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Stand Schickt
Steven W. Schierholt, Esq., Executive Dir. Date: Dec 15, 2022
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE STATE BOARD OF PHARMACY

(Case Numbers A-2020-0736 & A-2021-0230)

In The Matter Of:

Kroger Pharmacy #014447

1425 Columbus Avenue Lebanon, Ohio 45036 (License No. 02-1042850)

INTRODUCTION

The Matter of Kroger Pharmacy #014447 came for hearing on December 6, 2022 before the following members of the State of Ohio Board of Pharmacy (Board): Shawn Wilt, RPh, *Presiding*; Trina Buettner, RPh, Vice President; Mindy Ferris, RPh; Jason George, RPh; Victor Goodman, *Public Member*; T.J. Grimm, RPh; Jeff Huston, RPh; Rich Miller, RPh; and Christine Pfaff, RPh.

Kroger Pharmacy #014447 was represented by Mary Barley McBride. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

- 1. Kelli Waggoner, RPh, Respondent
- 2. Andrew Bouza, Agent of the Board

Respondent's Witnesses:

- 1. Kelli Waggoner, RPh
- 2. Michelle Izor, PharmD; The Kroger Co. Division Health Leader, Cincinnati Division

State's Exhibits:

- 1a. Notice Letter to Kelli Waggoner (6/8/2021)
- 1b. Patient Key
- 2. Notice Letter to Kelli Waggoner (9/3/2021)
- 3. Notice Letter to Kelli Waggoner (5/31/2022)
- 4. Notice Letter to Kelli Waggoner (9/15/2022)
- 5a. Notice Letter to Kroger Pharmacy #014447 (6/8/2021)
- 5b. Patient Key



- 6. Notice Letter to Kroger Pharmacy #014447 (9/3/2021)
- 7. Notice Letter to Kroger Pharmacy #014447 (5/31/2022)
- 8. Notice Letter to Kroger Pharmacy #014447 (9/15/2022)
- 9. Request for Hearing for Kelli Waggoner & Kroger Pharmacy #014447
- 10. Request for Hearing for Kelli Waggoner & Kroger Pharmacy #014447
- 11. Inspection Report
- 12. Kroger's Response to Inspection Report
- 13. Statement of Kelli Waggoner dated 7/21/2020
- 14. Statement of Stevens
- 15. Prescription for Patient B.R.
- 16. Kroger Documents Regarding June 28, 2020, Dispensing Error
- 17. Omitted n.a.
- 18. Theft & Loss Report from Kroger #014447 dated 6/17/2019
- 19. Theft & Loss Report from Kroger #014447 dated 9/4/2019
- 20. Theft & Loss Report from Kroger #014447 dated 4/20/2020
- 21. Theft & Loss Report from Kroger #014447 dated 7/7/2020
- 22. Theft & Loss Report from Kroger #014447 dated 4/12/2021
- 23. Statement of Deborah Estep
- 24. Email from Alison Cook to Andrew Bouza dated 5/6/2021
- 25. Statement of Kelli Waggoner dated 2/24/2022
- 26. Dispensing of Morphine IR
- 27. Theft & Loss Report from Kroger #014447 dated 11/22/2021
- 28. E-mail from Charles D'Imperio to Andrew Bouza dated 7/22/2022
- 29. Theft & Loss Report from Kroger #014447 dated 7/24/2022
- 30. Kroger #014447 Controlled Substance Action Plan
- 31. Shelf Maintenance Report dated 1/12/2022
- 32. Shelf Maintenance Report dated 2/16/2022

Respondent's Exhibits:

- A. Breach Root Cause Analysis Retraining with Pharmacy Staff sign-off (August, 2020)
- B. Release to Patient Return to Stock Retraining with special notation of handling controlled substances with Pharmacy Staff sign-off (August, 2020)
- C. Controlled Substance Action Plan (for Loss control and Prevention) with Pharmacy Staff sign-off (undated)
- E. Diagram of 7 camera locations

FINDINGS OF FACT

The parties stipulated to – and the Board hereby adopts as fact – the Allegations as set forth in Amended Notice of Opportunity for Hearing dated September 3, 2021, Case Numbers A-2020-0736 & A-2021-0230, reiterated herein and set forth below.

