



**IN THE MATTER OF:**

**CASE NO. A-2019-0130**

**CVS Pharmacy #6178**

c/o David Lightle, RPh  
143 E. Sandusky Ave.  
Bellefontaine, OH 43311

**License No. 02-2011500**

### **SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY**

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and CVS Pharmacy #6178 for the purpose of resolving all issues between the parties relating to the error in dispensing and pharmacy practice act violations. Together, the Board and CVS Pharmacy #6178 are referred to hereinafter as “the parties.”

#### **JURISDICTION**

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. CVS Pharmacy #6178 is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2011500.

#### **FACTS**

1. The Board initiated an investigation of CVS Pharmacy #6178, Terminal Distributor of Dangerous Drugs license number 02-2011500, related to CVS Pharmacy # error in dispensing and pharmacy practice act violations.
2. On or about July 14, 2021, the Board sent a Notice of Opportunity for Hearing to CVS Pharmacy #6178, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.
3. On or about August 13, 2021, CVS Pharmacy #6178, through counsel Brian Convery, timely requested an administrative hearing, which was subsequently scheduled for January 11, 2021.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

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



## TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. CVS Pharmacy #6178 neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated July 14, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. CVS Pharmacy #6178 agrees to pay to the Board a monetary penalty the amount of \$1,500.00. This fine will be attached to the TDDD license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to [www.elicense.ohio.gov](http://www.elicense.ohio.gov) and process the items in the cart.
4. The Board hereby imposes a written reprimand on CVS Pharmacy #6178's TDDD license, number 02-2011500.
5. CVS Pharmacy #6178 agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
6. CVS Pharmacy #6178 agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by CVS Pharmacy #6178 of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to CVS Pharmacy #6178 by the Board and will NOT discharge CVS Pharmacy #6178 from any obligation under the terms of this Agreement.
7. CVS Pharmacy #6178 agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. CVS Pharmacy #6178 understands that it has the right to be represented by counsel for review and execution of this agreement.
9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom CVS Pharmacy #6178 will operate.
10. CVS Pharmacy #6178 explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.
12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.
14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.
15. This Agreement shall become effective upon the date of the Board President's signature below.

*[SIGNATURE PAGE FOLLOWS]*

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:



\_\_\_\_\_  
Leo Larviere, on behalf of,  
CVS Pharmacy #6178, Respondent

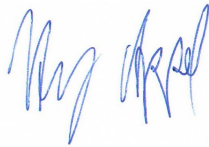
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\_\_\_\_\_  
Date of Signature

\_\_\_\_\_  
Attorney for Respondent (if applicable)



\_\_\_\_\_  
Rich Miller, RPh, President,  
State of Ohio Board of Pharmacy



\_\_\_\_\_  
Date of Signature

03.02.2022

\_\_\_\_\_  
Date of Signature

03.02.2022

\_\_\_\_\_  
Henry Appel, Ohio Assistant Attorney General

\_\_\_\_\_  
Date of Signature



**STATE OF**  
**OHIO**  
BOARD OF PHARMACY

**-THIS IS A RED INK STAMP-**  
I certify this to be a true and exact copy of  
the original document on file with the  
Ohio State Board of Pharmacy.  
*Steven W. Schierholt*  
Steven W. Schierholt, Esq., Executive Dir.  
Date: 07/14/2021  
**-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-2019-0130**

**CVS Pharmacy #6178**  
c/o David Lightle, RPh  
143 E. Sandusky Ave.  
Bellefontaine, OH 43311

**License No. 02-2011500**

July 14, 2021

Dear CVS Pharmacy #6178 and David Lightle:

**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, 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 has a current TDDD license with the Board under license number 02-2011500, which listed David Lightle as the Responsible Person during the relevant timeframes herein.

**ALLEGATIONS**

1. On or about December 5, 2018, while working at CVS Pharmacy Store #6178, Registered Pharmacy Technician April Ball performed Data Entry for Prescription#1711861 as alprazolam 2mg, "take 1 tablet by mouth every 6 hours as needed for anxiety [sic]", for a 79-year-old patient. The actual Prescription#1711861 was for Xanax 0.25mg Oral Tablet. David Lightle performed the Drug Utilization Review (DUR), where a high dose alert was displayed on the screen and was overridden. The patient had been on alprazolam 0.25mg for at least one year. The patient reported excessive drowsiness, and the dispensing error was discovered on December 6, 2018.

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

**T: (614) 466.4143 | F: (614) 752.4836 | [contact@pharmacy.ohio.gov](mailto:contact@pharmacy.ohio.gov) | [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)**



