IN THE MATTER OF: **CASE NO. A-2025-0229**

JMN Investments
DBA Game Day Men's Health Solon
6200 Som Center Rd. Ste D26
Solon, OH 44139

License No. 02-62002000

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and JMN Investments DBA Game Day Men's Health Solon for the purpose of resolving all issues between the parties relating to the Board investigation of JMN Investments DBA Game Day Men's Health Solon's possession and sale of non-FDA approved dangerous drugs obtained from unlicensed entities. Together, the Board and JMN Investments DBA Game Day Men's Health Solon 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. JMN Investments DBA Game Day Men's Health Solon (Game Day Men's Health Solon), located at 6200 Som Center Rd. Solon, OH, 44139, is a licensed TDDD under license number 02-62002000 and lists Karin Cseak, D.O. [Ohio Medical Board license number 34.006986CTR] as the Responsible Person and Darrin L. Kresevic as the owner.

FACTS

1. The Board initiated an investigation of Game Day Men's Health Solon, Terminal Distributor of Dangerous Drugs license number 02-62002000, related to Game Day Men's Health Solon's possession and sale of non-FDA approved dangerous drugs obtained from unlicensed entities.

2. On or about August 6, 2025, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Game Day Men's Health Solon, 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 September 3, 2025, Game Day Men's Health Solon, through counsel, Gregory Tapocsi, timely requested an administrative hearing, which was subsequently scheduled for January 7, 2026. This matter was settled 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. Game Day Men's Health Solon neither admits nor denies the allegations stated in the Summary Suspension/Notice of Opportunity for Hearing letter dated August 6, 2025; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. The Board will lift the summary suspension imposed on Game Day Men's Health Solon's TDDD license, number 02-62002000, and reinstate the license upon the effective date of this Agreement.

4. Game Day Men's Health Solon agrees to pay to the Board a monetary penalty in the amount of $25,000. This monetary penalty will be attached to the license record for Game Day Men's Health Solon and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine, a representative for Game Day Men's Health Solon 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 Game Day Men's Health Solon's TDDD license, number 02-62002000.

6. Game Day Men's Health Solon agrees that the current Responsible Person must complete the Board sponsored Responsible Person 101 Roundtable (1 hour) and six hours of approved continuing education (0.6 CEUs) in the topics of drug storage and handling, regulatory compliance and/or law/ethics. The Roundtable and 0.6 CEUs 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.

7. Gameday Men's Health Solon agrees that it will notify each patient, who has not already been notified, who was prescribed and/or received any medication(s) from Gameday Men's Health Solon that were not approved by the U.S. Food and Drug Administration (FDA), of the following: The medication is not a Food and Drug Administration (FDA) approved medication and it is not permitted to be prescribed, purchased, administered or shipped into Ohio.

8. Game Day Men's Health Solon 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.

9. Game Day Men's Health Solon 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 Game Day Men's Health Solon 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 Game Day Men's Health Solon by the Board and will NOT discharge Game Day Men's Health Solon from any obligation under the terms of this Agreement.

10. Game Day Men's Health Solon agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

11. Game Day Men's Health Solon understands that it has the right to be represented by counsel for review and execution of this agreement.

12. 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 Game Day Men's Health Solon will operate.

13. Game Day Men's Health Solon 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.

14. 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.

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

16. 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.

17. 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.

18. 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:

Darrin L. Kresevic, on behalf of,
Game Day Men's Health Solon, Respondent

10-22-2025
Date of Signature

Gregory Tapocsi, Attorney for Respondent

Date of Signature

Jeff Huston, RPh, President,
Ohio Board of Pharmacy

10/24/2025
Date of Signature

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:

Darrin L. Kresevic, on behalf of,
Game Day Men's Health Solon, Respondent

Date of Signature

Gregory Tapocsi

Gregory Tapocsi, Attorney for Respondent

10.24.25

Date of Signature

Jeff Huston, RPh, President,
Ohio Board of Pharmacy

10/24/2025

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: 8/6/2025
-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-2025-0229**

JMN Investments
DBA Game Day Men's Health Solon
6200 Som Center Rd. Ste D26
Solon, OH 44139

License No. 02-62002000

August 6, 2025

Dear JMN Investments DBA Game Day Men's Health Solon:

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 JMN Investments DBA Game Day Men's Health Solon'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 JMN Investments DBA Game Day Men's Health Solon'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 JMN Investments DBA Game Day Men's Health Solon'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. 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. Game Day Men's Health Solon, located at 6200 Som Center Rd. Solon, OH, 44139, is a licensed TDDD under license number 02-62002000 and lists Karin Cseak, D.O. [Ohio Medical Board license number 34.006986CTR] as the Responsible Person and Darrin L. Kresevic as the owner.