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the Board finds the following to be fact:

- 1. On or about June 28, 2020, a medication was mistakenly given to a patient at Kroger Pharmacy #014447, located at 1425 Columbus Avenue, Lebanon, Ohio, where Kelli Waggoner was the Responsible Person. Patient B.R. was prescribed three medications. When she arrived to pick-up her medications, she decided she no longer wanted prescription #2337687, oxycodone HCL 5 mg tablets, as her insurance did not cover the medication. Pharmacy technician Lauren Stevens cashed out patient B.R., however, prescription #2337687, 15 oxycodone HCL 5 mg tablets, was not removed from the packaged items. The loss of 15 oxycodone HCL 5 mg tablets, a Schedule II controlled substance, was discovered when the drug was randomly back counted.
- 2. It was discovered during an internal investigation by Kroger that there were only two cameras in operation in the pharmacy. The cameras did not capture any of the points of sale- the registers used by technicians to sell medications to customers.
- 3. On or about July 21, 2020, an inspection of Kroger Pharmacy was conducted by agents of the Board. The inspection resulted in four warnings/written responses required, including:
 - a. Security of the pharmacy drug stock is not adequate to detect and deter drug theft and diversion.
 - i. Pharmacy Consultation Room was unlocked and unsecured. The room was accessible to the public and not under supervision of a pharmacist.
 - ii. Within the room, cabinets containing hypodermic needles were not secure.
 - iii. The pharmacy did not have cameras to capture the employees working in the pharmacy.
 - b. Kroger Pharmacy #014447 has had several "Theft and Significant Loss Reports" in recent years, including:
 - i. Loss of 100 oxycodone 5 mg tablets, January 3, 2017.
 - ii. Loss of a bottle of hydrocodone-acetaminophen 5/325 tablets, June 17, 2019.
 - iii. 100 hydrocodone-acetaminophen 5/325 tablets mixed in with hydrocodone-acetaminophen 7.5/325 tablets, September 4, 2019.
 - iv. Prescription for hydrocodone-acetaminophen was miscounted/unable to determine which patient received 30 extra hydrocodone-acetaminophen 10/325 tablets, April 20, 2020.
 - c. Pharmacy's perpetual C-II drug inventory was not accurate.
 - i. The perpetual inventory in the computer indicated there were 413 oxycodone 5 mg tablets in the pharmacy. The on-hand count was 513.
 - d. Pharmacists requesting OARRS reports when appropriate.

- i. The computer system had a hard stop on requesting an OARRS Report when necessary, however, the pharmacy was not able to verify/provide the dates/times/users that had requested the reports.
- 4. On or about July 21, 2020, Lauren Stevens, pharmacy technician, spoke with an agent of the Board and stated the following:
 - a. She was a new technician and needed assistance cashing out patient B.R. on June 28, 2020. Kelli Waggoner, RPh, assisted her. She thought oxycodone prescription #2337687 was physically removed from the patient's bag, but she cannot say this occurred with certainty.
- 5. On or about April 12, 2021, Kelli Waggoner, Responsible Person, reported an additional loss of controlled substances to the Board by submitting a theft and loss report. Ms. Waggoner reported 80 amphetamine salt 5 mg capsules were missing from Kroger Pharmacy. Video surveillance was reviewed, and it was discovered that a pharmacy technician had inadvertently thrown away a stock bottle of amphetamine salt capsules, resulting in the reported loss. This loss occurred despite implementation of a corrective action plan following previous losses of controlled substances.

