



**STATE OF
OHIO**
BOARD OF PHARMACY

-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
Steven W. Schierholt, Esq., Executive Dir.
Date: 2/6/2024
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE STATE BOARD OF PHARMACY

Case Number A-2021-0567

In The Matter Of:

CVS #2063
7292 Fulton Drive, NW
Canton, OH 44718
License No. 02-2120950

INTRODUCTION

The Matter of CVS #2063 came for hearing on November 7, 2023, November 8, 2023, and January 11, 2024, before the following members of the State of Ohio Board of Pharmacy (Board): Trina Buettner, RPh, *Presiding*; Mindy Ferris, RPh, *Vice President*; Anthony Buchta, Sr., RPh; Victor Goodman, *Public Member*; T.J. Grimm, RPh; Jeff Huston, RPh; Rich Miller, RPh;¹ and Christine Pfaff, RPh.

Jason George, RPh; Absent.

CVS #2063 was represented by Kristina Dahmann and Lydia Reback. The State of Ohio was represented by Henry Appel and Caitlyn Johnson, Assistant Attorneys General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Nicole Lewis
2. Haille Stanick
3. Elaina Martauz
4. Kim Hollingshead
5. Lisa Dietsche
6. Giovanna Arvizu

Respondent's Witnesses:

1. Andrew Volcheck
2. Dennis K. McAllister

¹ Mr. Miller was not present on November 7 and November 8, 2023. However, pursuant to *Kremer v. State Medical Bd.*, 10th Dist. App. No. 95APE09-1247 (Mar. 12, 1996), 1996 Ohio App. LEXIS 949, 1996 WL 112665, he reviewed all testimony and evidence presented on those dates.



State's Exhibits:

- 1a. Notice Letter
- 1b. Amended Notice Letter
2. Request for Hearing
3. Initial Scheduling Letter
4. Current Scheduling Letter
5. Inspection 9/13/2021
6. Photos Taken 9/13/2021
7. Temp Alert Status
8. Response to 9/13/2021 Inspection
9. Inspection 9/20/2021
10. Photos Taken 9/20/2021
12. Inspection 11/19/2021
13. Pharmacists Workload Survey (2020)
14. Pharmacists Workload Survey (2021)
15. Pharmacy Technician Workload Survey (2021)

Respondent's Exhibits:

- A. Ohio Board of Pharmacy Executive Director Reports September 2021 & November 2021
- B. Ohio Board of Pharmacy Annual Reports RY 2020, 2021 & 2022
- C. Ohio Board of Pharmacy Inspection Reports (December 7, 2021 & September 12, 2023)
- D. CVS Pharmacy #2063 Compliance Report Data
- E. CVS Pharmacy #2063 AvD Report Excerpt
- F. CVS Pharmacy #2063 COVID Testing Information
- G. CVS Pharmacy #2063 Surrounding Area Maps and Nearby Sites
- H. State of Ohio & Ohio Department of Health COVID-19 Documents
- I. Dennis K. McAllister, R.Ph., FASHP Curriculum Vitae
- J. Pharmacy School Applications Data 2002-2023
- K. 2022 National Pharmacist Workforce Study Executive Summary May 31, 2023
- L. National Association of Board of Pharmacy Licensure Examination Passing Rates for 2020-2022 Graduates

FINDINGS OF FACT²

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the Board finds the evidence submitted and testimony presented by CVS #2063 did not refute, or adequately mitigate, the allegations presented in the August 2, 2023 Amended Notice of Opportunity for Hearing. Specifically, the Board finds Elaina Martauz's testimony on November 7, 2023, not to be credible, in part, due to her lack of recollection of the overall conditions and operations of CVS #2063, and due to the fact that she is currently employed as a Responsible Person at CVS. With respect to the testimony of Dennis K. McAllister, he did not testify to (or have knowledge of) the daily operations of CVS #2063 or CVS management response to the failed inspections. Instead, he attempted to attribute the operational failures to unavailable staffing, which the Board did not find persuasive. His most credible testimony was that as an educator, he would not place a pharmacy student in a practice setting like the condition of CVS #2063 in September and October of 2021.

Pursuant to the Board's authority to make de novo findings of fact, the Board finds CVS #2063's reliance on the manual temperature log to refute the allegations in the Notice letter to be unpersuasive, particularly given that it was not produced at the time of inspection. Further, CVS #2063 did not adequately explain the parameters of any electronic temperature monitoring system to in order to refute the findings made during the inspection. The Board also finds CVS #2063's security and storage of dangerous drugs deficient.

The Board ultimately finds that the operational deficiencies present at CVS #2063 created a public health risk and further, that the management response was wholly inadequate.