ALLEGATIONS

1. On or about June 3, 2025, a Board inspector conducted an inspection at JMN Investments DBA Game Day Men's Health Solon ("Game Day"), located at 6200 Som Center Road, Solon, Ohio. Franklyn Corlett, Game Day's Franchise Administrator, who is not a licensed healthcare professional, was present during the inspection. At the time of the inspection, Game Day employed Karin Cseak, DO, Responsible Person; Sarah Johnson, PA [Ohio Medical Board license 50.007815]; and Rick Racine, paramedic [license number 73789].

2. The inspection conducted on June 3, 2025 resulted in six warnings requiring written responses, including but not limited to:

    a. Security and control of controlled substances.

        i. Controlled substances are stored in a locked safe that requires biometric fingerprint scan to open; however, non licensed healthcare professional(s) have access.

            1. Game Day's franchise administrator, who is not a licensed healthcare professional, had access to the controlled substance safe.

        ii. The clinic employs a paramedic who administers testosterone, a Schedule III controlled substance.

    b. Purchased dangerous drugs from unlicensed drug distributors.

        i. Drugs were purchased from entities not licensed in Ohio.

        ii. Records received by the Board inspector included drug invoices/packing slips from Tandem Regeneration Therapeutics (not licensed with the Board), Preferred Rxx (not licensed with the Board), and Anazao.

1. The drugs on the invoice/packing slips from Tandem were labeled as received from Tx Performance Meds Pharmacy & Wellness and ProRx.

iii. After the inspection, clinic staff stated they placed orders through a drug representative from Modern Medical, for peptides. There were no invoices from Modern Medical (licensed with the Board); the clinic received the drugs with a packing slip from Preferred Rxx which did not contain an address. The drugs were labeled as from Preferred Rxx.

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

c. Patient-specific prescriptions were used as office stock.

i. The clinic ordered compounded topical pain cream from a compounding pharmacy using the owner's name. It was maintained for clinic use.

d. Temperature monitoring was not in compliance with the rules.

i. The clinic does not maintain a daily temperature log or a continuous temperature monitoring system for the refrigerators/freezers that are used to store drugs.

ii. The clinic is not open every day of the week so there are many days when the daily temperature is not documented as required.

e. Adulterated drugs were comingled with the active drug stock.

i. The Board inspector observed an open single dose vial with a Beyond Use Date (BUD) label, indicating the vial was intended to be used more than once. A single dose vial must be discarded after use.

f. Drug administration.

i. The clinic's records of administration indicate the clinic employs a paramedic to administer drugs, including peptides and testosterone. Paramedics are considered an unlicensed healthcare person in a clinic setting, per scope of practice rules. Paramedics are not permitted to administer controlled substances, i.e. testosterone, in this setting.

g. Personally furnishing.

i. The clinic pre-draws syringes of peptides and personally furnishes the medication for the patient to administer at home.

ii. Clinic staff stated the clinic will provide the patient with 4-6 weeks' worth of medication, which amounts to 5 injections per week. Personally furnishing pre-drawn syringes of medication is not permitted.

3. After the inspection, investigation revealed drugs observed from unlicensed drug distributors, including but not limited to: AOD-9604, BPC-157, BPC-157 combinations drugs and Ipamorelin combination drugs. These drugs are not approved by the U.S. Food and Drug Administration (FDA) and are not permitted to be compounded. These drugs are illegal in the United States.

    a. Note: These drugs are not permitted to be compounded because they lack USP/NF monograph, are not a component of an approved drug, and do not appear on the 503A bulk drug substances list.

4. On or about July 29, 2025, a Board Specialist and Board Agent (Board inspectors) conducted a follow-up inspection at Game Day. The Board inspectors were assisted by Franklyn Corlett and PA Johnson during their inspection.