CONCLUSIONS OF LAW

- 1. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.55 of the ORC, effective April 6, 2017:
 - a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and
 - b. A pharmacist... 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 Section 4729.55(B); and
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC Section 4729.55(C); and
 - d. Adequate safeguards are assured to carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC Section 4729.55(D).
- 2. Such conduct as set forth in the Findings of Fact, each constitutes a violation of each of the following divisions of Section 4729.57 of the ORC:
 - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and
 - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and

- d. 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).
- 3. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective March 1, 2019:
 - a. The responsible person shall be responsible for the practice of the profession of pharmacy, 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(A)(2); and
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and
 - c. 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
 - d. 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 the Findings of Fact, each constitutes a violation of the following sections of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017: All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion, OAC Rule 4729-9-05(A).
- 5. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729-9-11 of the OAC: A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Code shall provide 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, by the following procedures:
 - a. In a pharmacy: Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-

- site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion, OAC Rule 4729-9-11(A)(1); and
- b. Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
 - i. Any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, exempt narcotics, hypodermics, poisons, records relating to the distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:
 - 1. The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the state board of pharmacy, OAC Rule 4729-9-11(A)(2)(h)(i); and
 - 2. No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy, OAC Rule 4729-9-11(A)(2)(h)(ii); and
 - 3. Authorized personnel may have access if there is on-site supervision by a pharmacist, OAC Rule 4729-9-11(A)(2)(h)(iii); and
- c. Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs, OAC Rule 4729-9-11(E).
- 6. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729-9-02 of the Ohio Administrative Code (OAC), effective May 22, 2014, minimum standards for a pharmacy: All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the Administrative Code, OAC rule 4729-9-02(E)(3).
- 7. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following divisions of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019:
 - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and
 - b. Violating any provision of Chapter 4729. Of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7).

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, the State Board of Pharmacy hereby imposes a monetary penalty on Kroger Pharmacy #014447 in the amount of \$6,000 to be paid within six months of the issuance of this Order. To pay this fine, a Kroger representative must login to www.elicense.ohio.gov and process the items in the cart, or e-mail legal@pharmacy.ohio.gov to establish a payment plan, to be approved by the Board.

Additionally, Kroger Pharmacy #014447's Responsible Person must attend the "Responsible Person Roundtable" within six months of the issuance of this Order.

Further, the Board hereby grants the State's Motion to Seal the Record in this matter including, but not limited to, all confidential patient health information and security information contained in the record, specifically State's exhibits: 1b, 5b, 15, 16, and 26, and Respondent's Exhibit E.

Christine Pfaff moved for Findings of Fact; Rich Miller seconded the motion. Motion passed (Yes-8/No-0).

Christine Pfaff moved for Conclusions of Law; Rich Miller seconded the motion. Motion passed (Yes-8/No-0).

Christine Pfaff moved for Action of the Board; Rich Miller seconded the motion. Motion passed (Yes-8/No-0).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the State of Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin county. Such notices of appeal shall be filed within fifteen (15) days after the mailing of the notice of the State of Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: December 15, 2022

By: Stewar W. Schierholt For Executive Director

SWS/alg/kll

CMRRR: 9414 7118 9956 2335 7745 04

Cc: Mary Barley McBride - mmcbride@dmclaw.com



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Stand Schick
Steven W. Schierholt, Esq., Executive Dir.
Date: Dec 15, 2022

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE STATE BOARD OF PHARMACY

(Case Numbers A-2022-0112 & A-2022-0451)

In The Matter Of:

Kroger Pharmacy #014447

1425 Columbus Avenue Lebanon, Ohio 45036 (License No. 02-1042850)

INTRODUCTION

The Matter of Kroger Pharmacy #014447 came for hearing on December 6, 2022 before the following members of the State of Ohio Board of Pharmacy (Board): Shawn Wilt, RPh, *Presiding*; Trina Buettner, RPh, Vice President; Mindy Ferris, RPh; Jason George, RPh; Victor Goodman, *Public Member*; T.J. Grimm, RPh; Jeff Huston, RPh; Rich Miller, RPh; and Christine Pfaff, RPh.