Additionally, the Board finds the following to be fact:

1. On or about September 13, 2021, agents of the Board arrived at CVS #2063 (Respondent), located at 7292 Fulton Drive, NW, Canton, Ohio to conduct an inspection. The following issues were found:
 - a. Approximately ten vehicles were observed in the drive-thru lane.
 - b. A sign at the front door of the pharmacy stating the lobby of the pharmacy was closed and everyone must go through the drive thru.
 - c. The pharmacy barricade was observed to be closed except for one window. The open window had a sign which read "Vaccines Only" for patients to walk-up or schedule vaccinations.
 - d. It took pharmacy staff approximately 20 minutes to acknowledge Board staff at the vaccine window.
 - e. Board staff noticed two open totes from a Wholesale Distributor on the counter next to the window which were accessible from outside the pharmacy barricade.
 - f. Board staff found the pharmacy was not secure. There was a magnet inside the door jamb to keep the door open from the vaccination room into the pharmacy.

² The Board considered only the testimony and exhibits admitted during the hearing in determining its findings.

- g. The pharmacy was staffed with one pharmacist, one registered technician, and one care concierge. The pharmacist was assisting customers on the phone, taking transfers, and verifying prescriptions. The registered technician was assisting customers with COVID self-testing in the drive-thru. The care concierge was assisting customers in the drive-thru picking up prescriptions.
- h. The dispensing software showed the following at approximately 4:17pm:
 - 1. 64 pages of prescriptions (15 prescriptions per page) in QP (production) which date back to 9-1-2021 (for a total of 960 prescriptions).
 - 2. 5 pages of prescriptions (15 prescriptions per page) in QV (verification) totaling 75 prescriptions.
 - 3. 7 prescriptions (total) in QT (triage).
- i. An unlocked freezer containing Moderna COVID-19 vaccine was found outside the pharmacy barricade.
- j. Medications were being stored on the floor of the pharmacy.
- k. There were 48 totes from Wholesale Distributors stored inside the pharmacy.
- l. There were also opened and unopened boxes on floor in front of pharmacist workstation.
- m. There were multiple refrigerated and frozen medications that were still within the pharmacy as pharmacy staff was too short staffed to remove it.
- n. Pharmacy staff states they are short staffed because they lost seven pharmacy staff members (1 pharmacist and 6 pharmacy technicians) within a short time. They state they knew the staff members were leaving but did not know they were all going to leave at the same time.
- o. On September 11, 2021, the pharmacy closed the lobby of the pharmacy and started servicing patients through the drive thru. Pharmacy staff called their district leader and pharmacist scheduler to approve the closing of the inside barricade. The request to close the inside barricade was made because the pharmacy had been staffed with one pharmacist and one pharmacy technician. The pharmacy technician would be split between the front counter and the drive thru.
- p. Pharmacy staff and an assistant store manager stated they have asked district leaders to close the store down temporarily to get caught up filling prescriptions as well as clean and organize the pharmacy, but this request was denied.
- q. Pharmacy staff asked for assistance from a pharmacist and pharmacy technician to fill prescriptions after hours to get caught up. They were denied stating there is no staffing available to do so.
- r. The pharmacy felt very hot, and staff stated the AC unit was broken. The pharmacy staff have fans running inside the pharmacy to attempt to keep them cool. The pharmacy did not have a thermometer that could be seen inside the pharmacy capturing the ambient temperature. The thermometer was located by the end of the inspection. It was located at the top of pharmacy shelving inside the pharmacy, but the thermometer's display was not working.