5. The inspection revealed Game Day was in possession of illegally compounded drugs (listed in Allegation #6, below) purchased from Tandem Regenerative Therapeutics, a drug distributor that is not licensed with the Board. The invoices/packing slips indicated the Tandem Regenerative Therapeutics drugs were labeled as from TX Performance Meds Pharmacy & Wellness, a 503A compounding pharmacy, not licensed with the Board, and ProRx, also not licensed with the Board.

    a. Many of these drugs are not approved by the U.S. Food and Drug Administration (FDA) and are not permitted to be compounded because they lack USP/NF monograph, are not a component of an approved drug, and do not appear on the 503A bulk drug substances list.

6. Game Day was in possession of the following compounded drugs during the inspection:

    a. BPC/TB/GHKU/KPV 3 mg/3mg/10mg/3mg/mL

        i. 2 vials (5 mL vials)

    b. IGF-LR3 200 mcg/mL

        i. 1 unopened vial (5 mL vial) and 1 punctured/partial vial.

    c. CJC, Ipamorelin 1.2 mg, 2 mg/mL l

        i. 7 vials (5 mL vials)

    d. AOD-9604, Mots-C, Tesamorelin 12 mg, 2 mg, 3 mg/mL

        i. 3 vials (5 mL vials)

    e. BPC-157 3 mg/mL

        i. 4 vials (5 mL vials).

f. Sermorelin 3 mg/mL

   i. 2 vials (5 mL vials)

g. NAD+ injection 1000 mg (100 mg/mL)

   i. 6 vials

7. The inspection that occurred on or about July 29, 2025 resulted in three warnings requiring a written response, including but not limited to:

   a. Controlled substances were not maintained under appropriate supervision and control.

      i. The medical assistant, an unlicensed healthcare professional, had access to the safe where the testosterone was stored. Only a prescriber should be permitted access.

   b. Purchased dangerous drugs from unlicensed drug distributors.

      i. The clinic possessed dangerous drugs from unlicensed distributors.

      ii. The clinic completed an annual query on June 4, 2025; however, failed to complete a query prior to purchasing drugs prior to June 4. 2025.

   c. Adulterated drugs were comingled with the active drug stock.

      i. Observed a punctured, expired multi dose vial stored with the clinic's active drug stock.

      ii. Expired drugs that had not been opened were comingled with the active drug stock.

8. Records were requested by Board inspectors at the June 3, 2025 and July 29, 2025 inspections. An audit was conducted of the clinic's records. The following was revealed:

   a. Non-FDA approved and/or drugs not permitted to be compounded were personally furnished to multiple patients on 47 occasions between May 14, 2025 and July 29, 2025.

      i. Non-FDA approved and/or drugs not permitted to be compounded were personally furnished 16 times after the June 3, 2025 inspection.

   b. Records showed discrepancies between drugs purchased, received, drugs personally furnished to patients and the drugs observed during the inspection. Several vials were unaccounted for, and some invoices indicated there were more dangerous drugs delivered than documented.

9. During the June 3, 2025 and July 29, 2025 inspections, Board inspectors spoke with Sarah Johnson, PA and Franklyn Corlett. The following was stated:

a. Peptides were sold and personally furnished to patients; they were not administered on-site.

b. Testosterone and GLP-1 injections are administered at the clinic.

c. The clinic has a log and execl document to track drugs personally furnished to patients.

d. Mr. Corlett stated all invoices were provided to the Board (despite discrepancies discovered by Board inspectors).

e. The Responsible Person, Karin Cseak, DO was on site at the clinic about twice per month; PA Johnson was on site the days the clinic was open, usually Tuesdays, Wednesdays and Thursdays.

POTENTIAL VIOLATIONS OF LAW

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

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

[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, 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: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.

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

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

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

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.291(A) of the ORC, Drugs personally furnished by prescriber- Except when provided under section 4731.97 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section

4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

8. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-19-02(K) of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

9. 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: 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: 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, constitutes a violation 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.

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, 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. Except as provided in paragraphs (F) and (G) of this rule, controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access, OAC Rule 4729:5-19-03(B); and/or

    c. During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-

controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs, OAC Rule 4729:5-19-03(I); and/or

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

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

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

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

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

e. 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

f. 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 Rule 4729:5-3-14(A)(2) of the OAC, as effective March 1, 2020, General security requirements, 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.

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, Record Keeping, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

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

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

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

   i. For temperature logs, either:

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

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

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

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

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

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

15. 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).

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. 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).

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. 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/alg/jrn

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