Kroger Pharmacy #014447 was represented by Mary Barley McBride. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

- 1. Kelli Waggoner, RPh, Respondent
- 2. Andrew Bouza, Agent of the Board

Respondent's Witnesses:

- 1. Kelli Waggoner, RPh
- 2. Michelle Izor, PharmD; The Kroger Co. Division Health Leader, Cincinnati Division

State's Exhibits:

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- 1b. Patient Key
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- 3. Notice Letter to Kelli Waggoner (5/31/2022)
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- 10. Request for Hearing for Kelli Waggoner & Kroger Pharmacy #014447
- 11. Inspection Report
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- 13. Statement of Kelli Waggoner dated 7/21/2020
- 14. Statement of Stevens
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- 16. Kroger Documents Regarding June 28, 2020, Dispensing Error
- 17. Omitted n.a.
- 18. Theft & Loss Report from Kroger #014447 dated 6/17/2019
- 19. Theft & Loss Report from Kroger #014447 dated 9/4/2019
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- 21. Theft & Loss Report from Kroger #014447 dated 7/7/2020
- 22. Theft & Loss Report from Kroger #014447 dated 4/12/2021
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- 30. Kroger #014447 Controlled Substance Action Plan
- 31. Shelf Maintenance Report dated 1/12/2022
- 32. Shelf Maintenance Report dated 2/16/2022

Respondent's Exhibits:

- A. Breach Root Cause Analysis Retraining with Pharmacy Staff sign-off (August, 2020)
- B. Release to Patient Return to Stock Retraining with special notation of handling controlled substances with Pharmacy Staff sign-off (August, 2020)
- C. Controlled Substance Action Plan (for Loss control and Prevention) with Pharmacy Staff sign-off (undated)
- E. Diagram of 7 camera locations

FINDINGS OF FACT

The parties stipulated to – and the Board hereby adopts as fact – the Allegations as set forth in Amended Notice of Opportunity for Hearing dated September 15, 2022, Case Numbers A-2022-0112 & A-2022-0451, reiterated herein and set forth below.

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the Board finds the following to be fact:

- 1. On or about November 19, 2021, Kelli Waggoner was the Responsible Person for Kroger Pharmacy #014447, located at 1425 Columbus Avenue, Lebanon, Ohio, when a loss of 100 tablets of Morphine IR 15mg was discovered. From on or about August 16, 2021 (when the shipment of Morphine IR 15mg was received) to on or about November 19, 2021 the pharmacy dispensed Morphine IR 15mg to four different patients. After a review of the pharmacy's records, surveillance video, and a physical search of the pharmacy, there was no explanation found for the loss.
- 2. On or about January 12 and January 26, 2022, covert counts of Schedule II controlled substances were conducted. Additional- although less substantial- losses were discovered including, but not limited to, 130 ml of Hydromet 5mg/5ml solution, a Schedule II controlled substance.
- 3. On or about February 2, 2022, an action plan was implemented to address the loss of Morphine IR 15mg and other unexplained losses experienced by the pharmacy.
- 4. On or about May 18, 2022, the Board was notified a loss of 100 amphetamine salt 15mg tablets had occurred and Kroger staff's investigation was ongoing.
 - a. On or about July 24, 2022, the Board received notice that the investigation had been concluded and found there to be a loss of 99 tablets. The DEA-106 form stated the bottle of 100 amphetamine salt 15mg tablets was believed to have been thrown in the trash in error.
 - b. The Board was also notified that Kroger pharmacy staff reviewed video and checked the pharmacy to determine what happened to the missing drugs. The pharmacy was unable to determine the cause for the loss.