- s. Pharmacy staff were able to log into their wireless temperature monitoring system, TempAlert. During the review of TempAlert, RX Cooler 1 was reporting 46.4 degrees Fahrenheit at 4:32pm and there was no alert inside the pharmacy the temperature was out of range. RX Cooler 3 has not reported temperatures since 949am on July 30, 2021. RX Cooler 4 has not reported temperatures since 3:53 pm on March 29, 2021.
 - t. Pharmacy phones were not working properly.
 - u. The pharmacy technician has to go out to the drive thru at 7:30pm and remind patients the pharmacy closes at 9pm and tell them they would not be able to sell the medications after 9pm as their system shuts down and will not allow them to sell anything.
2. On or about September 14, 2021, an agent of the Board spoke with CVS Pharmacy's District Leader Pharmacist Dan Sidwell by phone. He made the following statements:
- a. Sidwell became district leader in charge of CVS #2063 (Respondent) in July 2021.
 - b. The pharmacy was short-staffed before he became district leader.
 - c. Sidwell stated this was the worst he had seen the staff shortage.
 - d. Sidwell stated he has been attempting to get help from other districts but has been unsuccessful.
 - e. CVS #2063 (Respondent) was in the process of hiring six new pharmacy technicians, but it is a long, slow process.
 - f. Sidwell stated there are no pharmacists or technicians available to assist this pharmacy.
 - g. Sidwell stated he agreed to allow CVS #2063 (Respondent) to close the inside barricade, but not the whole barricade. CVS #2063 (Respondent) was only supposed to close the drop off window.
3. On or about September 20, 2021, an agent of the Board arrived at CVS #2063 (Respondent) to conduct a follow-up inspection. The following issues were found:
- a. The pharmacy was staffed with one pharmacist, one registered pharmacy technician, and one pharmacy technician trainee. The pharmacist was transferring prescriptions by phone. The registered pharmacy technician was assisting with COVID self-testing in the drive-thru. The pharmacy technician trainee was assisting customers at the front window.
 - b. There were 30 bins ready to be verified by the pharmacist.
 - c. There were eight prescriptions (total) in QT (triage), ten pages of prescriptions (15 prescriptions per page) in QV (verification), and 19 pages of prescriptions (15 prescriptions per page) in QP (production).
 - d. There were 11 totes of medications to put away from a delivery that came in that day.
 - e. The phone system was not working properly.

4. On or about October 29, 2021, an agent of the Board spoke with a pharmacist on duty at CVS #2063 (Respondent). The Board representative was on hold for over 20 minutes before the pharmacy answered the phone. The following statements were made:
 - a. All pharmacy staff that was present for the September 2021 inspection quit or transferred out of CVS #2063 (Respondent).
 - b. The pharmacy was over a month behind in filling prescriptions.
 - c. At the time of the call, there were three pages of (15 prescriptions per page) in QT (triage), ten pages of prescriptions (15 prescriptions per page) in QV (verification), and 152 pages of prescriptions (15 prescriptions per page) in QP (production).
 - d. The pharmacy is attempting to triage lifesaving, life-sustaining medications especially antibiotics, pain medications and birth control.
5. On or about October 29, 2021, an agent of the Board spoke with CVS Pharmacy's new District Leader Pharmacist Kenneth Cook by phone. He made the following statements:
 - a. Kenneth Cook is the new district leader for CVS #2063 (Respondent) effective October 31, 2021.
 - b. Kenneth Cook was assembling a team to go into CVS #2063 (Respondent) to clean up and fill prescriptions.
 - c. Kenneth Cook said the pharmacy is in the process of hiring new pharmacy staff as well as transferring staff from an overstaffed CVS location.

CONCLUSIONS OF LAW

1. Such conduct as set forth in Findings of Fact Section, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective March 31, 2021:
 - 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, licensed health professional authorized to prescribe drugs, or other person authorized by the board, animal shelter or county dog warden licensed under section 4729.531 of the Revised Code, or a laboratory 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
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and

- d. Adequate safeguards are assured that the applicant will 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 4729.55(D).
2. Such conduct as set forth in Findings of Fact Section, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017:
 - 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 terminal distributor of dangerous drugs 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 Findings of Fact Section, each constitutes a violation of the following sections 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 terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and
 - d. 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)(25).
4. Such conduct as set forth in the Findings of Fact Section, each constitutes a violation of Rule 4729:5-5-02(G)(1) of the OAC, Minimum Standards for an outpatient pharmacy, Personnel, the pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code, as effective December 1, 2020.
5. Such conduct as set forth in paragraphs (1)(e), (1)(j), (1)(k), (1)(l), (1)(m), (1)(r), (1)(s), and (3)(e) of the Findings of Fact Section, each constitutes a violation of Rule 4729:5-5-02(E)(2) of the OAC, Minimum Standards for an outpatient pharmacy, all areas where drugs and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling, as effective December 1, 2020.