2. On or about January 8, 2019, a Board Specialist conducted an inspection of CVS Pharmacy Store #6178 and noted the following observations, which required a written response:
  - a. Three refrigerators were over-stuffed with product or stuffed with patient's medication waiting to be picked up;
  - b. The counter space where employees performed data entry and dispensing is inadequate, with large piles of paper, prescriptions, or baskets taking up the space;
  - c. Pharmacist work station was cluttered with paper, baskets, drinks, vials, bags, and left only enough space to put a basket on the counter;
  - d. The second data entry window was closed. There were piles of prescriptions that needed to be filed in this work space along with baskets of drugs.
  - e. The fax machine had various prescriptions either new or transferred out stacked in the machines and around it.
  - f. The pharmacy was short technicians due to a medical leave and an employee leaving. At 9:00 a.m., there was one pharmacist and three technicians. At 11:24 am, there was one pharmacist and 5 technicians. Within three and a half hours of being opened there were 282 prescriptions printed and 96 prescriptions verified (80 scripts an hour being counted or prepared for verification and 27 prescriptions being verified per hours). The phones have not stopped ringing, patients at pickup, and drive through. There have been noticeable times when the phones would have multiple callers and staff did not answer the phones. It was observed some of the time staff were assisting customers and other times the staff just ignored the phones. At 3:30 pm the pharmacy has a large influx of patients that come thru the drive thru and pick up window, in addition to the consistent ringing of the telephone. During this time all personnel were tied up with customers, phone, data entry, drive thru, verification, and dispensing with limited availability to assist telephone callers. It was discussed that this is the normal as local businesses are changing shift.
  - g. It was observed the RPh Lightle was not wearing his name tag, but later found a smock with the name tag and put it on. One technician was not wearing a name tag that identified that they were registered pharmacy technicians. Two technicians were not wearing name tags.
  - h. There is a large area in the back of the store where most of the drugs are stocked that the pharmacist does not have proper oversight nor are their cameras.
  - i. It was observed that pharmacy records are stored in the backroom and not within the secured cage.
  - j. The pharmacy was dirty, carpets not vacuumed, food crumbs in various corners and records in the pharmacy, clutter on every countertop in the pharmacy as well in the will call area and registers.
  - k. It was observed that temperature logs are pre-filled out for the month. Readings on the log do not match temperatures on the thermometers. The larger refrigerator had inconstant readings

between the digital thermometer and internal thermometer. One of the waiting bin refrigerators digital thermometer read 41 F, however the internal thermometer read 28 F. All freezers in the waiting bin refrigerators were frozen over.

- I. The following expired drugs were found to be commingled with drug common drug stock on the shelves:
  - i. Alora 0.075 3 boxes 10/2018
  - ii. Tri-luna 7 boxes expired 3/2018
  - iii. Brovana 15mcg/2ml 2 boxes expired 11/2018
  - iv. Sronyx expired 5/2018
  - v. Sronyx expired 1/2019 \*Birth control which is a 28-day supply- should have been removed from the shelf.
- m. The pharmacy was relying on RxNet and their "brain" for beyond use dating which was not appropriate for oral solutions pursuant to USP 795;
- n. It was observed the pharmacy codes prescriptions ex: "Magic Mouthwash", and does not put the drug name or concentration/strength on the label
- o. There were five CVS baskets, two smaller baskets of vials, and larger items on the floor that were return to stock medications.

#### **POTENTIAL VIOLATIONS OF LAW**

1. Such conduct as set forth in paragraph 1 of the Allegations section, if proven, constitutes a violation of section 3715.52(A)(2) of the ORC, the adulteration or misbranding of any food, drug, device or cosmetic, constituting a misdemeanor of the fourth degree, punishable by a maximum fine of \$2,000 if committed by an organization.
2. Such conduct as set forth in in paragraph 1 of the Allegations Section, if proven, constitutes a violation of section 3715.64(A)(1), 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 paragraph 1 of the Allegations Section, if proven, constitutes the following violation of divisions of (A)(10) of section 3715.64 of the ORC, Misbranding, each punishable by a maximum penalty of \$1,000 if committed by an organization:
  - 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 paragraph 2 of the Allegations Section, if proven, constitutes a violation of Rule 4729-9-02(E) of the OAC, each punishable by a maximum fine of \$1,000:

- a. The stock, library, and equipment shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings primarily used for the compounding and preparing of prescriptions and for the manufacture of pharmaceutical preparations, Rule 4729-9-02(E)(1) of the OAC; and/or
  - b. All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly conditions. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise indicated by the board, Rule 4729-9-02(E)(2) of the OAC; and/or
  - c. All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the OAC, Rule 4729-9-02(E)(2) of the OAC.
5. Such conduct as set forth in paragraph 2(g) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:3-3-01(A), 4729:3-3-03(A), and 4729:3-3-04(A) of the OAC, a [pharmacy technician] shall wear a name tag or badge which contains the designation ["Pharmacy Technician"], punishable by a maximum penalty of \$1,000.
  6. Such conduct as set forth in paragraph 2(g) of the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-02(G) The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.
  7. Such conduct as set forth in paragraphs 2(l)(i) through (l)(v) of the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-17 of the OAC, as effective March 1, 2017, each punishable by a maximum penalty of \$1,000: to prevent their use, adulterated drugs, as defined in rule 4729-9-01 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.
  8. Such conduct as set forth the Allegations Section, if proven, constitutes a violation of section 4729.55(D) of the ORC, adequate safeguards are assured to carry on the business of a TDDD in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner punishable by a maximum penalty of \$1,000.
  9. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of section 4729.57 of the ORC, a minor misdemeanor, each punishable by a maximum penalty of \$1,000:
    - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
    - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
    - c. Except as provided in 4729.89, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or

- d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or
  - e. Ceasing to satisfy the qualifications of a TDDD set forth in 4729.55 of the Revised Code, ORC Section 4729.57(B)(7).
6. Such conduct as set forth in the Allegations section, if proven, constitutes a violation of Rules 4729-9-19(A)(4) and (B)(3)(f) of the OAC, as effective October 5, 2015, not of good moral character and habits, punishable by a maximum fine of \$1,000.

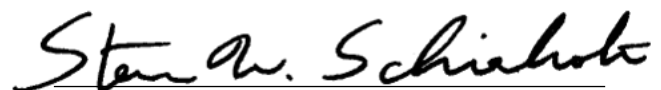
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

**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](mailto: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 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 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.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to [legal@pharmacy.ohio.gov](mailto: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/nmd/kll

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