CONCLUSIONS OF LAW

- 1. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.55 of the ORC, effective March 31, 2021:
 - A pharmacist... 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 Section 4729.55(B);
 and
 - 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 Section 4729.55(C); and

- c. Adequate safeguards are assured to carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC Section 4729.55(D).
- 2. Such conduct as set forth in the Findings of Fact, each constitutes a violation of each of the following divisions of Section 4729.57 of the ORC:
 - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and
 - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and
 - d. 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).
- 3. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective March 1, 2019:
 - a. The responsible person shall be responsible for the practice of the profession of pharmacy, 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(A)(2); and
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and
 - c. 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
 - d. 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 the Findings of Fact, each constitutes a violation of the following sections of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017: All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-

- 9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion, OAC Rule 4729-9-05(A).
- 5. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Rule 4729-9-11(A)(1) of the OAC: A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Code shall provide 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, by the following procedures: In a pharmacy: Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion.
- 6. Such conduct as set forth in the Findings of Fact, each constitutes a violation of the following divisions of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019:
 - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and
 - b. Violating any provision of Chapter 4729. Of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7).

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, the State Board of Pharmacy hereby imposes a monetary penalty on Kroger Pharmacy #014447 in the amount of \$6,000 to be paid within six months of the issuance of this Order. To pay this fine, a Kroger representative must login to www.elicense.ohio.gov and process the items in the cart, or e-mail legal@pharmacy.ohio.gov to establish a payment plan, to be approved by the Board.

Additionally, Kroger Pharmacy #014447's Responsible Person must attend the "Responsible Person Roundtable" within six months of the issuance of this Order.

Further, the Board hereby grants the State's Motion to Seal the Record in this matter including, but not limited to, all confidential patient health information and security information contained in the record, specifically State's exhibits: 1b, 5b, 15, 16, and 26, and Respondent's Exhibit E.

Christine Pfaff moved for Findings of Fact; Rich Miller seconded the motion. Motion passed (Yes-8/No-0).

Christine Pfaff moved for Conclusions of Law; Rich Miller seconded the motion. Motion passed (Yes-8/No-0).

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SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the State of Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin county. Such notices of appeal shall be filed within fifteen (15) days after the mailing of the notice of the State of Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: December 15, 2022

Steven W. Schierholt, Esg., Executive Directo

SWS/alg/kll

CMRRR: 9414 7118 9956 2335 7613 37

Cc: Mary Barley McBride - mmcbride@dmclaw.com



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Steven W. Schierholt, Esq., Executive Dir.

Date: Sep 15, 2022

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AMENDED NOTICE OF OPPORTUNITY FOR HEARING PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSEE

IN THE MATTER OF:

CASE NO. A-2022-0112 & A-2022-0451

License No. 02-1042850

Kroger Pharmacy #014447 c/o Kelli J. Waggoner, RPh 1425 Columbus Avenue Lebanon, Ohio 45036

September 14, 2022

Dear Kroger Pharmacy #014447 and Ms. Waggoner,

You are notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Terminal Distributor of Dangerous Drugs under authority of Section (TDDD) 4729.57 of the Revised Code.

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, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code 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 Revised Code.
- 2. Kroger Pharmacy #014447 has an active TDDD license with the Board under license number 02-1042850 which lists Kelli Waggoner as the Responsible Person.

ALLEGATIONS

1. On or about November 19, 2021, Kelli Waggoner was the Responsible Person for Kroger Pharmacy #014447, located at 1425 Columbus Avenue, Lebanon, Ohio, when a loss of 100 tablets of Morphine IR 15mg was discovered. From on or about August 16, 2021 (when the shipment of Morphine IR 15mg was received) to on or about November 19, 2021 the pharmacy dispensed Morphine IR 15mg to four different patients. After a review of the pharmacy's records, surveillance video, and a physical search of the pharmacy, there was no explanation found for the loss.

77 South High Street, 17th Floor, Columbus, Ohio 43215



- 2. On or about January 12 and January 26, 2022, covert counts of Schedule II controlled substances were conducted. Additional- although less substantial- losses were discovered including, but not limited to, 130 ml of Hydromet 5mg/5ml solution, a Schedule II controlled substance.
- 3. On or about February 2, 2022, an action plan was implemented to address the loss of Morphine IR 15mg and other unexplained losses experienced by the pharmacy.
- 4. On or about May 18, 2022, the Board was notified a loss of 100 amphetamine salt 15mg tablets had occurred and Kroger staff's investigation was ongoing.
 - a. On or about July 24, 2022, the Board received notice that the investigation had been concluded and found there to be a loss of 99 tablets. The DEA-106 form stated the bottle of 100 amphetamine salt 15mg tablets was believed to have been thrown in the trash in error.
 - b. The Board was also notified that Kroger pharmacy staff reviewed video and checked the pharmacy to determine what happened to the missing drugs. The pharmacy was unable to determine the cause for the loss.