6. Such conduct as set forth in paragraphs (1)(e), (1)(f), (1)(i), (1)(j), (1)(k), (1)(m), (1)(s) and (3)(e) of the Findings of Fact Section, each constitutes a violation of the following sections of Rule 4729:5-5-23 of the OAC, Security, control and storage of dangerous drugs in an outpatient pharmacy, as effective December 1, 2020:
 - a. If the pharmacy is located within a store or business, the pharmacist shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacist on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule, OAC Rule 4729:5-5-23(A)(3)(b); and
 - b. Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist, OAC Rule 4729:5-5-23(A)(6)(f); and
 - c. Refrigerators and freezers used for the storage of dangerous drugs shall maintain a temperature log with, at a minimum, daily observations, to ensure proper refrigeration and/or freezer temperatures are maintained, OAC Rule 4729:5-5-23(B)(1)(a); and
 - d. Refrigerators and freezers used for the storage of dangerous drugs shall maintain a temperature monitoring system capable of detecting and alerting staff of a temperature excursion to ensure proper refrigeration and/or freezer temperatures are maintained, OAC Rule 4729:5-5-23(B)(1)(b); and
 - e. 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 4729:5-5-23(B)(2).
7. Such conduct as set forth in the Findings of Fact Section, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible Person of a Terminal Distributor, 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 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 4729:5-2-01(E)(6).
8. Such conduct as set forth in the Findings of Fact Section, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020:
 - a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and
 - b. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and after consideration of the record as a whole, CVS #2063 is subject to an indefinite probationary period, effective as of the date of this Order. Upon demonstration of compliance with the terms of this Order, but no sooner than three years from the date of this Order, CVS #2063 may request – in writing – that it be released from probation. During the probationary period, CVS #2063 must demonstrate that it has remedied all violations identified in the Amended Notice of Opportunity for Hearing dated August 2, 2023, and is in compliance with Pharmacy Board rules and regulations as well as the terms of this Order. In lieu of requiring that CVS #2063 hire a Board-approved monitoring pharmacist, CVS #2063 will be subject to enhanced monitoring by the Board, at its discretion.

1. CVS #2063's Responsible Person and/or Board-approved designated representative of CVS Health LLC, shall appear before the Probation Committee upon request.
2. CVS #2063 must ensure that sufficient personnel are scheduled at all times in order to minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with requisite judgment, skill, competence, and safety to the public. Staffing levels shall not be solely based on prescription volume but, in determining the need for staff, CVS #2063 shall consider any other requirements of the practice of pharmacy by pharmacy personnel during working hours.
3. CVS #2063 must develop a process for its pharmacy staff to communicate requests for additional staff or reports of staffing concerns. Requests for additional staff or reports of staffing concerns shall be communicated and documented in writing by the responsible person or pharmacist on duty to their supervisor. These requests shall also be forwarded to or carbon copied to the Board at legal@pharmacy.ohio.gov, unless otherwise instructed by the Probation Committee.
4. CVS #2063 shall not retaliate against or discipline a pharmacist, pharmacy technician, pharmacy technician trainee, intern, or any other employee who communicates a request for additional staff or reports staffing concerns in accordance with paragraph (b), above, or reports concerns related to working conditions or

non-compliance with this Order to supervisor(s), CVS management, and/or the Board. Retaliation or discipline includes, but is not limited to:

- a. Removing or suspending the employee from employment;
 - b. Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
 - c. Transferring or reassigning the employee;
 - d. Denying the employee a promotion that otherwise would have been received; and
 - e. Reducing the employee in pay or position.
5. CVS #2063 must process (have completed final verification and be ready for patient pick-up) all new and refill (not generated by an auto-refill program) prescriptions within no more than three (3) business days of receiving the prescription. CVS #2063 must process (have completed final verification and be ready for patient pick-up) all refill prescriptions generated by an auto-refill program within no more than five (5) business days of receiving the prescription or the auto-refill notice.

“Business day” means any day, excluding holidays, where the pharmacy is open for business. Receipt of a new prescription occurs on the day when the prescription is transmitted or submitted to the pharmacy. Receipt of a refill prescription occurs on the day the refill request is submitted to the pharmacy by a patient, caregiver, or prescriber or when a refill request is generated as part of the auto-refill program.

- a. Time when there is a documented drug shortage or CVS #2063 documents the drug is not available from the drug distributor; when the prescription has been submitted to CVS #2063 but requires clarification or consultation by the issuing prescriber; and when the prescription requires prior authorization or is otherwise delayed because of the patient’s prescription insurance coverage, shall not be included in the three (3) or five (5) day time frames noted in the previous paragraph.
 - b. Compounded drug products; prescriptions with “do not fill until” dates or similar designations; prescriptions that the pharmacist - using their professional judgment - determines are of questionable, doubtful, or suspicious origin or cannot be safely provided or may negatively impact patient care; and prescriptions where the patient, caregiver, or issuing prescriber has requested transfer to another pharmacy are also not subject to these time frames.
 - c. Prescriptions where CVS #2063 has experienced: (a) a natural disaster (fire, flood, etc.), civil unrest, or human made disaster; (b) an outbreak of a pandemic illness or the declaration of a state or federal public health emergency; (c) a loss of power; or (d) an unplanned information technology system outage, shall not be included in the three (3) or five (5) day time frames.
 - d. The responsible person or pharmacist on duty shall communicate and document any prescription fills or refills that exceed the time limits set forth herein to their supervisor. These notifications shall also be forwarded to or carbon copied to the Board at legal@pharmacy.ohio.gov, unless otherwise instructed by the Probation Committee.
6. Pharmacists, pharmacy technicians, and interns shall not be required to administer vaccines when only a single pharmacist is on duty, and in that pharmacist’s professional judgment, the vaccine cannot be administered safely.
7. CVS #2063 shall bear any costs associated with the terms and conditions of this Order.

