

I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy. Stan a. Schiebote Steven W. Schierholt, Esq., Executive Dir. Date: Nov 28, 2023 -MUST HAVE BOARD SEAL TO BE OFFICIAL

THIS IS A RED INK STAMP-

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

IN THE MATTER OF:

CASE NO. A-2023-0419

License No. 02-2348950

CVS Pharmacy #10246 c/o Stacie Lynn Fishwick, RPh 4121 Monroe Street Toledo, OH 43606

November 28, 2023

Dear CVS Pharmacy #10246 and Stacie Lynn Fishwick, 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 #10246, located at 4121 Monroe Street, Toledo, Ohio, has an active TDDD license with the Board under license number 02-2348950, which lists Stacie Lynn Fishwick, RPh as the Responsible Person.

- 1. On or about September 28, 2023, agents of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct an inspection. The following issues were found:
  - a. Pharmacy drug stock does not sufficiently fit on all pharmacy shelves. Lack of space limits the employee's ability to maintain shelves in an organized manner to promote safe operations.
  - b. Drug shelves were dusty and cluttered.
  - c. The pharmacy counters were dirty.



- d. Patient specific prescriptions in bags for sale/pickup were observed to be stored on the floor near the main pharmacist counter.
- e. Pharmacy employee bags with food were observed being stored on the main pharmacy counter.
- f. Trash and tablets were observed on the pharmacy floor.
- g. Return-to-Stock labels dating back to August 28, 2023 that were not applied to Return-to-stock vials were found in the pharmacy.
- h. A patient bag for fluconazole solution from August 7, 023 was found observed in the reconstitution area.
- i. The pharmacy sink was dirty.
- j. The pharmacy is six (6) days behind in their dispensing queue.
- k. The pharmacy is understaffed, the responsible person does not have access to post positions, and staff does not believe the lack of staff has been addressed by district leaders.
- 2. CVS #10246 did not submit a satisfactory written response to the September 28, 2023 inspection. The response submitted did not include all the written responses required. The corrective action(s) that were included in the written response did not properly address the violations found during the inspection.

- 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
  - 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 April 4, 2023, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
  - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
  - c. 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 April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
  - c. 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
  - 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)(23).
- 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)(a), (1)(b), (1)(c), (1)(d), (1)(e), (1)(f), and (1)(i) 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 paragraph (2) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-3-03(E)(1) of the OAC, Inspections and corrective actions, the licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of

this rule, in a manner determined by the board, the action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s), as effective April 1, 2019, each punishable by a maximum penalty of \$1,000.

- 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 April 25, 2022, 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); and/or
  - c. 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).

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 service 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 SERVICE DATE OF THIS NOTICE. Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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

Sten a. Schiehok

SWS/jak/kll

cc: Brian Convery at <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>



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

Steven W. Schierholt, Esq., Executive Dir. Date: 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-2022-0453

CVS Pharmacy #10246 c/o Victoria Tebbe, RPh 4121 Monroe Street Toledo, OH 43606 License No. 02-2348950

August 2, 2023

Dear CVS Pharmacy #10246 and Victoria Tebbe, 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 #10246, located at 4121 Monroe Street, Toledo Ohio, has an active TDDD license with the Board under license number 02-2348950, which lists Victoria Tebbe, RPh as the Responsible Person.

- 1. On or about March 3, 2020, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. Failure to complete a controlled substance inventory with a change in responsible person, on or about February 2022.
  - b. Pharmacy was unable to provide information validating pharmacists and interns met the requirements to administer immunizations.
  - c. An error in dispensing and an error in data entry had occurred.



- d. Medications were stored on the floor of the pharmacy.
- e. Medications on shelves were overflowing and unorganized.
- f. Medications had fallen on the floor and had not been picked up.
- g. Pharmacy FillMaster was dirty, including a drug/residue buildup on the waterspout.
- h. Flavoring bottles and syringes used to remove flavoring were dusty and dirty.
- i. Pharmacy floor was dirty and littered with debris, including tablets.
- j. Carpet squares on the floor were dislodged.
- k. Sink in the pharmacy was dirty, including dirty food containers left soaking in the sink.
- I. Prescription labels abbreviated the name of the prescriber.
- m. Pharmacists were not initialing and dating prescriptions as required.
- 2. On or about October 23, 2020, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. An error in dispensing had occurred; delayed dispensing.
  - b. Staffing Levels were found to be insufficient for the volume of prescriptions.
    - i. Nine pages were observed in the pharmacy Queue Production/label print and filling (QP) and nine pages in the pharmacy Queue Verification/dispensing (QV). Prescriptions in the QV were dated October 20, 21, and 22.
    - ii. Bins with prescriptions for pharmacists to verify were stacked nine bins high by seven rows across (63 bins), many containing multiple prescriptions.
    - iii. Pharmacist on duty said the pharmacy averages 800-1,000 prescriptions and administers 30 flu shots per day with little to no pharmacist overlap.
  - c. Drug bottles and boxes were stored on the floor due to insufficient shelf space.
  - d. Pharmacy floor was littered with trash.
  - e. Loose tablets/capsules were observed on the floor and in the ScriptPro machine.
  - f. Dispensed prescriptions were piled on the floor and countertops waiting for patient pickup.

3. On or about April 15, 2021, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:

- a. Pharmacy floors were littered with debris in the fill area and around the ScriptPro machine.
- b. Loose tablets/capsules were found on the floor.
- c. Food crumbs were found on the floor near pharmacy workstations.
- d. Trash and cardboard boxes were stacked near the pharmacy drop-off area.
- e. Medication bottles and hypodermics were stored on the floor next to the shelf. The products had overflowed from inadequate shelf space.
- f. Multiple prescriptions in the will-call area were stored on the pharmacy floor.
- g. The FillMaster, used for non-sterile drug reconstitution, was dirty with a buildup of drug residue around the water dispensing tip, above the water dispensing tip, and on the basin reservoir.
- h. The area near the FillMaster, including prescriptions bagged and ready for patient pick-up, had visible spills from previous reconstitutions.
- i. Refrigerators Six and Eight were not displaying digital temperature readings from the SmartSense temperature monitoring devices or from the refrigerator built in digital displays. Staff were unable to view or provide records of temperature monitoring on-site.
- j. A prescription was observed in the QP queue waiting for home delivery. The prescription has been in the queue since December 24, 2020. Staff did not know if the patient had received the prescription or if the delivery date was a typo.
- 4. On or about September 9, 2021, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. Unlabeled amber vials containing medication stock were found on the pharmacy shelves.
  - b. An error in dispensing complaint regarding brand versus generic dispensing had occurred.
  - c. An error in dispensing complaint regarding medication dispensed to the wrong patient had occurred.
- 5. On or about March 3, 2022, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. The Board had not been notified of a new responsible person since the change in February 2022 and a controlled substance inventory was not conducted as required.
  - b. The sink was dirty. Mold and food residue was observed near the sink drain. Food particles were observed in the sink strainer. Board employees observed a pharmacist compounding cream in

- this area. The equipment used during compounding was placed in the sink when compounding was completed.
- c. Pharmacy shelves were overflowing with medications. Some medications had fallen from the shelves to the floor. Other medications were stored on the floor because the shelves were full.
- d. Shelving for drug storage had collapsed and medications were crushed beneath the shelving units. Drug stock crowded the aisle floors.
- e. Pharmacy shelves were excessively dusty/dirty.
- f. The reconstitution area/FillMaster was piled with boxes and trash. Shelves surrounding the FillMaster were covered in a pink residue. The tip of the FillMaster was caked with drug residue and was crusty. Boxes stored on the floor limited safe access to the FillMaster. Staff had to lean over trash and debris to use the FillMaster for drug reconstitution.
- g. Trash cans were overflowing.
- h. Pharmacy floors were littered with trash, tablets/capsules, food particles, paper, cotton, and packaging materials.
- i. Patient-dispensed prescriptions were stored on the floor in the will-call area. Empty shelves were observed in the will-call area where the patient specific prescriptions could have been stored.
- j. The counter used for non-sterile compounding was overflowing with OTC medications and return to stock bottles. Staff food and beverages were also stored in this area. Moldy/rotting food was found on the counter.
- k. A delivery of dangerous drugs arrived around 9:00am and was not put away when Board staff left the pharmacy at approximately 6:00pm.
- I. A bin full of prescription bags to be returned to stock was observed near the pharmacy will-call area.
- m. Over 22 expired or adulterated medications were on the pharmacy shelves. One return to stock product was found originally dispensed with expired drug product. Drugs stored/stocked in the pharmacy ScriptPro were not updated with the expiration date and lot number of the stocked product. Numerous products were labeled as expiring in 2021. It was unknown if the drug products in the ScriptPro were expired or mislabeled.
- 6. On or about March 8, 2022, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. The Board had not been notified of a new responsible person since the change occurred on February 28, 2022 and a controlled substance inventory was not conducted as required.

- b. The pharmacy continues to store drug stock on the floor. Some drug stock appears to have fallen off pharmacy shelves and was left on the floor. Return to Stock amber vials had rolled underneath pharmacy shelves and refrigerator units.
- c. Pharmacy shelves remain dusty/dirty.
- d. Shelves around the FillMaster remain splattered with reconstituted drug residue, boxes remain stacked around this area limiting safe access to the FillMaster. Trash in this area is still overflowing.
- e. Pharmacy floor remains littered with tablets/capsules and general trash. Pharmacy floors have not been vacuumed or cleaned.
- f. Tablets/capsules remain scattered on the floor in and near the ScriptPro machine. Due to inappropriate stocking, this area was observed littered with more tablets than observed during the previous inspection.
- g. Pharmacy CVS warehouse order was delivered around 11am. Twenty-nine totes were not unpacked by the completion of the inspection at 4:30pm.
- h. Bins full of return to stock medications are still present in the pharmacy.
- A review of 49 prescriptions was conducted for order entry accuracy. During the review, 15
  prescriptions (31%) were found to have addresses on the prescription which did not match the
  address in the patient profile.
- j. Expired/adulterated medications identified during the previous inspection remained where board employees left them. Additional spot-check by board staff on March 8, 2022 found an additional 14 expired drug products on pharmacy shelves.
- k. A wholesale drug return prepared 12/7/2021 remains in the pharmacy.
- 7. On or about March 14, 2022, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. Seven totes of drugs received from Cardinal were not put away by the end of the board's inspection (approximately six hours).
  - b. Return to stock drugs from March 8, 2022 were not yet processed. A new bin of return to stock drugs was also observed.
  - c. The Board had not been notified of a new responsible person since the change in February 2022 and a controlled substance inventory was not conducted, as required.
  - d. Expired medications were found on pharmacy shelves. Boxes for return of expired medications via reverse distribution were observed in the pharmacy.