POTENTIAL VIOLATIONS OF LAW

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55 of the ORC, effective March 31, 2021, each punishable by a maximum penalty of \$150:
 - A pharmacist... 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 Section 4729.55(B); and/or
 - 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 Section 4729.55(C); and/or
 - c. Adequate safeguards are assured to carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC Section 4729.55(D).
- 2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, 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. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or
 - d. 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).

- 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 March 1, 2019, each punishable by a maximum penalty of \$500:
 - a. The responsible person shall be responsible for the practice of the profession of pharmacy, 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(A)(2); and/or
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and/or
 - c. 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
 - d. 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 the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017, each punishable by a maximum penalty of \$500: All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion, OAC Rule 4729-9-05(A).
- 5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-11(A)(1) of the OAC, punishable by a maximum penalty of \$500: A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Code shall provide 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, by the following procedures: In a pharmacy: Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion.

- 6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following divisions of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, 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. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7).

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 State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

The Board is in receipt of your request for a hearing dated June 13, 2022; no additional request for a hearing is necessary. Per the previous scheduling notice, your hearing is scheduled for Tuesday, December 6, 2022.

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 STATE BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

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I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

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Steven W. Schierholt, Esq., Executive Dir. Date: 09/03/2021

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AMENDED NOTICE OF OPPORTUNITY FOR HEARING PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSEE

IN THE MATTER OF:

CASE NO. A-2020-0736 A-2021-0230 I-2020-1163

License No. 02-1042850

Kroger Pharmacy #014447 c/o Kelli J. Waggoner, RPh 1425 Columbus Avenue Lebanon, Ohio 45036

September 3, 2021

Dear Kroger Pharmacy #014447 and Ms. Waggoner,

5 Columbus Avenue

You are notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Terminal Distributor of Dangerous Drugs under authority of Section (TDDD) 4729.57 of the Revised Code.

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, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code 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 Revised Code.
- 2. Kroger Pharmacy #014447 has an active TDDD license with the Board under license number 02-1042850 which lists Kelli Waggoner as the Responsible Person.

ALLEGATIONS

1. On or about June 28, 2020, a medication was mistakenly given to a patient at Kroger Pharmacy #014447, located at 1425 Columbus Avenue, Lebanon, Ohio, where Kelli Waggoner was the Responsible Person. Patient B.R. was prescribed three medications. When she arrived to pick-up her medications, she decided she no longer wanted prescription #2337687, oxycodone HCL5 mg tablets, as her insurance did not cover the medication. Pharmacy technician Lauren Stevens cashed out patient B.R., however, prescription

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#2337687, 15 oxycodone HCL 5 mg tablets, was not removed from the packaged items. The loss of 15 oxycodone HCL 5 mg tablets, a Schedule II controlled substance, was discovered when the drug was randomly back counted.