8. CVS #2063 shall comply with all laws and regulations governing the practice of pharmacy in the State of Ohio. Any violation of the foregoing terms and conditions of this Order, or any statute or regulation governing the practice of pharmacy in the State of Ohio, shall constitute grounds for further discipline or issuance of a notice of opportunity for hearing to consider additional disciplinary action, including and up to revocation of Respondent's license.
9. This Order shall remain in effect until the Board has notified CVS Pharmacy #2063 in writing that it is released from probation.
10. Pursuant to Section 4729.57 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of \$250,000. This fine will be attached to your license record and must be paid no later than 90 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

Ms. Ferris moved for Findings of Fact; Mr. Huston seconded the motion. Motion passed (Yes-7/No-0).

Ms. Ferris moved for Conclusions of Law; Mr. Huston seconded the motion. Motion passed (Yes-7/No-0).

Ms. Ferris moved for Action of the Board; Mr. Huston seconded the motion. Motion passed (Yes-7/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 service 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: February 6, 2024

By: 

Steven W. Schierholt, Esq., Executive Director

SWS/jak/jrn

cc: Brian Convery at Brian.Convery@CVSHealth.com
Kristina Dahmann at Kristina.Dahmann@icemiller.com
Lydia Reback at Lydia.Reback@icemiller.com
Henry Appel at Henry.Appel@ohioago.gov
Caitlyn Johnson at Caitlyn.Johnson@ohioago.gov



**STATE OF
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BOARD OF PHARMACY

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I certify this to be a true and exact copy of
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Ohio State Board of Pharmacy.
Steven W. Schierholt
Steven W. Schierholt, Esq., Executive Dir.
Date: Aug 02, 2023
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

**AMENDED NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE**

IN THE MATTER OF:

CASE NO. A-2021-0567

CVS Pharmacy #2063
c/o Abby Yannerella, RPh
7292 Fulton Drive, NW
Canton, OH 44718

License No. 02-2120950

August 2, 2023

Dear CVS Pharmacy #2063 and Abby Yannerella, RPh:

You are hereby 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 (TDDD) under authority of Section 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, restrict, limit, or refuse to grant or renew any license issued pursuant to section 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. CVS Pharmacy #2063, located at 7292 Fulton Drive, NW, Canton Ohio, has an active TDDD license with the Board under license number 02-2120950, which lists Abbey Yannerella, RPh as the Responsible Person.

ALLEGATIONS

1. On or about September 13, 2021, agents of the Board arrived at CVS #2063, located at 7292 Fulton Drive, NW, Canton, Ohio to conduct an inspection. The following issues were found:
 - a. Approximately ten vehicles were observed in the drive-thru lane.
 - b. A sign at the front door of the pharmacy stating the lobby of the pharmacy was closed and everyone must go through the drive thru.
 - c. The pharmacy barricade was observed to be closed except for one window. The open window had a sign which read "Vaccines Only" for patients to walk-up or schedule vaccinations.

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

T: (614) 466.4143 | F: (614) 752.4836 | contact@pharmacy.ohio.gov | www.pharmacy.ohio.gov



- d. It took pharmacy staff approximately 20 minutes to acknowledge Board staff at the vaccine window.
- e. Board staff noticed two open totes from a Wholesale Distributor on the counter next to the window which were accessible from outside the pharmacy barricade.
- f. Board staff found the pharmacy was not secure. There was a magnet inside the door jamb to keep the door open from the vaccination room into the pharmacy.
- g. The pharmacy was staffed with one pharmacist, one registered technician, and one care concierge. The pharmacist was assisting customers on the phone, taking transfers, and verifying prescriptions. The registered technician was assisting customers with COVID self-testing in the drive-thru. The care concierge was assisting customers in the drive-thru picking up prescriptions.
- h. The dispensing software showed the following at approximately 4:17pm:
 - 1. 64 pages of prescriptions (15 prescriptions per page) in QP (production) which date back to 9-1-2021 (for a total of 960 prescriptions).
 - 2. 5 pages of prescriptions (15 prescriptions per page) in QV (verification) totaling 75 prescriptions.
 - 3. 7 prescriptions (total) in QT (triage).
- i. An unlocked freezer containing Moderna COVID-19 vaccine was found outside the pharmacy barricade.
- j. Medications were being stored on the floor of the pharmacy.
- k. There were 56 totes from Wholesale Distributors stored inside the pharmacy.
- l. There were also opened and unopened boxes on floor in front of pharmacist workstation.
- m. There were multiple refrigerated and frozen medications that were still within the pharmacy as pharmacy staff was too short staffed to remove it.
- n. Pharmacy staff states they are short staffed because they lost seven pharmacy staff members (1 pharmacist and 6 pharmacy technicians) within a short time. They state they knew the staff members were leaving but did not know they were all going to leave at the same time.
- o. On September 11, 2021, the pharmacy closed the lobby of the pharmacy and started servicing patients through the drive thru. Pharmacy staff called their district leader and pharmacist scheduler to approve the closing of the inside barricade. The request to close the inside barricade was made because the pharmacy had been staffed with one pharmacist and one pharmacy technician. The pharmacy technician would be split between the front counter and the drive thru.