- 8. On or about April 5, 2022, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct an inspection. The following issues were found:
  - a. A random review of patient profiles showed multiple instances where the patient address did not match the address on dispensed prescriptions.
  - b. Expired medications were found on the pharmacy shelves.
- 9. On or about June 27, 2022, an agent of the Board arrived at CVS #10246, located at 4121 Monroe Street, Toledo, Ohio to conduct at inspection. The following issues were found:
  - a. Loose tablets were inside and underneath the ScriptPro and around the pharmacy production areas.
  - b. Areas near the reconstitution area were splattered with reconstituted drug product.
  - c. The FillMaster area had a collection of foil seals and other debris around it.
  - d. The tip of the FillMaster was caked with residue and required replacement.
  - e. Expired medications were found on pharmacy shelves, including a product expired 5/2021.
- 10. During the inspections conducted on March 3, 2022 and March 8, 2022, multiple staff members of CVS #10246 were interviewed by representatives of the Board about the conditions of the pharmacy. They made the following statements:
  - a. The pharmacy is always short staffed.
  - b. The workplace was described as hectic. There is no downtime to catch up on tasks.
  - c. Morale among store employees is poor.
  - d. 14-day return to stocks are not completed on time. Sometimes they are not completed for 21-days.
  - e. There are daily call-offs, or no-call no shows. Almost every shift experiences a call-off or no show.
  - f. Staff are permitted to no-call no-show for weeks at a time and then show up for a scheduled shift without any discipline from CVS.
  - g. There is no contingency plan for staff shortages.
  - h. Although the pharmacy is closed for lunch, staff rarely stop to take a break or eat because they are so far behind.
  - i. The pharmacy is not regularly cleaned, vacuumed, or dusted. There is no time to conduct these activities.

- j. Some catch-up used to occur during the overnight hours (when the pharmacy was open 24-hours), but when CVS shortened the pharmacy operation hours, they cut staff hours as well, so there were less people to do to same amount of work in less time, and things got worse.
- k. There are too many autofills. CVS is too aggressive with autofills, and there are too many return to stock prescriptions.
- I. Supervisors/District Managers do not respond to staff calls for help.
- m. Corners are cut to dispense prescriptions.
- n. The responsible person has no staffing authority.
- o. Patients go without their mediations because balances on hand are incorrect in the computer and there is no time to identify and correct the mistakes.
- p. The pharmacy is always 5-6 days behind. Patients need to call prescriptions in at least 7-days in advance if they hope to pick them up before they run out.
- q. The pharmacy has been 4000-5000 prescriptions behind.
- r. There are 9 phone lines and there is no time to answer them. If pharmacy staff answer phones, they get nothing else done.
- s. Customers have complained that they are on hold for 2 hours.
- t. People do not want to work at this store because of the lack of staff and the lack of support from district managers and corporate.
- 11. On or about March 3, 2022, a review of 49 prescriptions dispensed at CVS #10246 was conducted by a Specialist from the Board to determine if any errors in dispensing were occurring at the pharmacy. The results were as follow:
  - a. 15 (31%) of the prescriptions reviewed were dispensed with a potentially inaccurate patient address.
  - b. 7 (14%) of the prescriptions reviewed had errors in the directions to the patients.
  - c. 4 (8%) of the prescriptions reviewed had addresses on file for the prescriber that did not match the prescriber address on the prescription.
  - d. 6 (12%) of the prescriptions reviewed were missing information on the paper prescription, therefore a complete prescription accuracy review could not be completed.

- 12. Multiple audits consisting of 241 controlled substances were conducted by representatives from the Board between on or about November 11, 2021 and on or about April 27, 2022. The audits were finalized by June 27, 2022. The following was discovered by the agents of the Board:
  - a. The audit showed 105 overages and/or shortages (42%).
  - b. Significant losses were discovered for dextroamphetamine/amphetamine mixed salts 5mg, tramadol ER 100mg, Adderall XR 20mg, Adderall XR 30mg, carisoprodol 350mg, methylphenidate LA ER 30mg and Adderall XR 25mg.
  - c. Additional losses and overages were discovered, some of which were reported to the board, but many were not reported at all, or not reported in a timely fashion. Conducting the audit proved difficult because CVS records showed multiple significant inventory adjustments and changes in medication counts conducted during "cycle counts" which were never investigated. Furthermore, the accuracy of cycle counts conducted was questionable.
  - d. Board investigators found cycle counts decreasing inventory counts when drugs were received into inventory on that day, which would theoretically increase inventory counts/values. It remains questionable if counts were entered as negative numbers in error, or if staff were entering negative numbers to mask the diversion of drugs received on that day.
  - e. The inaccuracy of records and constant large fluctuations in inventory counts calls to question the reliability of the CVS inventory management system.

- 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
  - 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 4729.55 of the ORC, as effective April 6, 2017 and March 22, 2020, 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, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code 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).
- 3. 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).
- 4. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or

- c. 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)(23).
- 5. 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).
- 6. 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.
- 7. Such conduct as set fothr 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. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC 4729:5-2-01(E)(3); and/or
- d. 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
- e. 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 paragraphs (5)(m), (6)(j), (7)(d), (8)(b), and (9)(e) of the Allegation Section, if proven, each constitutes a violation of section Rule 4729:5-3-06(A) of the OAC, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons. As effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000.
- 9. Such conduct as set forth in paragraphs (1)(a), (5)(a), (6)(a), (7)(c), and 12 of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-07 of the OAC, Controlled Substance Inventory Requirements, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
  - a. Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014), OAC Rule 4729:5-3-07(A); and/or
  - All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date, OAC Rule 4729:5-3-07(B); and/or
  - The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-3-07(C); and/or
  - d. All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable, OAC Rule 4729:5-3-07(D).

- 10. 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).
- 11. Such conduct as set forth in the Allegation Section, if proven, each constitutes a violation of section Rule 4729:5-5-04(B) of the OAC, Record Keeping, all records maintained in accordance with this rule shall be uniformly maintained for a period of three years, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000.
- 12. Such conduct as set forth in the Allegation Section, if proven, each constitutes a violation of section Rule 4729-5-27(C) of the OAC, Record Keeping, All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours, as effective January 20, 2015, each violation punishable by a maximum penalty of \$1,000.

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.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to <a href="mailto:legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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 Directo

SWS/jak/kll

CMRRR: 9414 7118 9956 2097 3433 83

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



THIS IS A RED INK STAMPI certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Stand Schick
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-2022-0570** 

License No. 02-2014750

CVS Pharmacy #1756 c/o Daniel Owusu-Bremang, RPh 8467 East Main Street Reynoldsburg, OH 43068

August 2, 2023

Dear CVS Pharmacy #1756 and Daniel Owusu-Bremang, 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 #1756, located at 8467 East Main Street, Reynoldsburg, Ohio, has an active TDDD license with the Board under license number 02-2014750, which lists Daniel Owusu-Bremang, RPh as the Responsible Person.

- 1. On or about December 16, 2021, representatives of the Board arrived at CVS #1756, located at 8467 East Main Street, Reynoldsburg, Ohio to conduct at inspection. The following issues were found:
  - a. There were 699 prescriptions in the work queue.
  - b. At least 480 prescriptions were "past due" according to the "promise time" in the system.
  - c. Pharmacy counters and floors were observed to be cluttered with boxes, supplies, records, and totes/baskets/boxes of dangerous drugs.



- d. Pharmacy had loose tablets and capsules, paper scraps, and packaging on the floor.
- e. The pharmacy sink was dirty.
- f. Pharmacy FillMaster was dirty, including a drug/residue buildup on the machine and water nozzle.
- g. Prescriptions were stacked on shelves and drawers and not organized by prescription number.
- h. Controlled substance prescriptions were not separated from non-controlled substance prescriptions.
- i. A controlled substance inventory started in July 2021 due to a change in responsible person was still in progress and not completed.
- j. The drug collection receptacle located outside the barrier of the pharmacy was not secure. It was overfilled with collected medication causing the door not to close and secure properly.
- k. Multiple return to stock vials were observed in the pharmacy stock. Several vials were determined to be beyond the assigned expiration dates.
- Five boxes/totes of prescription vials that were pulled from will-call on December 15, 2021 were
  observed in the pharmacy. The prescriptions had not been processed through the dispensing
  system as returned to stock and showed as dispensed prescriptions. Prescriptions were found to
  have been filled as early as September 8, 2021.
- m. Pharmacy technician staff were not wearing nametags.
- n. Multiple manufacturer containers of expired medication were found in the pharmacy drug stock.
- 2. On or about June 7, 2022, representatives of the Board arrived at CVS #1756, located at 8467 East Main Street, Reynoldsburg, Ohio to conduct at inspection. The following issues were found:
  - a. Expired drugs were found within the active drug stock with the oldest expiration date being March 31, 2021.
  - b. There were unfilled prescriptions not filed and stacked on a counter dating back to March 2021.
  - c. The registered pharmacy technician was not wearing a nametag.
- 3. On or about September 2, 2022, Daniel Owusu-Bremang, responsible person for CVS #1756,was interviewed by phone by a Specialist from the Board. He made the following statements:
  - a. The pharmacy was very short-staffed at the time of the issue with the drug collection receptacle and had only one pharmacy technician on staff.

- b. It took all their efforts to dispense prescriptions and other duties were unfortunately ignored, including monitoring the drug collection receptacle.
- c. Pharmacy staffing has improved and the pharmacy is now fully staffed.
- d. He would reach out CVS leadership about staffing issues and they would provide help when they could, but the entire district was experiencing staffing issues.
- e. The issue with expired medications being on the shelves was due to the lack of staff. The pharmacy was unable to keep up to date with prescription processing, so the review of medication expiration dates was missed.

- 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
  - 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 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.
- 4. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
  - c. 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)(23).
- 5. 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).
- 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. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC 4729:5-2-01(E)(3); and/or
- d. 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
- e. 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 paragraphs (1)(k), (1)(n), and (2)(a) of the Allegation Section, if proven, each constitutes a violation of section Rule 4729:5-3-06(A) of the OAC, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons. As effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000.
- 8. Such conduct as set forth in paragraph (1)(i) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-07 of the OAC, Controlled Substance Inventory Requirements, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
  - a. Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014), OAC Rule 4729:5-3-07(A); and/or

- b. All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date, OAC Rule 4729:5-3-07(B); and/or
- c. The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-3-07(C).
- 9. Such conduct as set forth in paragraph (1)(j) of 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).
- 10. Such conduct as set forth in paragraphs (1)(g) and (2)(b) of the Allegation Section, if proven, each constitutes a violation of section Rule 4729:5-5-04(B) of the OAC, Record Keeping, all records maintained in accordance with this rule shall be uniformly maintained for a period of three years, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000.
- 11. Such conduct as set forth in paragraph (1)(j) of the Allegation Section, if proven, each constitutes a violation of section Rule 4729:10-1-02(A) of the OAC, Authorized Collectors, An authorized collector may operate a drug collection receptacle if they meet the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (4/1/2018), as effective August 1, 2019, each violation punishable by a maximum penalty of \$1,000.

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 February 23, 2023; no additional request for a hearing is necessary.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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, Esg., Executive Director

# SWS/jak/kll

CMRRR: 9414 7118 9956 2097 3244 74

Cc: Brian Convery – <u>Brian.Convery@CVSHealth.com</u>



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

Stand. Schick

Steven W. Schierholt, Esq., Executive Dir.