- 2. It was discovered during an internal investigation by Kroger that there were only two cameras in operation in the pharmacy. The cameras did not capture any of the points of sale- the registers used by technicians to sell medications to customers.
- 3. On or about July 21, 2020, an inspection of Kroger Pharmacy was conducted by agents of the Board. The inspection resulted in four warnings/written responses required, including:
 - a. Security of the pharmacy drug stock is not adequate to detect and deter drug theft and diversion.
 - i. Pharmacy Consultation Room was unlocked and unsecured. The room was accessible to the public and not under supervision of a pharmacist.
 - ii. Within the room, cabinets containing hypodermic needles were not secure.
 - iii. The pharmacy did not have cameras to capture the employees working in the pharmacy.
 - b. Kroger Pharmacy #014447 has had several "Theft and Significant Loss Reports" in recent years, including:
 - i. Loss of 100 oxycodone 5 mg tablets, January 3, 2017.
 - ii. Loss of a bottle of hydrocodone-acetaminophen 5/325 tablets, June 17, 2019.
 - iii. 100 hydrocodone-acetaminophen 5/325 tablets mixed in with hydrocodone-acetaminophen 7.5/325 tablets, September 4, 2019.
 - iv. Prescription for hydrocodone-acetaminophen was miscounted/unable to determine which patient received 30 extra hydrocodone-acetaminophen 10/325 tablets, April 20, 2020.
 - c. Pharmacy's perpetual C-II drug inventory was not accurate.
 - i. The perpetual inventory in the computer indicated there were 413 oxycodone 5 mg tablets in the pharmacy. The on-hand count was 513.
 - d. Pharmacists requesting OARRS reports when appropriate.
 - i. The computer system had a hard stop on requesting an OARRS Report when necessary, however, the pharmacy was not able to verify/provide the dates/times/users that had requested the reports.
- 4. On or about July 21, 2020, Lauren Stevens, pharmacy technician, spoke with an agent of the Board and stated the following:
 - a. She was a new technician and needed assistance cashing out patient B.R. on June 28, 2020. Kelli Waggoner, RPh, assisted her. She thought the oxycodone prescription #2337687 was physically removed from the patient's bag, but she cannot say this occurred with certainty.
- 5. On or about April 12, 2021, Kelli Waggoner, Responsible Person, reported an additional loss of controlled substances to the Board by submitting a theft and loss report. Kelli Waggoner reported 80 amphetamine salt 5 mg capsules were missing from Kroger Pharmacy. Video surveillance was reviewed, and it was discovered that a pharmacy technician had inadvertently thrown away a stock bottle of amphetamine salt

capsules, resulting in the reported loss. This loss occurred despite implementation of a corrective action plan following previous losses of controlled substances.

POTENTIAL VIOLATIONS OF LAW

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55 of the ORC, effective April 6, 2017, each punishable by a maximum penalty of \$150:
 - a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or
 - A pharmacist... 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 Section 4729.55(B); and/or
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC Section 4729.55(C); and/or
 - d. Adequate safeguards are assured to carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC Section 4729.55(D); and/or
 - e. If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation, ORC Section 4729.55(E).
- 2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, 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. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or
 - d. 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).
- 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 March 1, 2019, each punishable by a maximum penalty of \$500:

- a. The responsible person shall be responsible for the practice of the profession of pharmacy, 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(A)(2); and/or
- b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and/or
- c. 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
- d. 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); and/or
- 4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017, each punishable by a maximum penalty of \$500: All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion, OAC Rule 4729-9-05(A).
- 5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-11 of the OAC, each punishable by a maximum penalty of \$500: A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Code shall provide 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, by the following procedures:
 - a. In a pharmacy: Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion, OAC Rule 4729-9-11(A)(1); and/or

- b. Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
 - i. Any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, exempt narcotics, hypodermics, poisons, records relating to the distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:
 - 1. The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the state board of pharmacy, OAC Rule 4729-9-11(A)(2)(h)(i); and/or
 - 2. No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy, OAC Rule 4729-9-11(A)(2)(h)(ii); and/or
 - 3. Authorized personnel may have access if there is on-site supervision by a pharmacist, OAC Rule 4729-9-11(A)(2)(h)(iii); and/or
- c. Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs, OAC Rule 4729-9-11(E).
- 6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-02 of the Ohio Administrative Code (OAC), effective May 22, 2014, minimum standards for a pharmacy, each punishable by a maximum penalty of \$1,000: All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the Administrative Code, OAC rule 4729-9-02(E)(3).
- 7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following divisions of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, 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. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7).

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 State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

The Board is in receipt of your request for a hearing dated June 22, 2021; no additional request for a hearing is necessary. Per the previous scheduling notice, your hearing is scheduled for Monday, December 6, 2021.

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 STATE BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

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