

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

THIS SETTLEMENT AGREEMENT (“Agreement”) is between Ohio CVS Stores, LLC (“CVS”) and the State of Ohio Board of Pharmacy (“Board”) (defined below).

RECITALS

WHEREAS, CVS is a corporation with its headquarters at 1 CVS Drive, Woonsocket, Rhode Island, 02895;

WHEREAS, CVS represents that it owns and operates approximately 350 retail pharmacies in the State of Ohio, including all of the pharmacies identified or referenced in this Agreement;

WHEREAS, each retail pharmacy owned by CVS and identified or referenced in this Agreement has or had an Ohio terminal distributor of dangerous drugs (“TDDD”) license with the Board;

WHEREAS, pursuant to R.C. 4729.57 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 R.C. 4729.55 to practice as a TDDD in the State of Ohio. Additionally, R.C. 4729.57 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 Ohio Revised Code;

WHEREAS, the Board has issued twenty two (22) Notices of Opportunity for Hearing, which notices are expressly incorporated into this Agreement (“notice letters”) to the below-listed CVS retail pharmacies due to alleged violations of the Ohio Revised Code and the Ohio Administrative Code;

WHEREAS, CVS neither admits nor denies the allegations in the notices but, for the purposes of avoiding further administrative action, CVS acknowledges the representations of the Board that the Board has evidence sufficient to sustain the allegations and finds them to violate Chapter 4729. of the Ohio Revised Code and the rules promulgated thereunder in the Ohio Administrative Code, as alleged in the notice letters;

WHEREAS, CVS and the Board desire to settle and resolve their disputes as set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, agreements, warranties, and representations set forth in this Agreement, constituting consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **Definitions.** For the purposes of this Agreement, the following terms shall have the following meanings, regardless of wherein the Agreement those terms are used (i.e.,

in the recitals or in another location):

- a. “Board” means the State of Ohio Board of Pharmacy.
- b. “Covered Conduct” means:
 - i. Allegations in the notice letters issued by the Board to the CVS Settlement Stores listed in Section 1(c) of this Agreement resulting in the administrative hearing case numbers listed in Section 1(c) of this Agreement;
 - ii. With regard to Pharmacy #5364, allegations regarding identification of expired drugs in active drug stocks on April 24, 2023, May 23, 2023, and August 14, 2023;
 - iii. With regard to Pharmacy #3455, allegations regarding minimum standards violations identified during an August 2, 2023, on-site inspection and allegations regarding untimely filling of prescriptions identified during an October 24, 2023, on-site inspection; and
 - iv. Allegations regarding compliance with the requirements of Ohio Admin. Code 4729:5-5-04, as further defined in Ohio Admin. Code 4729:5-5-01(I).
- c. The “CVS Settlement Stores” include the following retail pharmacies:

Pharmacy Number	Case Number	Date(s) of Notice of Opportunity for Hearing	Location
Pharmacy #3356	Case No. A-2021-0241	August 2, 2023 (Amended), August 12, 2022 (Original)	Painesville
Pharmacy #3321	Case Nos. A-2021-0508 & A-2022-0087	January 5, 2023	Wooster
Pharmacy #6268	Case No. A-2021-0578	December 22, 2022	Steubenville
Pharmacy #8248	Case No. A-2021-0583	August 2, 2023 (Amended), August 17, 2022 (Original)	Massillon
Pharmacy #4101	Case No. A-2022-0046	December 22, 2022	Chagrin Falls
Pharmacy #4351	Case Nos. A-2022-0341 & A-2022-0572	January 11, 2023	Willoughby
Pharmacy #10246	Case Nos. A-2022-0453 & A-2023-0419	August 2, 2023 (Amended), December 22, 2022 (Original) November 28, 2023	Toledo

Pharmacy #3404	Case Nos. A-2022-0508 & A-2023-0362	November 28, 2023, and November 28, 2023	Xenia
Pharmacy #7644	Case No. A-2022-0527	January 3, 2023	Kettering
Pharmacy #2528	Case Nos. A-2022-0533 & A-2022-0671	August 2, 2023 (Amended), March 31, 2023 (Amended), February 9, 2023 (Original) and August 2, 2023 (Amended), March 31, 2023 (Original)	Dayton
Pharmacy #4348	Case No. A-2022-0565	January 11, 2023	Willoughby Hills
Pharmacy #1756	Case No. A-2022-0570	August 2, 2023 (Amended), February 15, 2023 (Original)	Reynoldsburg
Pharmacy #16660	Case No. A-2023-0129	July 24, 2023	Rossford
Pharmacy #6183	Case No. A-2023-0142	August 16, 2023	Springfield
Pharmacy #6153	Case No. A-2023-0152	August 16, 2023	Columbus
Pharmacy #6086	Case No. A-2023-0136	August 16, 2023	Lebanon
Pharmacy #3393	Case No. A-2023-0236	November 28, 2023	Aurora
Pharmacy #3467	Case No. A-2023-0341	January 16, 2024	Dayton
Pharmacy #4401	Case No. A-2023-0491	January 26, 2024	Dayton
Pharmacy #6155	Case No. A-2023-0377	January 26, 2024	Westerville
Pharmacy #3455	n/a	n/a	Coshocton
Pharmacy #5364	n/a	n/a	Germantown