Date: Aug 02, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

License No. 02-2014300

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

IN THE MATTER OF: CASE NO. A-2022-0533 A-2022-0671

CVS Pharmacy #2528 c/o Jesse Keller, RPh 2801 Far Hill Ave. Dayton, Ohio 45419

August 2, 2023

Dear CVS Pharmacy #2528:

o Jesse Keller, 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 #2528 located at 2801 Far Hill Ave., Dayton, Ohio, has an active TDDD license with the Board under license number 02-2014300, which lists Jesse Keller as the Responsible Person.

- 1. On or about June 3, 2022, CVS Pharmacy #2528, located at 2801 Far Hills Avenue, Dayton, Ohio, submitted an initial Report of Theft or Loss of Controlled Substances (DEA-106 Form) to the Board. The final Report was submitted on or about June 10, 2022, and indicated a loss of 73 oxycodone/acetaminophen 5/325 mg tablets. CVS Pharmacy was unable to determine a reason for the loss.
- 2. On or about November 28, 2022, CVS Pharmacy #2528, located at 2801 Far Hills Avenue, Dayton, Ohio submitted an initial Report or Loss of Controlled Substances (DEA-106 Form) to the Board. The final Report was submitted on or about November 29, 2022, and indicated a loss of 70 amphetamine combo 15mg tablets. CVS Pharmacy was unable to determine the reason for the loss.



- 3. A review of previous losses submitted by CVS Pharmacy #2528 included:
  - a. February 16, 2021: a reported loss of tramadol HCL 50 mg tablets and lorazepam 0.5 mg tablets. The losses were later determined by CVS not to be significant losses.
  - b. November 4, 2021: a reported loss of 100 hydromorphone 4 mg tablets. CVS was unable to determine a reason for the loss.
- 4. On or about August 29, 2022, an agent of the Board spoke with a floater pharmacist at the CVS Pharmacy #2528. He stated there was no Responsible Person working at this location.
- 5. On or about September 22, 2022, agents of the Board conducted an inspection at CVS Pharmacy #2528. The inspection revealed the following:
  - a. CVS Pharmacy #2528 had one floater pharmacist working. There had not been a Responsible Person since Tyler Philo, RPh left on May 26, 2022. Notice had not been made to the Board regarding the Responsible Person leaving.
  - b. A change of Responsible Person inventory had not been completed since the former Responsible Person left in May 2022.
  - c. Other staff included: four registered pharmacy technicians and one pharmacy technician trainee, a store manager, and an unlicensed individual in the pharmacy helping check out patients at the cash register.
  - d. The pharmacist on duty stated he had worked the day prior and had administered over 90 vaccinations; the average number a vaccinations per day was approximately 60. This location dispensed an average of 775 prescriptions per day.
  - e. There were currently 1,155 prescriptions in the que waiting to be filled. They had an additional 150 prescriptions waiting to be checked by the pharmacist and nine prescriptions waiting to be entered into the system. CVS Pharmacy #2528 was seven days behind on prescriptions.
  - f. Agents observed plastic baskets stacked on the pharmacy counter and floor near the counter waiting to be filled.
  - g. The counters were cluttered and disorganized. The floors had visible debris.
  - h. The pharmacist was not able to obtain the balance on-hand for oxycodone/apap 5/325 tablets from April 30, 2022, which was the day of the annual inventory because the internal system would only allow him to check back to July 12, 2022. The CII counts were unable to be located.
- 6. On or about September 15, 2022, an agent of the Board interviewed Jeanne Getter, RPh, a former employee of CVS Pharmacy #2528. She stated the following:
  - a. In April 2022, she was asked to be the temporary pharmacy manager at this location. She was asked to fill-in after the Responsible Person, Tyler Philo, RPh, left CVS in April 2022. Ms. Getter left CVS in August 2022.
  - b. The CII safe was a mess from the time she started. She asked the previous Responsible Person and also the District Leader about cleaning up the safe, but it never happened.
  - c. When the previous Responsible Person left, there was no change of pharmacist inventory done because Ms. Getter was told it would be temporary and CVS would get someone to take over the Responsible Person position. No one ever became the permanent Responsible Person, which is why Ms. Getter left CVS in August.

- d. CVS Pharmacy #2528 absorbed another pharmacy when it closed. The dispensings increased by CVS never increased staff. In August 2022, this location absorbed an additional pharmacy when it closed. Staff at this location was not increased.
- e. Former co-workers at this location stated they had administered approximately 100 flu shots per day; only one pharmacist was working per day. Additionally, CVS had approximately 100 pages in their que.
- f. Ms. Getter estimated the pharmacy dispensed 500 prescriptions per day and administered flu shots, with only one pharmacist on duty.
- 7. On or about September 15, 2022, an agent of the Board interviewed Tyler Philo, RPh, a former Responsible Person for CVS Pharmacy #2528. He stated the following:
  - a. He left CVS Pharmacy on May 26, 2022. He left after CVS Pharmacy #2528 absorbed the business from another CVS location that closed. Prior to absorbing the other location's business, he would dispense between 2,200 and 2,500 prescriptions per week. The location they absorbed dispensed between 800 and 900 prescriptions per week.
  - b. For approximately six weeks after absorbing the closed CVS's business, there were three pharmacists working at CVS Pharmacy #2528 which allowed for overlapping shifts. After six weeks, there were only two pharmacists with very few overlapping shifts.
  - c. This location had one full-time pharmacy technician and one part-time pharmacy technician.
  - d. He asked his manager for help- due to the workload- but never received additional help.
  - e. He was not aware he was still listed as the Responsible Person for CVS Pharmacy #2528.

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 22, 2020 and March 31, 2021, each punishable by a maximum penalty of \$1,000: 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.
- 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(B) 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 Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729:5-5-02(G)(1) of the OAC, Minimum Standards for an Outpatient Pharmacy, as effective December 1, 2020: Personnel, The pharmacy shall be appropriately staffed to operate in a safe

- and effective manner pursuant to section 4729.55 of the Revised Code, each violation punishable by a maximum penalty of \$1,000.
- 4. 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 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).
- 5. 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 \$1,000: 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).
- 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, each 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); and/or
  - c. For all locations licensed as a terminal distributor of dangerous drugs: A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC Rule 4729:5-2-01(E)(1); and/or
  - d. When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, OAC Rule 4729:5-2-01(E)(2); and/or

- e. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC 4729:5-2-01(E)(3); and/or
- f. 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
- g. 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).
- 7. Such conduct as set forth in the Allegation Section, if proven, each constitutes a violation of section Rule 4729-5-27(C) of the OAC, Record Keeping, All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours, as effective January 20, 2015, each violation punishable by a maximum penalty of \$1,000.
- 8. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
  - c. 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
- 9. 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. 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

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 February 24, 2023; no additional request for a hearing is necessary.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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/ALG/jak/kll

CMRRR: 9414 7118 9956 2097 3771 28

cc: Brian Convery at <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>



-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. Stan a Schiebote Steven W. Schierholt, Esq., Executive Dir. Date: Jan 05, 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-2021-0508** A-2022-0087

License No. 02-0129150

CVS Pharmacy #3321 c/o Noah Sackitey, R.Ph. 2284 Back Orrville Road Wooster, OH 44691

January 5, 2023

Dear CVS Pharmacy #3321 and Mr. Noah Sackitey, R.Ph.:

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 #3321, located at 2284 Back Orrville Road, Wooster, OH 44691, has an active TDDD license with the Board under license number 02-0129150, which lists Noah Sackitey, R.Ph. as the Responsible Person.

### **ALLEGATIONS**

1. From on or about February 3, 2021 to on or about May 18, 2021, CVS Pharmacy #3321, located 2284 Back Orrville Road, Wooster, Ohio, allowed a pharmacy technician trainee to administer immunizations they were not qualified to administer. The United States Department of Health and Human Services (HHS) Emergency Preparedness Act regarding COVID-19 pandemic gave "Qualified Pharmacy Technicians" the authorization to administer childhood as well as the COVID-19 vaccine. The State of Ohio Board of Pharmacy created a guidance document and issued it on January 19, 2021, "Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic." It states a pharmacy technician trainee does



not qualify as a "Qualified Pharmacy Technician." The unqualified technician administered the following immunizations during this time:

- a. Twenty Shingrix (shingles) vaccines.
- b. One Pneumovax-23 (pneumonia) vaccine.
- c. One Prevnar (pneumococcal conjugate) vaccine.
- d. Four flu (inactivated) vaccines.
- 2. On or about January 12, 2022, agents of the Board arrived at CVS #3321, located at 2284 Back Orrville Road, Wooster, Ohio to conduct an inspection. The following issues were found:
  - a. At 3:57pm the pharmacy was staffed with one pharmacist, one registered pharmacy technician, five pharmacy technician trainees, and one pharmacy support personnel. The pharmacist was verifying prescriptions in QV (Verification). Three pharmacy technician trainees were filling prescriptions from QP (Production). One pharmacy technician trainee was assisting customers with COVID self-testing in the drive thru. The registered pharmacy technician was assisting customers with new prescriptions and entering prescriptions into RxConnect. One pharmacy technician trainee was assisting customers at the front counter of the pharmacy.
  - b. The pharmacy had 120 prescriptions (8 pages of 15 prescriptions per page) in QT (Triage). There were 540 prescriptions (36 pages of 15 prescriptions per page) in QP (Production). There were 1170 prescriptions (78 pages of 15 prescriptions per page) in QV (Verification).
  - c. The pharmacist on duty was a pharmacy manager from another store. She had come in to assist in staffing the pharmacy. The pharmacy had to be closed intermittently due to the lack of a pharmacist. The pharmacy could be closed for the day or before or after lunch due to the lack of a pharmacist. The pharmacist on duty states they are actively triaging prescriptions to ensure lifesaving, life-sustaining medications are filled in a timely manner.
  - d. CVS #3321 did not have an active responsible person with the Board when the inspection occurred. The pharmacy was without a responsible person from November 15, 2021 until February 4, 2022.
  - e. Multiple issues of cleanliness were observed in the pharmacy. The issues included the following:
    - i. Numerous pills were observed on the floor of the pharmacy.
    - ii. Numerous pills were found on the floor of the ScriptPro automatic vial filler.
    - iii. Numerous medications found to be stored on the floor of the pharmacy.

- iv. Multiple baskets of medications were visible and within reach of the public. They were stored next to data entry window behind a moveable plexiglass divider on the pharmacy counter.
- v. Pharmacy distribution totes were in the pharmacy needed to be unpacked. There were multiple totes dating back to January 5, 2022.
- vi. The Pharmacy FillMaster reconstitution device was observed to be dirty. The tip of the FillMaster had an unknown substance stuck to it.
- f. During inspection SOBP agents observed five trainees actively working in the pharmacy with only one pharmacist supervising. A waiver had not been filed with the Board to allow five trainees to work under the supervision of one pharmacist.

- Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.95(C) of the ORC, No terminal distributor of dangerous drugs shall knowingly allow any person employed or otherwise under the control of the person who owns, manages, or conducts the terminal distributor to violate division (A) of 4729.95 of the ORC, which states: No person who is not a pharmacist, pharmacy intern, registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee shall knowingly engage in any of the activities listed in section 4729.91 of the Revised Code in a location licensed as a terminal distributor of dangerous drugs, a misdemeanor of the second degree, punishable by a maximum penalty of \$4,000.
- 2. 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 22, 2020 and March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
  - a. A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code 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
  - 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
  - c. 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).
- 3. 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).
- 4. 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).
- 5. 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. 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

- d. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to other, OAC Rule 4729:5-4-01(B)(25); 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).
- 6. Such conduct as set forth in paragraphs (3)(e)(i), (3)(e)(ii), (3)(e)(iii), (3)(e)(iv), (3)(e)(v), and (3)(e)(vi) 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.

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 September 13, 2022; no additional request for a hearing is necessary. Per the previous scheduling notice, your hearing is scheduled for Monday, April 3, 2023.

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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. Schieholt, Esg., Executive Director

SWS/jak/kll

CMRRR: 9414 7118 9956 2106 4568 37



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

Stand Schick
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-2021-0241

License No. 02-0127950

CVS #3356 c/o Kaylee Ann McKinnon, R.Ph. 265 East Erie Street Painesville, OH 44077

August 2, 2023

Dear CVS #3356 and Ms. Kaylee Ann McKinnon, R.Ph.:

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 #3356, located at 265 East Erie Street, Painesville, Ohio, has an active TDDD license with the Board under license number 02-0127950, which lists Kaylee Ann McKinnon, R.Ph. as the Responsible Person.

- 1. On October 20, 2020, due to the Board receiving multiple complaints regarding your pharmacy, an Inspector from the Board conducted an inspection At CVS #3356, located at 265 East Erie Street, Painesville, Ohio. The following was observed:
  - a. The pharmacy was staffed with one pharmacist and two pharmacy technicians. The pharmacist was observed to be checking prescriptions; one pharmacy technician was assisting customers performing COVID- 19 self-tests (in the drive thru) and the other pharmacy technician was observed to be filling prescriptions for the pharmacist to check.
  - b. The pharmacy also had a front store member in the pharmacy acting as a cashier.



- c. The pharmacy had 15 bins awaiting pharmacist verification.
- d. Pharmacy had 195 prescriptions in QP (production), 90 prescriptions in QT (Triage), and 255 prescriptions in QV (Verification).
- e. Pharmacy also had 62 doctor calls to make.
- f. This CVS Pharmacy processes 600-1000 prescriptions per day.
- g. This pharmacy location employs one 40hr/week pharmacy technician, one 31hr/week pharmacy technician and two pharmacists.
- h. The pharmacist will be alone from 5pm-9pm.
- 2. On February 23, 2021, due to the Board receiving multiple complaints regarding your pharmacy, an Inspector from the Board conducted an inspection At CVS #3356. The following was observed:
  - a. The pharmacy was staffed with one pharmacist, two pharmacy technicians and one pharmacy support personnel.
  - b. The pharmacist was observed verifying prescriptions, the two pharmacy technicians were filing medications and the support person was assisting customers at the pickup window.
  - c. There were 11 prescription bins awaiting pharmacist verification.
  - d. The pharmacy had 585 prescriptions in QP (Production), 3 prescriptions in QT (Triage), 105 prescriptions in QV (75 prescriptions in PV1, 20 prescriptions in PV2), 38 individual doctor calls in RC (one doctor may have multiple requests).
- 3. On March 11, 2021, due to the Board receiving multiple complaints regarding your pharmacy, an Inspector from the Board conducted an inspection At CVS #3356. The following was observed:
  - a. The pharmacy was staffed with one pharmacist and three registered pharmacy technicians.
  - b. The pharmacist was verifying prescriptions, one technician was filling prescriptions, one technician was entering prescriptions, and the other was assisting customers in the drive thru.
  - c. There were 30 prescriptions on the counter awaiting pharmacist verification.
  - d. There were 22 prescriptions in QP (Production), 4 prescriptions in QT (Triage), 39 prescriptions in QV (Verification), and 22 prescriptions in RC.
  - e. This pharmacy performs COVID testing in the drive thru but does not perform any COVID vaccinations.

4. From on or about February 20, 2021 to on or about March 7, 2021, CVS #3356 was without a Responsible Person. The change of responsible person paperwork was filed on March 17, 2021.

- 1. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55(D) of the ORC, as effective March 22, 2020, 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, each violation punishable by a maximum penalty of \$1,000.
- 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 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.
- 4. 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. 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
  - d. Employs a responsible person that does not meet the requirements set forth in rule 4729:5-2-01 of the Administrative Code, OAC Rule 4729:5-4-01(B)(21); and/or
  - e. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to other, OAC Rule 4729:5-4-01(B)(25).

5. Such conduct as set forth in paragraph (4) of the Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729:5-2-01(E)(2) of the OAC, as effective March 1, 2019, when there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, each violation punishable by a maximum penalty of \$1,000.

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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 8941 44

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 NOS. A-2023-0236

CVS Pharmacy #3393 c/o, John Macchiarella, RPh 118 W. Garfield Road Aurora, Ohio 44202

November 28, 2023

Dear CVS Pharmacy #3393:

License No. 02-0926900

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 #3393, located at 118 W. Garfield Road, Aurora, Ohio, has an active TDDD license with the Board, license number 02-0926900, which lists John Macchiarella, RPh, as the Responsible Person.

#### **ALLEGATIONS**

1. On or about March 6, 2023, CVS Pharmacy #3393, located at 118 W. Garfield Road, Aurora, Ohio, filed a Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated there was a loss of 338 tramadol 50 mg tablets. The form indicated the loss occurred on February 8, 2023 and the description of how the loss occurred was unknown.



- 2. On or about August 23, 2022, CVS Pharmacy #3393, filed a Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated there was a loss of 70 dexmethylphenidate 20 mg ER tablets. The form indicated the reason for the loss was unknown.
- 3. On or about February 15, 2022, CVS Pharmacy #3393, filed a Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated there was a loss of 438 tramadol 50 mg tablets. The form indicated the reason for the loss was unknown.
- 4. On or about March 30, 2022, the Board conducted an inspection of the pharmacy. During the inspection, an audit of various medications was completed whereby the on-hand amount of the drugs was compared against the dispensing software. The following was discovered:
  - a. There was a shortage of 43 tablets of 50 mg tramadol.
  - b. There was a shortage of 1 tablet of 50 mg tramadol (different NDC number).
  - c. A baggie containing tramadol was acetaminophen waiting to be entered into the dispensing software to be destroyed was counted. The bag contained 56 tablets, but it should have contained 51 tablets (this would have caused a 5 tablet shortage).
- 5. On or about April 6, 2023, the Board conducted an inspection of the pharmacy. An audit of all tramadol 50 mg tablets was conducted with no discrepancies found (between the on-hand amount and dispensing software). A written response was required as a result of the March 6, 2023 loss of tramadol tablets. The response indicated the following:
  - a. "Review of tape and filled RX's in waiting bin of both controlled and non-controlled products identified significant errors, with over 75% of scripts audited having a discrepancy of some sort, positive or negative."
  - b. Technicians were not double-counting controlled substances.
  - c. The response, filed with the Board on or about May 4, 2023, indicated CVS was taking steps to address the issues outlined.

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 31, 2021, each punishable by a maximum penalty of \$150: 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.
- 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(B) 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 4729:5-3-14 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$500: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).
- 4. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
  - c. 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).
- 5. 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 service 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, 17<sup>th</sup> 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 30<sup>TH</sup> DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE. Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30<sup>th</sup> day following the service 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, Esg., Executive Director

SWS/alg/kll

cc: Brian Convery, via email: <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>



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

Steven W. Schierholt, Esq., Executive Dir. Date: Nov 28, 2023

MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: CASE NOS. A-2022-0508
A-2023-0362

CVS Pharmacy #3404 c/o, Courtney Seekins, RPh 35 S. Allison Avenue Xenia, Ohio 45385

November 28, 2023

Dear CVS Pharmacy #3404:

License No. 02-0133800

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 #3404, located at 35 S. Allison Avenue, Xenia, Ohio, has an active TDDD license with the Board, license number 02-0133800, which lists Courtney Seekins, RPh, as the Responsible Person.

#### **ALLEGATIONS**

1. On or about February 17, 2022, CVS Pharmacy #3404, located at 35 S. Allison Ave., Xenia, Ohio, filed an initial Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated there was a loss of 60 hydrocodone/apap 5/325 mg tablets. There was no reason listed for the loss. On or about June 23, 2022, CVS notified the Board that after review, the reason for the loss is unknown and was suspected to be a miscount on a prescription.



- a. On or about August 29, 2022, agents of the Board conducted an inspection at CVS Pharmacy #3404. During the inspection, it was discovered that neither Mrs. Seekins, Responsible Person, nor Brian Schweer, CVS Pharmacy District Leader, had any knowledge of the loss.
- b. It was later discovered by the new District Leader of CVS that there were two losses which occurred in September 2021 and October 2021, but were not reported until February 2022.
- 2. On or about April 3, 2023, CVS Pharmacy #3404, filed an initial notification of theft of loss. The report was for lorazepam 0.5 mg tablets but the amount was not listed. On or about April 4, 2023, it was reported to the Board that the number of lorazepam missing was 301 tablets, but CVS was still investigating.
  - a. On or about May 5, 2023, CVS submitted an update DEA-106 Form to the Board. The form stated the investigation determined the loss was not significant and showed a loss of zero.
  - b. On or about May 12, 2023, after follow-up from an agent of the Board regarding the discrepancy, Michael Spiller, CVS District Leader, reported the loss was actually 435 tablets.
  - c. On or about June 14, 2023, CVS sent an updated Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated the following losses- with different NDC #'s occurred: 484 0.5 mg lorazepam tablets and 132 0.5 lorazepam tablets. The report indicated the pharmacy did not identify any reason for the loss.

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 31, 2021, each punishable by a maximum penalty of \$150: 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.
- 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(B) 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 4729:5-3-02 of the OAC, as effective October 31, 2021, each punishable by a maximum penalty of \$500:

- a. A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location: The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss, OAC Rule 4729:5-3-02(A)(1); and/or
- b. The theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss, OAC Rule 4729:5-3-14(B).
- 4. 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 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$500: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).
- 5. 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).
- 6. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
  - c. 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).

- 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 service 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 SERVICE DATE OF THIS NOTICE. Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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/alg/kll

cc: Brian Convery, via email: <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>





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

IN THE MATTER OF:

CASE NO. A-2023-0341

License No. 02-0102000

CVS Pharmacy #3467 c/o Lauren Ashley Jraisat, RPh 1300 Wilmington Ave. Dayton, OH 45420

January 16, 2024

Dear CVS Pharmacy #3467 and Lauren Jraisat, 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 #3467, located at 1300 Wilmington Ave., Dayton, Ohio, has an active TDDD license with the Board under license number 02-0102000, which lists Lauren Ashley Jraisat, RPh, as the Responsible Person.