- p. Pharmacy staff and an assistant store manager stated they have asked district leaders to close the store down temporarily to get caught up filling prescriptions as well as clean and organize the pharmacy, but this request was denied.
 - q. Pharmacy staff asked for assistance from a pharmacist and pharmacy technician to fill prescriptions after hours to get caught up. They were denied stating there is no staffing available to do so.
 - r. The pharmacy felt very hot, and staff stated the AC unit was broken. The pharmacy staff have fans running inside the pharmacy to attempt to keep them cool. The pharmacy did not have a thermometer that could be seen inside the pharmacy capturing the ambient temperature. The thermometer was located by the end of the inspection. It was located at the top of pharmacy shelving inside the pharmacy, but the thermometer's display was not working.
 - s. Pharmacy staff were able to log into their wireless temperature monitoring system, TempAlert. During the review of TempAlert, RX Cooler 1 was reporting 46.4 degrees Fahrenheit at 4:32pm and there was no alert inside the pharmacy the temperature was out of range. RX Cooler 3 has not reported temperatures since 949am on July 30, 2021. RX Cooler 4 has not reported temperatures since 3:53 pm on March 29, 2021.
 - t. Pharmacy phones were not working properly.
 - u. The pharmacy technician has to go out to the drive thru at 7:30pm and remind patients the pharmacy closes at 9pm and tell them they would not be able to sell the medications after 9pm as their system shuts down and will not allow them to sell anything.
2. On or about September 14, 2021, an agent of the Board spoke with CVS Pharmacy's District Leader Pharmacist Dan Sidwell by phone. He made the following statements:
- a. Sidwell became district leader in charge of CVS #2063 in July 2021.
 - b. The pharmacy was short-staffed before he became district leader.
 - c. Sidwell stated this was the worst he had seen the staff shortage.
 - d. Sidwell stated he has been attempting to get help from other districts but has been unsuccessful.
 - e. CVS #2063 was in the process of hiring six new pharmacy technicians, but it is a long, slow process.
 - f. Sidwell stated there are no pharmacists or technicians available to assist this pharmacy.
 - g. Sidwell stated he agreed to allow CVS #2063 to close the inside barricade, but not the whole barricade. CVS #2063 was only supposed to close the drop off window.
3. On or about September 20, 2021, an agent of the Board arrived at CVS #2063 to conduct a follow-up inspection. The following issues were found:

- b. The pharmacy was staffed with one pharmacist, one registered pharmacy technician, and one pharmacy technician trainee. The pharmacist was transferring prescriptions by phone. The registered pharmacy technician was assisting with COVID self-testing in the drive-thru. The pharmacy technician trainee was assisting customers at the front window.
 - c. There were 30 bins ready to be verified by the pharmacist.
 - d. There were eight prescriptions (total) in QT (triage), ten pages of prescriptions (15 prescriptions per page) in QV (verification), and 19 pages of prescriptions (15 prescriptions per page) in QP (production).
 - e. There were 11 totes of medications to put away from a delivery that came in that day.
 - f. The phone system was not working properly.
4. On or about October 29, 2021, an agent of the Board spoke with a pharmacist on duty at CVS #2063. The Board representative was on hold for over 20 minutes before the pharmacy answered the phone. The following statements were made:
 - a. All pharmacy staff that was present for the September 2021 inspection quit or transferred out of CVS #2063.
 - b. The pharmacy was over a month behind in filling prescriptions.
 - c. At the time of the call, there were three pages of (15 prescriptions per page) in QT (triage), ten pages of prescriptions (15 prescriptions per page) in QV (verification), and 152 pages of prescriptions (15 prescriptions per page) in QP (production).
 - d. The pharmacy is attempting to triage lifesaving, life-sustaining medications especially antibiotics, pain medications and birth control.
5. On or about October 29, 2021, an agent of the Board spoke with CVS Pharmacy's new District Leader Pharmacist Kenneth Cook by phone. He made the following statements:
 - a. Kenneth Cook is the new district leader for CVS #2063 effective October 31, 2021.
 - b. Kenneth Cook was assembling a team to go into CVS #2063 to clean up and fill prescriptions.
 - c. Kenneth Cook said the pharmacy is in the process of hiring new pharmacy staff as well as transferring staff from an overstaffed CVS location.

