

6/9/25

Date of Signature

Gregory Tapocsi, Attorney for Respondent

6-9-25

Date of Signature

Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

6.9.2025

Date of Signature

-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: 5/12/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: **CASE NO. A-2025-0122**

Jenerous Hydration, LLC **License No. 02-62001627**
c/o Jennifer Rummell, CNP
232 W. 3rd Street, Suite 320
Dover, Ohio 44622

May 12, 2025

Dear Jenerous Hydration, LLC:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Jenerous Hydration, LLC's (Jenerous Hydration'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 Jenerous Hydration, LLC'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 Jenerous Hydration, 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. 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. Pursuant to Section 4729.571(A)(2) 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 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.

4. Jenerous Hydration, LLC, located at 232 W. 3rd Street, Suite 320, Dover, Ohio, is a licensed TDDD under license number 02-62001627 and lists Jennifer Rummell, CNP [Ohio Board of Nursing license number APRN.CNP.0029553] as the Responsible Person since the license was issued on November 16, 2023.

ALLEGATIONS

1. On or about April 29, 2025, a Board Agent and a Board Specialist (Board inspectors) conducted an inspection at Jenerous Hydration, located at 232 W. 3rd Street, Suite 320, Dover, Ohio. During the inspection, Board inspectors met with Jennifer Rummell, CNP, [License no. APRN.CNP.0029553], the Responsible Person and owner of the clinic.

2. The inspection revealed Jenerous Hydration was in possession of 15 vials of patient-specific retatrutide, including:

    a. Nine 8mg/mL 4mL vials (unopened); and

    b. Six 8mg/2mL vials (5 unopened, 1 punctured)

        i. Note: Retatrutide is not a Food and Drug Administration (FDA)-approved medication. During the time of use at Jenerous Hydration retatrutide was undergoing Phase III trials. Jenerous Hydration was not part of these Phase III trials.

3. The inspection of Jenerous Hydration conducted by Board inspectors resulted in six warnings requiring a written response and an additional warning that did not require a written response, including:

    a. Controlled substances (testosterone pellets) were stored in a locking cabinet; however, the key was in the lock.

        i. NP Rummel was not on site during the initial part of the inspection which allowed clinic staff unsupervised access to the cabinet.

        ii. Clinic staff (Registered Nurses) had access to non-patient specific controlled substances.

    b. The clinic purchased non-FDA approved medication from Brooksville Pharmaceuticals.

        i. 15 vials of patient-specific retatrutride, purchased on April 25, 2025, were located in the clinic's refrigerator.

    c. The clinic was operating as a pick-up station; however, it does not meet the requirements to operate as a pick-up station.

        i. Board inspectors observed many vials of patient-specific semaglutide and tirzepatide. These medications do not meet the pick-up station requirements and must be shipped directly to the patient.

        ii. The medication must be sent home with the patient for whom they were prescribed and may not be maintained at the clinic.

d. Observed several multi-dose vials with labels that did not include the date the vial was opened and/or the beyond-use date.

    i. In addition to the vials that did not include a date, several multi-dose vials were observed to include a "date opened" label; however, the date was greater than 28 days and therefore should be treated as an adulterated drug.

e. Expired (adulterated drugs) were not stored in a separate area.

    i. Several expired drugs were comingled in the active drug stock.

    ii. The following expired drugs were found in active drug stock:

        1. 1 vial NAD (expired 7/26/2023), 1 vial bacteriostatic water (expired 4/1/2025), 1 opened vial Tri-Immune Boost (glutathione, ascorbic acid, zinc sulfate) (expired 6/23/2024), 1 epi-pen (expired 5/2023), and atropine 1mg/10mL abboject (expired 8/1/2023).

f. The clinic engaged in compounding of immediate-use, sterile non-hazardous drugs involving the transfer of more than three commercially available manufactured packages.

    i. There were recipes observed that are used by the clinic. The recipes included three drugs to be added to the IV bag. When compounding an IV bag, only two drugs are permitted to be added to the IV bag.

    ii. NP Rummel stated she misunderstood the rule and believed she was permitted to add three drugs to the bag.

g. Personally furnishing records did not include positive identification of the prescriber personally furnishing the drugs.

4. During the inspection, NP Rummel was interviewed by a Board inspector. She stated the following:

    a. She found out about retatrutide from a client.

    b. She discovered retatrutide was available from Brooksville Pharmaceuticals, located at 16140 Flight Path Dr., Brooksville, Florida. As of the time of purchasing, Brooksville Pharmaceuticals was Board-licensed to distribute drugs into Ohio.

    c. NP Rummell prescribed retatrutide to her patients via Brooksville Pharmaceuticals and the prescriptions were delivered to RP Rummell's other clinic, Jenerous Hydration, LLC (02-62000840), located at 1518 Sharon Valley Rd. SE, New Philadelphia, Ohio.

        i. Jenerous Hydration, LLC located in New Philadelphia, Ohio is also owned by NP Rummell. She uses it as an extra storage space. She stated dangerous drugs were delivered to the New Philadelphia location then transferred to Jenerous Hydration located in Dover, Ohio.

        ii. Note: On May 5, 2025, Jenerous Hydration, LLC located in New Philadelphia, Ohio was inspected. There was no retatrutride on site.

d. She received a discount from Brooksville by shipping the retatrutide directly to her clinic for multiple patients at one time. Her patients would then pay her for their drug and pick their prescription up from Jenerous Hydration (Dover location).

e. She started prescribing retatrutide “maybe two months ago.”

f. NP Rummell provided a copy of an invoice dated April 25, 2025 which included delivery of 12 vials of patient-specific retatrutide, for seven patients, to Jenerous Hydration’s New Philadelphia location.

g. She asked how she should know the retatrutide was not an approved drug.

POTENTIAL VIOLATIONS OF LAW

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

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

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

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

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 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.

3. 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, 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).

4. 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:

---

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).

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… licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

5. 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).

6. 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).

7. 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).

8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, 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

   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 compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device, OAC Rule 4729:7-3-04(B)(1); and/or

   c. 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).

9. Such conduct as set forth in the Allegations Section, if proven, each 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.

    a. 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 Rule 4729:5-3-06(A).

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

11. 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. 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

    b. 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).

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

13. 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, as effective February 4, 2021, 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 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

c. Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale, OAC Rule 4729:5-19-04(H).

14. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, 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 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)(1).

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/alg/kll

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