#### **ALLEGATIONS**

- 1. On or about May 2023, CVS #3467 (TDDD 02-0102000), located at 1300 Wilmington Ave., Dayton, Ohio, identified the loss of controlled substances due to suspected diversion. CVS #3467 failed to notify the Board of the initial losses until June 22, 2023, and an official Board Theft or Loss Report was not submitted for the following controlled substances until July 17, 2023:
  - a. #460 Alprazolam 0.5mg tablets (schedule-IV controlled substance);
  - b. #23 Alprazolam 0.5mg tablets (schedule-IV controlled substance);



- c. #23 Alprazolam 0.5mg tablets (schedule-IV controlled substance);
- d. #279 Alprazolam 2mg tablets (schedule-IV controlled substance);
- e. #135 Buprenorphine 8mg sublingual tablets (schedule-III controlled substance);
- f. #510 Buprenorphine 8mg sublingual tablets (schedule-III controlled substance).
- 2. On or about May 25, 2023, pharmacy technician trainee Ariana Clark was interviewed by CVS Loss Prevention due to a report of her working in the pharmacy while under the influence of illicit fentanyl. During the interview, Ariana Clark admitted an addiction to fentanyl and to using fentanyl before her scheduled pharmacy shifts. CVS Pharmacy #3467 did not report this information to the Board.

- 1. Such conduct as set forth in paragraph (1) of the Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729:5-3-02(A) of the OAC, as effective October 31, 2021, Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents, each violation punishable by a maximum penalty of \$1,000:
  - a. A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance ...:
    - i. The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss, OAC 4728:5-3-02(A)(1);
- 2. Such conduct as set forth in paragraph (2) of the Allegations Section, if proven, constitutes a violation of the following section of Rule 4729:1-4-02 of the OAC, as effective April 25, 2022, Duty to report, each violation punishable by a maximum penalty of \$1,000:
  - a. The following shall be reported to the board:
    - i. Except as provided in paragraph (C)(1)(a) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties, OAC Rule 4729:1-4-02(C)(1).
- 3. Such conduct as set forth in the 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. A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or

- b. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or
- c. 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).
- 4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-2-01, as effective April 25, 2022, Responsible person terminal distributor, 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).
- 5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
  - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
  - c. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).
- 6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3).

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 service 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, 17<sup>th</sup> 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 30<sup>TH</sup> DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE. Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30<sup>th</sup> day following the service 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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

Sten a. Schiebok

SWS/zas/jrn

cc: Brian Convery, Sr. Legal Counsel, Brian.Convery@CVSHealth.com.



-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. Stan a. Schiebok Steven W. Schierholt, Esq., Executive Dir. Date: Dec 22, 2022 MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF:

**CASE NO. A-2022-0046** 

License No. 02-0776200

CVS Pharmacy #4101 c/o Laurie Maglietta, RPh 34 Shopping Plaza Drive Chagrin Falls, OH 44022

December 22, 2022

Dear CVS Pharmacy #4101 and Ms. Maglietta:

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 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, restrict, limit, reprimand, 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. CVS Pharmacy #4101, located at 34 Shopping Plaza Drive, Chagrin Falls, Ohio, has an active TDDD license with the Board under license number 02-0776200, which lists Laurie Maglietta, RPh as the current Responsible Person.

#### **ALLEGATIONS**

- 1. On or about May 17, 2021, while Ashton Atkins was working as the Responsible Person at CVS Pharmacy #4101, located at, 34 Shopping Plaza Drive, Chagrin Falls, Ohio, an agent of the Board discovered Mr. Atkins had a lapsed basic life support (BLS) certification. The following information was discovered:
  - a. Mr. Atkins completed Basic Life Support Training for Healthcare Providers provided by the American Red Cross on June 21, 2017; it expired after two years, on or about June 21, 2019.
  - b. There were no COVID-19 waivers issued by the Board that permitted Mr. Atkins to administer vaccines while his BLS certification was expired.



- c. Mr. Atkins had administered vaccines at CVS during the time his BLS certification was expired.
- d. Mr. Atkins had been allowing pharmacy technicians to administer COVID-19 vaccines while he was the only pharmacist on duty.
- e. During a COVID-19 based inspection of the pharmacy, the following violations were discovered:
  - i. A vaccine vial was observed at room temperature and not labeled with the time it was removed from the freezer, or a beyond use date.
  - ii. Vaccines in the refrigerator were not labeled with a date removed from the freezer and/or not labeled with a beyond use date.
  - iii. Vaccines were observed without the date and time of first use recorded on the vial.
  - iv. Written responses required and warnings were issued for beyond use dates.
  - v. Written warnings were issued for not having minimum/maximum monitoring for vaccine storage, per Ohio Department of Health requirements.
- 2. On or about November 19, 2021, CVS staff confirmed:
  - a. Employees are responsible for their own [BLS] licensure.
  - b. Supervisors can sign off that BLS was completed. It's best practice to get a copy of the BLS certificate prior to signing off that the certificate was completed.
  - c. A BLS certification for Mr. Atkins was not obtained.
  - d. CVS was not sure if technicians were administering COVID vaccines while Mr. Atkins was on duty without another supervising pharmacist.
- 3. The Board received a list of all vaccines administered when Mr. Atkins was on duty from on or about May 17, 2021 to on or about June 30, 2021. The document lists Mr. Atkins as the verifying pharmacist on 69 records and identifies him as the immunizer after the period in which CVS and Mr. Atkins stated he stopped immunizing. Although CVS provided Mr. Atkins' work schedule, which confirmed he was working each day of the documented administrations, there is not accurate electronic record keeping of the immunizer at the pharmacy during this time period.
- 4. On or about September 27, 2021, Mr. Atkins, the Responsible Person, spoke with an agent of the Board. He stated the following:
  - a. His BLS certification expired in 2019.
  - b. He was told by CVS supervisors they checked the box "yes" in the CVS portal to confirm his BLS certification was completed.
  - c. It was not anyone's job to confirm that Mr. Atkins had his BLS certification, but CVS Corporate should have been aware.
  - d. After it was confirmed Mr. Atkins' BLS certification was expired, Mr. Atkins was told he was permitted to allow technicians to provide COVID-19 vaccines when he was the only pharmacist on duty.

#### POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:1-3-02(M) of the OAC, effective as of December 1, 2020, each punishable by a maximum penalty of \$500: A pharmacist administering immunizations in accordance with this rule shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

- 2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-5-04(A)(6) of the Ohio Revised Code, as effective December 1, 2020, Record Keeping: There shall be positive identification of the licensed or registered individuals responsible for performing the following activities authorized under Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code: Administering immunizations pursuant to section 4729.41 of the Revised Code.
- 3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:1-3-02(O) of the OAC, effective as of December 1, 2020, each punishable by a maximum penalty of \$500: A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers immunizations in accordance with this rule:
  - a. Proof of successful completion of a training course specified in paragraph (A) of this rule, Rule 4729:1-3-02(O)(1); and/or
  - b. Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (M) of this rule, Rule 4729:1-3-02(O)(2).
- 2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-22(B) of the OAC, as effective May 12, 2017, Records of administering, dispensing, personally furnishing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the dangerous drug was administered, dispensed, or used, each punishable by a maximum fine of \$1,000.
- 3. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of Section 4729.55(D) of the ORC, as effective April 6, 2017 and March 22, 2020, TDDD license requirements, each violation punishable by a maximum penalty of \$500: 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).
- 4. 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 \$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 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).
- 5. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective 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 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).
- 6. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective 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 terminal distributor of dangerous drugs 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.

**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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> day following the mailing of this notice, the State of Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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

Stan a. Schiebet

SWS/alg/kll

CMRRR: 9414 7118 9956 2128 2612 42



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

Stewn W. Schierholt, Esq., Executive Dir. Date: Jan 11, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: CASE NOS. A-2022-0565

CVS Pharmacy #4348 c/o Devrajsinh Solank, RPh

28700 Chardon Road Willoughby Hills, Ohio 44092

January 11, 2023

Dear CVS Pharmacy #43484:

License No. 02-0433950

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 #4348, located 28700 Chardon Road, Willoughby Hills, Ohio, has an active TDDD license with the Board, license number 02-0433950, which lists Devrajsinh Solank, RPh, as the Responsible Person.

#### **ALLEGATIONS**

- On or about August 1, 2022, the Board received a Report of Theft or Loss of Controlled Substances (DEA-106 Form) from CVS Pharmacy #4348, located at located 28700 Chardon Road, Willoughby Hills, Ohio. The report indicated a significant loss of 575 tramadol 50mg (a Schedule IV controlled substance). The report stated the loss occurred on June 9, 2022. The pharmacy was unable to identify a reason for the loss.
- 2. CVS Pharmacy #4348 had previously reported the following unexplained losses to the Board:



- a. April 12, 2021: 499 alprazolam 2mg (a Schedule IV controlled substance).
- b. August 24, 2021: 479 zolpidem tartrate 10mg (a Schedule IV controlled substance).
- 3. On or about September 23, 2022, agents of the Board performed an inspection. During the inspection, the following observations were noted:
  - a. The responsible person was not the responsible person listed with the Board.
  - b. Drugs were stored on the floor; dust was observed on the shelves. The pharmacy was disorganized and cluttered.
  - c. The pharmacy was unable to locate a written response that was required for the two significant losses listed above and an inspection that occurred on September 7, 2021.

- 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(B) 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 4729:5-3-14 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$500: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).
- 5. 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).

- 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 and April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
  - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
  - c. 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.

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

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Steven W. Schierholt, Esq., Executive Director

SWS/alg/kll

CMRRR: 9414 7118 9956 2166 0038 66



I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy. Stan a. Schiebok Date: Jan 11, 2023 -MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: CASE NOS. A-2022-0341

CVS Pharmacy #4351 c/o, Albert Dowling, RPh 6005 Som Center Road

Willoughby, Ohio 44094

January 11, 2023

Dear CVS Pharmacy #4351:

License No. 02-0448600

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 #4351, located 6005 Som Center Road, Willoughby, Ohio, has an active TDDD license with the Board, license number 02-0448600, which lists Albert Dowling, RPh, as the current Responsible Person.

#### **ALLEGATIONS**

- 1. On or about April 6, 2021, CVS Pharmacy #4351, located at 6005 Som Center Road, Willoughby, Ohio, filed an initial Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated the loss occurred on March 16, 2021, and the investigation revealed the loss was not significant, listing the loss as 0 tablets of lorazepam 1 mg.
- 2. On or about May 11, 2021, CVS Pharmacy #4351 submitted another Report of Theft or Loss of Controlled Substances. The report indicated the loss was not significant, listing the loss as 0 tablets of diazepam 5mg.



- 3. An agent of the Board spoke with a loss prevention manager at CVS. CVS advised the pharmacy was recently remodeled and believed the loss was due to disorganization and inventory control issues. A spreadsheet with the annual count was submitted to the Board. The final loss of each drug listed in the Reports of Theft and Loss were as follows:
  - a. Lorazepam 1mg tablets (Schedule IV controlled substance): loss of 141
  - b. Diazepam 5mg tablets (Schedule IV controlled substance): loss of 106
- 4. On or about July 21, 2021, an inspection of the pharmacy was conducted. Agents observed medications spilling off the pharmacy shelving in the back of the pharmacy and numerous medication stock bottles stored on the floor of the pharmacy. Additionally, the pharmacy was observed to be dirty.