POTENTIAL VIOLATIONS OF LAW

1. 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 March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:

- a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or
 - b. A pharmacist, licensed health professional authorized to prescribe drugs, or other person authorized by the board, animal shelter or county dog warden licensed under section 4729.531 of the Revised Code, or a laboratory will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or
 - d. Adequate safeguards are assured that the applicant will 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 4729.55(D).
2. 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 September 29, 2017, 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 terminal distributor of dangerous drugs 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 Allegations Section, if proven, each constitutes a violation of the following sections 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. Violating any provision of the federal drug abuse control law or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); 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. 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)(25).
4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-5-02(G)(1) of the OAC, Minimum Standards for an outpatient pharmacy, Personnel, the pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000.
 5. Such conduct as set forth in paragraphs (1)(e), (1)(j), (1)(k), (1)(l), (1)(m), (1)(r), (1)(s), and (3)(e) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-5-02(E)(2) of the OAC, Minimum Standards for an outpatient pharmacy, all areas where drugs and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000.
 6. Such conduct as set forth in paragraphs (1)(e), (1)(f), (1)(i), (1)(j), (1)(k), (1)(m), (1)(s) and (3)(e) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-23 of the OAC, Security, control and storage of dangerous drugs in an outpatient pharmacy, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000:
 - a. If the pharmacy is located within a store or business, the pharmacist shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacist on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule, OAC Rule 4729:5-5-23(A)(3)(b); and/or
 - b. Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist, OAC Rule 4729:5-5-23(A)(6)(f); and/or
 - c. Refrigerators and freezers used for the storage of dangerous drugs shall maintain a temperature log with, at a minimum, daily observations, to ensure proper refrigeration and/or freezer temperatures are maintained, OAC Rule 4729:5-5-23(B)(1)(a); and/or
 - d. Refrigerators and freezers used for the storage of dangerous drugs shall maintain a temperature monitoring system capable of detecting and alerting staff of a temperature excursion to ensure proper refrigeration and/or freezer temperatures are maintained, OAC Rule 4729:5-5-23(B)(1)(b); and/or

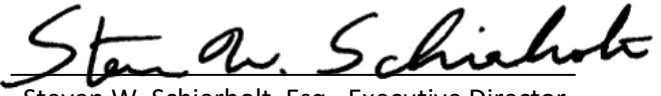
- e. The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs, OAC Rule 4729:5-5-23(B)(2).
7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible Person of a Terminal Distributor, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
- 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).
 - 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 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 4729:5-2-01(E)(6).
8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020, each violation punishable by a maximum penalty of \$1,000:
- a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
 - b. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

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 January 12, 2023; no additional request for a hearing is necessary. Per the previous scheduling notice, your hearing is scheduled for Tuesday, November 7, 2023, and Wednesday, November 8, 2023.

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.

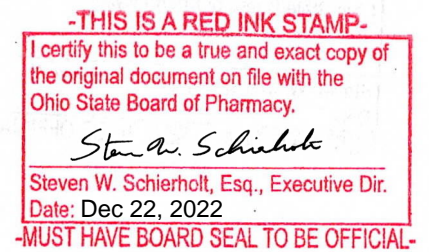
BY ORDER OF THE STATE BOARD OF PHARMACY


Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll

CMRRR: 9414 7118 9956 2097 8529 60

cc: Brian Convery at Brian.Convery@CVSHealth.com



**NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE**

IN THE MATTER OF:

CASE NO. A-2021-0567

CVS Pharmacy #2063
c/o Abby Yannerella, RPh
7292 Fulton Drive, NW
Canton, OH 44718

License No. 02-2120950

December 22, 2022

Dear CVS Pharmacy #2063 and Abby Yannerella, RPh:

You are hereby 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 (TDDD) under authority of Section 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, restrict, limit, or refuse to grant or renew any license issued pursuant to section 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. CVS Pharmacy #2063, located at 7292 Fulton Drive, NW, Canton Ohio, has an active TDDD license with the Board under license number 02-2120950, which lists Abbey Yannerella, RPh as the Responsible Person.