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 31, 2021, each punishable by a maximum penalty of \$150: 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.
- 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(B) 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 4729:5-3-14 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$500: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).

- 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 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.

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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

SWS/alg/kll

CMRRR: 9414 7118 9956 2166 0476 31



#### -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.

Sten a. Schiebote Steven W. Schierholt, Esq., Executive Dir.

Date: Jan 11, 2023 MUST HAVE BOARD SEAL TO BE OFFICIAL

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

License No. 02-0448600

IN THE MATTER OF: CASE NOS. A-2022-0572

Dangerous Drugs (TDDD) under authority of Section 4729.57 of the Revised Code.

CVS Pharmacy #4351 c/o, Albert Dowling, RPh 6005 Som Center Road

Willoughby, Ohio 44094

January 11, 2023

Dear CVS Pharmacy #4351:

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

#### **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 #4351, located 6005 Som Center Road, Willoughby, Ohio, has an active TDDD license with the Board, license number 02-0448600, which lists Albert Dowling, RPh, as the current Responsible Person.

#### **ALLEGATIONS**

- 1. On or about January 7, 2022, Gregory Garner, RPh, while working as a pharmacist at CVS Pharmacy #4351, located at 6005 Som Center Road, Willoughby, Ohio, verified RX 2389258 for patient 1. The prescription was issued for ropinirole 1 mg for patient 1. The label on the prescription bottle correctly stated "ropinirole 1 mg" for patient 1, however, the bottle contained digoxin 0.125 mg.
- 2. On or about January 13, 2022, patient 1 received the incorrect medication. Patient 1 ingested approximately 27 tablets of the incorrect medication and experienced adverse effects including increased



anxiety, rapid heart rate, and sweating. On or about February 3, 2022, Patient 1 picked up a prescription refill from the pharmacy and realized the tablets looked different than those she had ingested from the previous bottle. The pharmacy identified the medication and confirmed the previous bottle contained digoxin 0.125 mg. On or about February 14, 2022, patient 1 went to the emergency room for accidental drug ingestion and was released in stable condition with no digoxin toxicity.

3. An investigation by the Board revealed the incorrect medication was dispensed to patient 1. The dispensing records at CVS Pharmacy #4351 indicated Gregory Garner, RPh, verified the medication; however, he was not alerted the scan of the medication was bypassed. Additionally, the pharmacy had no record indicating the medication was scanned during prescription production. The dispensing software permitted the medication to be verified without scanning the bottle or alerting the pharmacist the standard safety procedure may or may not have been completed.

- 1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52(A) of the ORC, the adulteration or misbranding of any food, drug, device, or cosmetic, a misdemeanor of the fourth degree, punishable by a maximum penalty of \$2,000 if committed by an organization.
- 2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.64(A)(1), as effective March 21, 2017, Misbranded drug its labeling is false or misleading in any particular, punishable by a maximum penalty of \$1,000.
- 3. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of divisions (A)(10) of section 3715.64 of the ORC, as effective March 21, 2017, Misbranding, each violation punishable by a maximum penalty of \$1,000:
  - a. It is a drug and its container is so made, formed, or filled as to be misleading, ORC Section 3715.64(A)(10)(a); and/or
  - b. The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, is neither the brand or drug prescribed nor a generically equivalent drug, ORC Section 3715.64(A)(10)(d).
- 4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.55(D) of the ORC, effective March 31, 2021, punishable by a maximum penalty of \$150: 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.
- 5. 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(B) 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).
- 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.

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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

CVS #4351 A-2022-0572 3

SWS/alg/klll

CMRRR: 9114 7118 9956 2160 9474 87



## -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.

Sten a. Schiehok Steven W. Schierholt, Esq., Executive Dir. Date: Jan 26, 2024 -MUST HAVE BOARD SEAL TO BE OFFICIAL

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

IN THE MATTER OF:

CASE No. A-2023-0491

License No. 02-0719300

CVS Pharmacy #4401 c/o Matthew Bayman, R.Ph. 5981 Far Hills Ave. Dayton, OH 45429

January 26, 2024

Dear CVS Pharmacy #4401 and Matthew Bayman, R.Ph.:

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, 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 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 #4401 has an active TDDD license with the Board under license number 02-0719300, which lists Matthew Bayman, R.Ph. as the Responsible Person.

#### **ALLEGATIONS**

- 1. On or about June 29, 2023, CVS Pharmacy #4401, located at 5981 Far Hills Avenue, Dayton, Ohio, submitted a Drug Enforcement Administration (DEA) 106 Form to the Board reporting the loss of 618 alprazolam 2mg tablets, a Schedule IV controlled substance. On or about August 9, 2023, CVS Pharmacy #4401 submitted an updated DEA 106 Form to the Board reporting the loss of 618 alprazolam 2mg tablets, National Drug Code (NDC) #00228203910, and that CVS Pharmacy #4401 was unable to determine a reason for the loss.
- 2. On or about October 5, 2023, CVS Pharmacy #4401 submitted an updated DEA 106 Form to the Board reporting the loss was now 700 alprazolam 2mg tablets, National Drug Code (NDC) #00228203910. There

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



was also an additional loss reported of 428 alprazolam 2mg tablets, NDC #65862067905. The DEA 106 Form stated the suspected employee had not returned to the pharmacy after they had been interviewed.

- 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
  - 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 if committed by an organization:
  - 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 4729.52(B)(7).
- 3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-4-01(B) of the OAC, as effective April 25, 2022, the Board may impose the sanctions as set forth in paragraph (A) of this rule for any of the following, each violation is punishable by a maximum penalty of \$1,000 if committed by an organization:
  - 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 terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7).
- 4. Such conduct as set for 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 and April 25, 2022, 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).
- 5. Such conduct as set for 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:
  - 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, 17<sup>th</sup> 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 30<sup>TH</sup> DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE. Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. If you are a corporation, 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 30<sup>th</sup> day following the service of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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

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



-THIS IS A RED INK STAMP-I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Steven W. Schierholt, Esq., Executive Dir. Date: Aug 16, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL

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

IN THE MATTER OF:

**CASE NO. A-2023-0136** 

License No. 02-2013650

CVS Pharmacy #6086 c/o Francis Mensah Ahenkan, RPh 605 Columbus Avenue Lebanon. OH 45036

August 16, 2023

Dear CVS Pharmacy #6086 and Francis Mensah Ahenkan, 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 #6086, located at 605 Columbus Avenue, Lebanon, Ohio, has an active TDDD license with the Board under license number 02-2013650, which lists Francis Mensah Ahenkan, RPh as the Responsible Person.

#### **ALLEGATIONS**

- 1. On or about September 29, 2022, agents of the Board conducted an inspection at CVS #6086, located at 605 Columbus Avenue, Lebanon, Ohio. The following issues were found:
  - a. A file of controlled substance (Schedule II, III, IV, and V) prescriptions marked as March 2022 was found containing controlled substance prescriptions dated from March 2022 through June 2022.
  - b. A file of controlled substance (Schedule II, III, IV, and V) prescriptions marked November 27, 2021, was found containing controlled substance prescription dated February 2022.



- c. Multiple expired drugs, including Colesevelam hydrochloride 626mg, armour thyroid 2 grain tablets, quinapril 40mg tablets, and quetiapine 200mg tablets, were in the active drug stock. They had expired between June 1, 2022 and August 30, 2022.
- 2. On or about October 20, 2022, you dispensed expired heparin 5000u/mL injections to Patient A.B. Patient A.B. administered one dose of the expired heparin 5000u/mL injection.
- 3. On or about November 7, 2022, agents of the Board conducted an inspection at CVS #6086, located at 605 Columbus Avenue, Lebanon, Ohio. The following issues were found:
  - a. Multiple expired drugs, including creams and ointments, were in the active drug stock. They had expired between August 2022 and October 2022.
  - b. Multiple return to stock vials were expired.
- 4. On or about November 7, 2022, an agent spoke with Luan Dinh, RPh, Responsible Person for CVS #6086. He said he took the expired heparin back from Patient A.B. returned it and removed all expired heparin 5000u/mL from the shelves.

- 1. Such conduct as set forth in paragraphs (1)(a) and (1)(b) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-03 of the OAC, Filing and Storage of Prescriptions, all original outpatient prescriptions shall be filed in the following manner, each punishable by a maximum penalty of \$1,000:
  - a. Prescriptions for Schedule II controlled substances shall be maintained in a separate prescription file for Schedule II prescriptions, OAC Rule 4729:5-5-03(A); and/or
  - b. Prescriptions for Schedule III, IV, and V controlled substances shall be maintained in a separate prescription file for Schedule III, IV, and V prescriptions, OAC Rule 4729:5-5-03(B); and/or
  - c. Prescriptions for non-controlled substances shall be maintained in a separate prescription file for non-controlled prescriptions, OAC Rule 4729:5-5-03(C); and/or
  - d. Prescriptions containing multiple drug orders shall be filed in the most restrictive file, OAC Rule 4729:5-5-03(D).
- 2. Such conduct as set forth in paragraph (2) of the Allegations Section, if proven, constitutes a violation of section 3715.52(A) of the ORC, the adulteration or misbranding of any food, drug, device, or cosmetic, a misdemeanor of the fourth degree, punishable by a maximum penalty of \$2,000 if committed by an organization.
- 3. Such conduct as set forth in paragraph (2) of the Allegations Section, if proven, constitutes a violation of section 3715.64(A)(1), as effective March 21, 2017, Misbranded drug its labeling is false or misleading in any particular, punishable by a maximum penalty of \$1,000.

- 4. Such conduct as set forth in paragraph (2) of the Allegations Section, if proven, constitutes a violation of section 3715.64(A)(10)(a) of the ORC, as effective March 21, 2017, Misbranding, it is a drug and its container is so made, formed, or filled as to be misleading, punishable by a maximum penalty of \$1,000.
- 5. 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
  - 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).
- 6. 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).
- 7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

- b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
- c. 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)(23).
- 8. 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. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC 4729:5-2-01(E)(3); and/or
- 9. Such conduct as set forth in paragraphs (1)(c), (2)(a) and (2)(b) of the Allegation Section, if proven, each constitutes a violation of section Rule 4729:5-3-06(A) of the OAC, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons. As effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000.

**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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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

Jan Ou Schrehr

SWS/jak/kll

CMRRR: 9414 7118 9956 2006 4294 74

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



THIS IS A RED INK STAMPI certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Standard Schulch
Steven W. Schierholt, Esq., Executive Dir. Date: Aug 16, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF:

**CASE NO. A-2023-0152** 

CVS Pharmacy #6153 c/o Tiffany Olberding, RPh 2532 E. Main Street Columbus. OH 43209 License No. 02-2011600

August 16, 2023

Dear CVS Pharmacy #6153 and Tiffany Olberding, 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 #6153, located at 2532 E. Main Street, Columbus, Ohio, has an active TDDD license with the Board under license number 02-2011600, which lists Tiffany Olberding, RPh as the Responsible Person.