ALLEGATIONS

1. On or about September 13, 2021, agents of the Board arrived at CVS #2063, located at 7292 Fulton Drive, NW, Canton, Ohio to conduct an inspection. The following issues were found:
 - a. Approximately ten vehicles were observed in the drive-thru lane.
 - b. A sign at the front door of the pharmacy stating the lobby of the pharmacy was closed and everyone must go through the drive thru.
 - c. The pharmacy barricade was observed to be closed except for one window. The open window had a sign which read "Vaccines Only" for patients to walk-up or schedule vaccinations.

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

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- d. It took pharmacy staff approximately 20 minutes to acknowledge Board staff at the vaccine window.
- e. Board staff noticed two open totes from a Wholesale Distributor on the counter next to the window which were accessible from outside the pharmacy barricade.
- f. Board staff found the pharmacy was not secure. There was a magnet inside the door jamb to keep the door open from the vaccination room into the pharmacy.
- g. The pharmacy was staffed with one pharmacist, one registered technician, and one care concierge. The pharmacist was assisting customers on the phone, taking transfers, and verifying prescriptions. The registered technician was assisting customers with COVID self-testing in the drive-thru. The care concierge was assisting customers in the drive-thru picking up prescriptions.
- h. The dispensing software showed the following at approximately 4:17pm:
 - 1. 64 pages of prescriptions (15 prescriptions per page) in QP (production) which date back to 9-1-2021 (for a total of 960 prescriptions).
 - 2. 5 pages of prescriptions (15 prescriptions per page) in QV (verification) totaling 75 prescriptions.
 - 3. 7 prescriptions (total) in QT (triage).
- i. An unlocked freezer containing Moderna COVID-19 vaccine was found outside the pharmacy barricade.
- j. Medications were being stored on the floor of the pharmacy.
- k. There were 56 totes from Wholesale Distributors stored inside the pharmacy.
- l. There were also opened and unopened boxes on floor in front of pharmacist workstation.
- m. There were multiple refrigerated and frozen medications that were still within the pharmacy as pharmacy staff was too short staffed to remove it.
- n. Pharmacy staff states they are short staffed because they lost seven pharmacy staff members (1 pharmacist and 6 pharmacy technicians) within a short time. They state they knew the staff members were leaving but did not know they were all going to leave at the same time.
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 - q. Pharmacy staff asked for assistance from a pharmacist and pharmacy technician to fill prescriptions after hours to get caught up. They were denied stating there is no staffing available to do so.
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- a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or
 - b. A pharmacist, licensed health professional authorized to prescribe drugs, or other person authorized by the board, animal shelter or county dog warden licensed under section 4729.531 of the Revised Code, or a laboratory will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or
 - d. Adequate safeguards are assured that the applicant will 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 4729.55(D).
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- 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 terminal distributor of dangerous drugs 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 Allegations Section, if proven, each constitutes a violation of the following sections 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. Violating any provision of the federal drug abuse control law or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); 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. 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)(25).
4. Such conduct as set forth in paragraphs (1)(e), (1)(j), (1)(k), (1)(l), (1)(m), (1)(r), (1)(s), and (3)(e) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-5-02(E)(2) of the OAC, Minimum Standards for an outpatient pharmacy, all areas where drugs and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000.
 5. Such conduct as set forth in paragraphs (1)(e), (1)(f), (1)(i), (1)(j), (1)(k), (1)(m), (1)(s) and (3)(e) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-23 of the OAC, Security, control and storage of dangerous drugs in an outpatient pharmacy, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000:
 - a. If the pharmacy is located within a store or business, the pharmacist shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacist on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule, OAC Rule 4729:5-5-23(A)(3)(b); and/or
 - b. Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist, OAC Rule 4729:5-5-23(A)(6)(f); and/or
 - c. Refrigerators and freezers used for the storage of dangerous drugs shall maintain a temperature log with, at a minimum, daily observations, to ensure proper refrigeration and/or freezer temperatures are maintained, OAC Rule 4729:5-5-23(B)(1)(a); and/or
 - d. Refrigerators and freezers used for the storage of dangerous drugs shall maintain a temperature monitoring system capable of detecting and alerting staff of a temperature excursion to ensure proper refrigeration and/or freezer temperatures are maintained, OAC Rule 4729:5-5-23(B)(1)(b); and/or
 - e. 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 4729:5-5-23(B)(2).

6. 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 of a Terminal Distributor, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
 - 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).
 - 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 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 4729:5-2-01(E)(6).
7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020, each violation punishable by a maximum penalty of \$1,000:
 - a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
 - b. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

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.

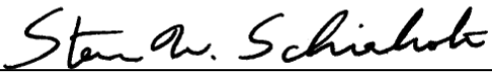
IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will **not** be accepted). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING 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 mailing of this notice, the State of 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 STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

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