## **ALLEGATIONS**

- 1. On or about October 17, 2022, agents of the Board arrived at CVS #6153, located at 2532 E. Main Street, Columbus, Ohio to conduct an inspection. The following issues were found:
  - a. Pharmacy counters were cluttered and dirty.
  - b. Drug shelves were dusty and cluttered.
  - c. Pharmacy aisles were lined with stock bottles and trash (prescription inserts, foil, bits of paper).
  - d. Most staff were not wearing a nametag or had a nametag with the wrong job title.



- e. In August 2022, CVS #6183 absorbed prescriptions from CVS #342 which closed in August 2022. The pharmacy went from filling 2,500 to 2,700 prescriptions per week to filling 4,400 prescriptions the week ending October 15, 2022.
- f. The pharmacy had 102 immunizations scheduled from 2:30pm to 8:00pm with three pharmacists present. One scheduled until 5:00pm, one scheduled until 6:00pm, and one scheduled as the sole pharmacists from 6:00 to 9:00pm. 24 of the immunizations were scheduled from 6:00pm to 8:00pm.
- g. The pharmacy is dispensing between 600-800 prescriptions per day and administering up to eight or more immunizations every 15 minutes.
- h. There were 1,233 prescriptions in the work queue.
- i. Pharmacy staff stated the pharmacy had issues with the vaccination workload because of the number of vaccinations which could be scheduled. Two appointments could be made during a 15-minute window, and each of those appointments could include up to four people receiving two vaccinations each. The scheduling system should limit the number of vaccines scheduled to eight per 15-minutes.
- j. Pharmacy staff stated local staff cannot see vaccination appointments beyond the current day and did not have control over how many appointments were scheduled. Staff could cancel appointments, but do not do so because it causes additional work when the customer and corporate office inquire as to why the appointments were cancelled.
- 2. CVS #6153 did not submit a written response to the October 17, 2022 inspection within 30 days of the inspection.
- 3. On or about December 8, 2022, an agent of the Board arrived at CVS #6153 to an inspection. The following issues were found:
  - a. Pharmacy counters were cluttered and dusty.
  - b. Pharmacy sink was dirty.
  - c. Drug shelves were dusty, cluttered, and overflowing.
  - d. Pharmacy aisles were lined with stock bottles and trash (prescription inserts, foils, bits of paper, and loose pills).
  - e. Most staff were not wearing a nametag or had a nametag with the wrong job title.
  - f. There were 1,372 prescriptions in the work queue. The pharmacy dispenses an average of 700 prescriptions per day. The pharmacy was five days behind in the work queue.

- g. The pharmacy had one full-time and two part-time pharmacy technicians available. The responsible person was responsible for hiring the positions and noted difficulty in finding time to devote to the hiring process.
- h. The pharmacy was administering approximately 50 immunizations per day.

- 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)(a), (1)(b), (1)(c), (3)(a), (3)(b), (3)(c), and (3)(d) 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)(d) and (3)(e) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-5-02(G)(2) of the OAC, Minimum Standards for an outpatient pharmacy, Personnel, an employee of a pharmacy must be identified by a name tag that includes the employee's job title, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000.
- 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).

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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 2006 4644 51

cc: Brian Convery at <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>



-THIS IS A RED INK STAMP certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy. Stan a. Schiebote Steven W. Schierholt, Esq., Executive Dir. Date: Jan 26, 2024

MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF:

CASE No. A-2023-0377

License No. 02-2011650

CVS Pharmacy #6155 c/o Chase Marburger, R.Ph. 145 South State Street Westerville, OH 43081

January 26, 2024

Dear CVS Pharmacy #6155 and Chase Marburger, R.Ph.:

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, 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 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 #6155 has an active TDDD license with the Board under license number 02-2011650, which lists Chase Marburger, R.Ph. as the Responsible Person.

### **ALLEGATIONS**

1. From on or about April 30, 2023 to on or about May 11, 2023, CVS Pharmacy #6155, located at 145 South State Street, Westerville, Ohio, had a loss of 650 tramadol 50mg tablets, a Schedule IV controlled substance. On or about July 17, 2023, CVS Pharmacy #6155 submitted a Drug Enforcement Administration (DEA) 106 Form to the Board reporting the loss of 650 tramadol 50mg tablets. CVS Pharmacy #6155 was unable to determine a reason for the loss.



- 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
  - 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 if committed by an organization:
  - 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 4729.52(B)(7).
- 3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-4-01(B) of the OAC, as effective April 25, 2022, the Board may impose the sanctions as set forth in paragraph (A) of this rule for any of the following, each violation is punishable by a maximum penalty of \$1,000 if committed by an organization:
  - 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 terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7).
- 4. Such conduct as set for 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 and April 25, 2022, 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).
- 5. Such conduct as set for 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:
  - 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).

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, 17<sup>th</sup> 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 30<sup>TH</sup> DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE. Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. If you are a corporation, 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 30<sup>th</sup> day following the service of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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. Schieholt, Esq., Executive Director

SWS/jak/kll

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



THIS IS A RED INK STAMPI certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Stand Schickt
Steven W. Schierholt, Esq., Executive Dir. Date: Aug 16, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

License No. 02-2010750

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

IN THE MATTER OF: CASE NO. A-2023-0142

CVS Pharmacy #6183 c/o Ryan Young, RPh 2987 Derr Road Springfield, Ohio 45503

August 16, 2023

Dear CVS Pharmacy #6183 and Ryan Young, 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 #6183 located at 2987 Derr Road, Springfield, Ohio, has an active TDDD license with the Board under license number 02-2010750, which lists Ryan Young as the Responsible Person.

# **ALLEGATIONS**

- 1. On or about February 1, 2023, agents of the Board conducted an inspection at CVS Pharmacy #6183. The inspection revealed the following:
  - a. Nicholas Ferguson was listed as the Responsible Person on the license, effective October 21, 2022. RPh Ferguson had not worked at that location since December 30, 2022. There had not been a Responsible Person since he left on December 30, 2022.
  - b. A controlled substance inventory was last completed on April 30, 2022. A change of Responsible Person inventory was not completed when a change occurred in October 2022. A change of



Responsible Person inventory had not been completed since the former Responsible Person left in at the end of December 2022.

- c. The counters were cluttered and disorganized.
- d. Pharmacy floors were cluttered with visible debris, paper, seven bags full of trash, trash cans were overflowing, and dangerous drugs were on the floor.
- e. Approximately 38 green, CVS warehouse totes, dating back to December 13, 2022, were in the aisles waiting for drugs to be placed on shelves.
- f. Six full totes of return to stock drugs dating back to October 2022 were observed.
- g. A stack of hardcopy prescriptions was observed in a basket that have not been filed.
- h. Hard copy prescriptions dating back to October 2022 were located in a shelving bin that were not separated between Schedule II controlled substances and Schedule III-V controlled substances.

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 31, 2021, each punishable by a maximum penalty of \$1,000: 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.
- 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(B) 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 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.

- 4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022, each 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); and/or
  - c. For all locations licensed as a terminal distributor of dangerous drugs: A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC Rule 4729:5-2-01(E)(1); and/or
  - d. When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, OAC Rule 4729:5-2-01(E)(2); and/or
  - e. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC 4729:5-2-01(E)(3); and/or
- 5. Such conduct as set forth in paragraphs (3)(c), (3)(d), (3)(e), and (3)(f) of the Allegations Section, if proven, each constitutes a violation of section 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 (3)(g) and (3)(h) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-03 of the OAC, Filing and Storage of Prescriptions, all original outpatient prescriptions shall be filed in the following manner, each punishable by a maximum penalty of \$1,000:
  - a. Prescriptions for Schedule II controlled substances shall be maintained in a separate prescription file for Schedule II prescriptions, OAC Rule 4729:5-5-03(A); and/or

b. Prescriptions for Schedule III, IV, and V controlled substances shall be maintained in a separate prescription file for Schedule III, IV, and V prescriptions, OAC Rule 4729:5-5-03(B); and/or

c. Prescriptions for non-controlled substances shall be maintained in a separate prescription file for non-controlled prescriptions, OAC Rule 4729:5-5-03(C); and/or

d. Prescriptions containing multiple drug orders shall be filed in the most restrictive file, OAC Rule 4729:5-5-03(D).

7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:

a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or

c. 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

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 February 24, 2023; no additional request for a hearing is necessary. Per the previous scheduling notice, your hearing is scheduled for Wednesday, August 9, 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

Sten a. Schiebok

Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll

CMRRR: 9414 7118 9956 2006 6482 88

cc: Brian Convery at <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>



THIS IS A RED INK STAMPI certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Stand Schick
Steven W. Schierholt, Esq., Executive Dir. Date: Dec 22, 2022

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF:

**CASE NO. A-2021-0578** 

CVS Pharmacy #6268 c/o Danielle Taciuch, R.Ph. 2217 Sunset Blvd. Steubenville, OH 43952 License No. 02-2010400

December 22, 2022

Dear CVS Pharmacy #6268 and Ms. Danielle Taciuch, R.Ph.:

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.
- CVS Pharmacy #6268, located at 2217 Sunset Blvd., Steubenville, OH 43952, has an active TDDD license
  with the Board under license number 02-2010400, which lists Danielle Taciuch, R.Ph. as the Responsible
  Person.

# **ALLEGATIONS**

1. From on or about April 24, 2021 to on or about August 24, 2021, CVS Pharmacy #6268, located 2217 Sunset Blvd., Steubenville, Ohio, allowed three pharmacy technician trainees to administer immunizations they were not qualified to administer. The United States Department of Health and Human Services (HHS) Emergency Preparedness Act regarding COVID-19 pandemic gave "Qualified Pharmacy Technicians" the authorization to administer childhood as well as the COVID-19 vaccine. The State of Ohio Board of Pharmacy created a guidance document and issued it on January 19, 2021, "Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic." It states a pharmacy technician trainee does not qualify as a "Qualified Pharmacy Technician." The three unqualified



technicians administered one hundred and twenty-six (126) COVID-19 vaccine immunizations during this time.

- 1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.95(C) of the ORC, No terminal distributor of dangerous drugs shall knowingly allow any person employed or otherwise under the control of the person who owns, manages, or conducts the terminal distributor to violate division (A) of 4729.95 of the ORC, which states: No person who is not a pharmacist, pharmacy intern, registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee shall knowingly engage in any of the activities listed in section 4729.91 of the Revised Code in a location licensed as a terminal distributor of dangerous drugs, a misdemeanor of the second degree, punishable by a maximum penalty of \$4,000.
- 2. 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 22, 2020 and March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
  - a. A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code 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
  - 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
  - c. 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).
- 3. 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).

- 4. Such conduct as set forth in the Allegation Section, if proven, each constitutes a violation of the following section of Rule 4729:5-2-01(A)(2) of the OAC, as effective March 1, 2019, 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, each violation punishable by a maximum penalty of \$1,000.
- 5. 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. 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
  - d. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to other, OAC Rule 4729:5-4-01(B)(25); and/or

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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 2128 8712 74



-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.

Stander Schiebet

Steven W. Schierholt, Esq., Executive Dir.
Date: Jan 03, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL

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

IN THE MATTER OF:

**CASE NOS. A-2022-0527** 

CVS Pharmacy #7644 c/o Christian Yepgang, RPh 1785 Woodman Drive Kettering, Ohio 45420

January 3, 2023

Dear CVS Pharmacy #7644:

Inactive License No. 02-1009000

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 #7644, located 1785 Woodman Drive, Kettering, Ohio, had an active TDDD license with the Board, license number 02-1009000, which listed Christian Yepgang, RPh, as the Responsible Person. The license was inactivated, and the pharmacy was closed, on or about May 25, 2022.

## **ALLEGATIONS**

1. On or about February 11, 2022, the Board received a Report of Theft or Loss of Controlled Substances (DEA-106 Form) indicating variances in lorazepam, from CVS Pharmacy #7644, located at located 1785 Woodman Drive, Kettering, Ohio. On or about May 2, 2022, an updated Report was submitted and indicated the following significant losses of lorazepam (a Schedule IV controlled substance):

a. Lorazepam 1 mg: 2,058 tabletsb. Lorazepam .5 mg: 580 tablets



- c. Lorazepam 2 mg: 73 tabletsd. Lorazepam .5 mg: 64 tablets
- 2. On or about May 16, 2022 and June 6, 2022, an agent of the Board obtained additional information from CVS staff. Staff stated that although employee theft was suspected, video was inconclusive and due to the employees having knowledge of the daily counts of medication, it is suspected the employee(s) ceased the diversion. Once the counts started in February 2022, there were no additional losses. Additionally, it was reported by staff that deliveries of medications were not being checked in a timely manner and "control bags" would remain on the floor for several days. The cause of the significant losses was unable to be determined prior to the pharmacy's closure.

- 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. 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(B) 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 4729:5-3-14 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$500: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).
- 5. 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).
- 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 and April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

- b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
- c. 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).

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

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Steven W. Schierholt, Esq., Executive Director

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CMRRR: 9414 7118 9956 2102 1282 26



THIS IS A RED INK STAMPI certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.

Steven W. Schieholt, 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

License No. 02-2126000

IN THE MATTER OF: CASE NO. A-2021-0583

Dangerous Drugs (TDDD) under authority of Section 4729.57 of the Revised Code.

CVS Pharmacy #8248 c/o Terri Anthony, RPh 1130 Lincoln Way East Massillon, Ohio 44646

August 2, 2023

Dear CVS Pharmacy #8248 and Ms. Anthony:

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

#### **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 #8248, located at 1130 Lincoln Way East, Massillon, Ohio, has an active TDDD license with the Board under license number 02-2126000, which lists Terri Anthony, RPh as the Responsible Person.

### **ALLEGATIONS**

- 1. On or about October 12, 2021, an agent of the Board conducted an inspection at CVS pharmacy #8248, located at 1130 Lincoln Way East, Massillon, Ohio. The inspection revealed the following:
  - a. The pharmacy had 5 prescriptions total in QT (triage) awaiting data entry.
  - b. There were 2025 prescriptions (135 pages of 15 prescriptions per page) in QP (production). The oldest prescription was sitting in the queue since September 29, 2021.
  - c. There were 7 prescriptions total in QV (awaiting verification by a pharmacist).
  - d. There were 30 prescriptions in RC (provider called, refill requested). The oldest prescription was sitting in the queue since October 6, 2021.
  - e. The pharmacy would close intermittently due to understaffing. During these time periods, patients were unable to pick-up/ receive their prescriptions.



- 2. On or about November 19, 2021, agents of the Board conducted a second inspection at CVS pharmacy #8248. The inspection revealed the following, for which a written response was required or a warning was issued for the following observations:
  - a. The Responsible Person, Abbey Yannerella, was listed as the Responsible Person at this location as well as CVS #2063; however, she was no longer working at CVS #8248.
  - b. The pharmacy needed to be cleaned; numerous pills were observed on the floor and the shelves were dusty.
  - c. The drug collection receptacle outside the pharmacy barricade was observed to be so full the container could not close all the way. Agents were able to remove medications from the receptacle since it could not close and was overflowing.
- 3. On or about November 23, 2021, agents of the Board arrived at CVS Pharmacy #8248 to obtain records in relation to a prescription. The investigation revealed the following:
  - a. Patient 1's prescription, #0896297, for amlodipine 5mg was in CVS's system as "Print Ready" since November 15, 2021. It was never dispensed to Patient 1.
  - b. The pharmacist on duty stated when prescriptions are in the queue for over 14 days they are deleted from the queue. The prescription's status indicating "Print Ready" means the prescription was processed through insurance. When a prescription is deleted from the queue, the pharmacy does not reverse the insurance claim.
  - c. Patient 1 stated the following:
    - i. Patient 1 ran out of her blood pressure medication for two days.
    - ii. She contacted her doctor to request a new prescription be sent to another pharmacy. She had to have insurance perform an override to allow her to receive her prescription from the other pharmacy.
    - iii. All of her medications have been transferred to the other pharmacy.
- 4. On or about December 10, 2021, agents of the Board conducted an additional inspection. The inspection resulted in several written responses required and revealed the following:
  - a. Abbey Yannerella, RPh was still listed as the responsible person despite not working there; however, Nayan Patel, RPh stated he was the new responsible person, effective November 28, 2021.
  - b. An inventory, required whenever there is a change of responsible person, had not been completed by the new responsible person.
  - c. There were five pages of 15 prescriptions per page in QT (triage) awaiting data entry.
  - d. There were 13 prescriptions in QV1 (awaiting data entry verification by a pharmacist).
  - e. There were 59 pages of 15 prescriptions per page in QV2 (awaiting final verification by a pharmacist).
  - f. There were 112 prescriptions in PV2 (awaiting final verification by the pharmacist). These prescriptions were found stacked in baskets on the counter and on the floor.
  - g. The pharmacy deletes anything that is in their production queue (QP) for 14 days or more.
    - i. The responsible person stated the deletion of these prescriptions from the queue is a requirement from the Centers of Medicare/Medicaid. He stated these prescriptions drop back into the queue at 14 days.
    - ii. When asked to explain this process further, he could not elaborate.
- 5. On or about February 4, 2022, the Board received notification that Nayan Patel, RPh was the responsible person for CVS Pharmacy #3321. Upon discovering Mr. Patel was responsible person for two locations without receiving Board approval to do so, an agent of the Board contacted CVS District Leadership. The

District Leader notified the Board Mr. Patel is no longer the responsible person of CVS Pharmacy #8248. Mr. Patel is the responsible person of CVS Pharmacy #3321 as of February 4, 2021.

- 6. On or about March 3, 2022, an agent of the Board arrived at CVS #8248 to issue written responses required for the following violations:
  - a. Failing to change the responsible person within 10 days (the change of responsible person was submitted after the inspection, on March 4, 2022).
  - b. Failing to complete a change of responsible person inventory.
  - c. Failing to respond to the written responses issued during the November 19, 2021, and December 10, 2021, inspections.

- 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, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code 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 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 section of Rule 4729:5-5-02(G)(1) of the OAC, Minimum Standards for an Outpatient Pharmacy, as

- effective December 1, 2020: Personnel, The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code, each violation punishable by a maximum penalty of \$1,000.
- 4. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729:5-3-03(E) of the OAC, Inspections and corrective actions, as effective April 1, 2018, each violation punishable by a maximum penalty of \$1,000: The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:
  - a. The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s), Rule 4729:5-3-03(E)(1); or
  - b. An explanation disputing the observed violations, Rule 4729:5-3-03(E)(2).
- 5. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729:5-2-01(A) of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000: Except as provided in paragraph (B) of this rule, for a pharmacy licensed as a terminal distributor of dangerous drugs: Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission in accordance with paragraph (G) of this rule.
- 6. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01(E) of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000: For all locations licensed as a terminal distributor of dangerous drugs:
  - a. A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC Rule 4729:5-2-01(E)(1); and/or
  - b. When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, OAC Rule 4729:5-2-01(E)(2); and/or
  - c. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC Rule 4729:5-2-01(E)(3); and/or
  - d. 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

- e. A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site, OAC Rule 4729:5-2-01(E)(5).
- 7. 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. 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).

The Board is in receipt of your request for a hearing dated September 13, 2022; no additional request for a hearing is necessary.

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, 17<sup>th</sup> 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 30<sup>TH</sup> 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 30<sup>th</sup> 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 <a href="legal@pharmacy.ohio.gov">legal@pharmacy.ohio.gov</a> 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/alg/kll

Encl: Patient ID Key

CMRRR: 9414 7118 9956 2097 3301 54

cc: Brian Convery at <a href="mailto:Brian.Convery@CVSHealth.com">Brian.Convery@CVSHealth.com</a>



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

Stand Schick

Steven W. Schierholt, Esq., Executive Dir.
Date: Jul 24, 2023

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: CASE NOS. A-2023-0129

CVS Pharmacy #16660 c/o, Kelly Howell, RPh 9666 Olde US 20 Rossford, Ohio 43460

July 24, 2023

Dear CVS Pharmacy #16660:

License No. 02-2571050

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 #16660, located at 9666 Olde US 20, Rossford, Ohio, has an active TDDD license with the Board, license number 02-2571050, which lists Kelly Howell, RPh, as the Responsible Person.

## **ALLEGATIONS**

- 1. On or about January 4, 2022, CVS Pharmacy #16660, located at 9666 Olde US 20, Rossford, Ohio, filed an initial Report of Theft or Loss of Controlled Substances (DEA-106 Form). The report indicated the loss was discovered on November 12, 2021, and the store could not identify a reason for the loss. The investigation revealed a loss of 413 Alprazolam .5 mg tablets.
- 2. On or about April 14, 2022, an agent of the Board spoke with the CVS District Asset Protection Leader. He stated that no active/ongoing losses were discovered and the losses were due to operational error at the



pharmacy. He did not know why the losses were reported months after discovery. He reported the losses to CVS' regulatory office and the office later reported to the Board.

- 3. On or about July 12, 2022, an inspection of the pharmacy was conducted. The following drug variances were discovered by agents of the Board during a partial audit:
  - a. Alprazolam .5 mg tablets, negative 86 tablets (negative 499 including the previous loss)
  - b. Lorazepam .5 mg tablets, overage of 79 tablets
  - c. Oxycodone-apap 5-325, negative 24 tablets
  - d. Hydrocodone-apap 5-325, negative 251 tablets

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 31, 2021, each punishable by a maximum penalty of \$150: 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.
- 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(B) 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 4729:5-3-02 of the OAC, as effective October 31, 2021, each punishable by a maximum penalty of \$500:
  - a. A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location: The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss, OAC Rule 4729:5-3-02(A)(1); and/or
  - b. The theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss, OAC Rule 4729:5-3-14(B).

- 4. 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 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$500: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
  - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
  - b. 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).
- 5. 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).
- 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).

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BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schieholt, Esq., Executive Director

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