- d. “Released Claims” means any and all administrative claims of any nature that were brought or could have been brought by the Board against the Settlement Stores relating to or arising out of Covered Conduct identified in Section 1(b)(i) through 1(b)(iii) of this Agreement and all claims that could have been brought by the Board against all licensed TDDD locations relating to or arising out of Covered Conduct identified in Section 1(b)(iv) of this Agreement.
- e. “Releasers” means CVS and all of its officials, members, subsidiary or affiliate corporations or other organizations and entities, servants, agents, employees, parents, successors, and assigns, and also each CVS Settlement Store identified in Section 1(c) of this Agreement.
- f. “Selected Pharmacies” means CVS Pharmacy numbers 1756, 2528, 3321, 3455, 6153, 6183, 8248, and 10246.
- g. “Virtual Verification” is a method by which a pharmacist conducts final product verification through viewing of images of the product and labeling in lieu of

physical examination by manual manipulation of the drug product.

2. **Recitals.** The recitals form a part of this Agreement.

3. **Obligations of CVS.**

a. Monetary Penalty:

- i. Within 30 days of the Effective Date of this Agreement, CVS will pay the Board \$1,250,000. For payment purposes, this fine will be attached to the license record for Pharmacy #10246. To pay this fine CVS must log in to www.license.ohio.gov and process the items in the cart. Alternatively, if paying by check, it can be mailed or physically brought to the Board Office M – F; 9:00am – 5:00pm. Checks must be certified, or a cashier’s check, made payable to ‘**Ohio Treasurer of State.**’ CVS and the Board Staff may agree in writing to an alternative payment method. If CVS fails to pay this sum within 30 days of the Effective Date of this Agreement, interest will accrue, beginning on the 31st day after the Effective Date of this Agreement, at the rate of 5% per year.

b. Probation:

- i. The Board will place the Selected Pharmacies on probation for a three-year period, beginning on the Effective Date of this Agreement and ending at 12:00 am EST, on the third anniversary of the Effective Date of this Agreement.
- ii. During this three-year probationary period, the Selected Pharmacies must comply with all laws and regulations governing the practice of pharmacy in the State of Ohio. During the three-year probationary period after the Effective Date, any violation of Section 3(e) of this Agreement, or any state or federal statute or regulation governing the practice of pharmacy in the State of Ohio, by any Selected Pharmacy may result in the issuance of a notice letter and additional disciplinary action, including and up to revocation of the TDDD license with respect to that Selected Pharmacy.

c. Additional Monitoring:

- i. In addition to the penalty specified in Section 3(a)(i) of this Agreement, CVS will pay approximately \$83,333 per year, for each of the next three years after the Effective Date, to the Board to cover the cost of enhanced monitoring by the Board, for a total additional penalty of \$250,000. This cost will be attached to the license record for Pharmacy #10246. To pay this, CVS must log in to www.license.ohio.gov and process the items in the cart. Alternatively, if paying by check, it can be mailed or physically brought to the Board Office M – F; 9:00am – 5:00pm. Checks must be

certified, or a cashier's check, made payable to 'Ohio Treasurer of State.' The first payment of \$83,334 must be received within 30 days of the Effective Date, the second payment of \$83,333 must be received on the first anniversary of the Effective Date, and the final payment of \$83,333 must be received by the second anniversary of the Effective Date. Any late payments will accrue interest beginning on the day after the payment is due, at the rate of 5% per year.

d. Compliance Liaison:

- i. CVS shall appoint an Ohio Compliance Liaison, who shall be a licensed Ohio pharmacist, to act as a channel for communications between the Board and CVS regarding compliance with state and federal pharmacy laws and rules. The appointment of the named Ohio Compliance Liaison is subject to Board approval, which shall not be unreasonably withheld.
- ii. For the period of probation, the Compliance Liaison shall be reasonably available to Board inspectors and staff and will receive copies of all pharmacy inspections conducted by the Board. The Compliance Liaison shall attend Board meetings upon request of the Board or the Board's probation committee.

e. Compliance with Proposed Administrative Rules:

- i. Within forty-five (45) days of the Effective Date, the CVS Settlement Stores will comply with proposed Ohio Adm.Code 4729:5-5-02.1, 4729:5-5-02.3, and 4729:5-5-02.4 ("Proposed Rules") (attached as Exhibit A), until such time that the Proposed Rules become final. At that time, all CVS stores in Ohio will comply with the final adopted Rules package.

f. Withdrawal of request for hearing:

- i. CVS withdraws all requests for pending administrative hearings regarding the CVS Settlement Stores that have received notices of opportunity for hearing as listed in Section 1(c) of this Agreement. Each CVS Settlement Store that has received a notice of opportunity for an administrative hearing before the Board hereby 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 from such a hearing or the lack of such a hearing.
- ii. CVS also agrees not to request an administrative hearing regarding CVS store numbers 3455, and 5364 for any Covered Conduct.

g. Positive Identification:

- i. On December 6, 2021, the Board determined that CVS's electronic method

of capturing positive identification “[did] not meet secure means of personal identification” CVS was ordered by the Board to comply with Ohio’s positive identification rules—including Ohio Adm.Code 4729:5-5-04—within six months of the Board’s decision (June 6, 2022). ([R-2022-0289](#))

- ii. On December 5, 2022, the Board rejected CVS’s Proposal on an Alternative Method for Positive Identification which requested that CVS be permitted to capture positive identification via an electronic end-of-day report with a signed paper attestation ([R-2023-0137](#)). The Board did not extend the time, which had lapsed, for CVS to comply with Ohio Adm.Code 4729:5-5-04.
- iii. Thus, CVS acknowledges that the Board has determined that CVS’s current system of positive identification is not compliant with the requirements of Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I).
- iv. In lieu of the Board pursuing administrative action against CVS for violations of Ohio Adm.Code 4729:5-5-04, CVS will make changes to its current electronic positive identification system to address compliance with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), at all licensed TDDD locations within fifteen (15) months of the Effective Date of this Agreement. The Board shall make the final determination as to whether CVS is in compliance with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01.
- v. If the Board determines that CVS is not compliant with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), within fifteen (15) months of the Effective Date of this Agreement, the Board will issue a reasoned determination and may assess an additional fine of one hundred thousand dollars (\$100,000).
- vi. If the Board determines that CVS is still not compliant with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), within sixteen (16) months of the Effective Date of this Agreement, the Board will issue a reasoned determination and may assess an additional fine of fifty thousand dollars (\$50,000).
- vii. If the Board determines that CVS is still not compliant with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), within seventeen (17) months of the Effective Date of this Agreement, the Board will issue a reasoned determination and may assess an additional fine of fifty thousand dollars (\$50,000).
- viii. If the Board determines that CVS is still not compliant with Ohio

Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), within eighteen (18) months of the Effective Date of this Agreement, the Board will issue a reasoned determination and may assess an additional fine of one hundred and fifty thousand dollars (\$150,000). For every month thereafter that the Board determines that CVS is non-compliant with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), the Board will issue a reasoned determination and may assess an additional one hundred and fifty thousand dollars (\$150,000) each month the Board determines CVS is not compliant.

- ix. CVS may request, and the Board agrees to consider, a tolling of the dates set out in Section 3(g)(iv)–(viii) of this Agreement for documented delays in the completion of the obligation set out in Section 3(g)(iv) of this Agreement caused by government orders; pandemic; or public health emergencies; and any similar events that impact the work or otherwise cause delay beyond the control of CVS and which could not have reasonably been foreseen. CVS may submit any request for a tolling of the timelines, as well as any supporting documentation, to the Board in writing, and the Board agrees to grant any reasonable requests and has sole discretion as to whether a request is reasonable and whether to grant any requested tolling.

h. Virtual Verification:

- i. CVS acknowledges that Virtual Verification is not authorized for use at any terminal distributor of dangerous drug locations in the State of Ohio absent Board approval. CVS represents that it is not currently using Virtual Verification in the State of Ohio and will not begin to utilize such a system unless and until it is authorized to do so by the Board.

4. **Obligations of the Board.**

- a. Consistent with Section 3(g) of this Agreement, the Board will forego acting against CVS for violations of Ohio Adm.Code 4729:5-5-04, in exchange for CVS ensuring compliance with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01(I), at all licensed terminal distributors of dangerous drugs within fifteen (15) months of the Effective Date of this Agreement as stated in Section 3(g) of this Agreement. On the date that is fifteen months from the Effective Date of this Agreement, the Board may make the determination as to whether CVS is in compliance with Ohio Adm.Code 4729:5-5-04, as further defined in Ohio Adm.Code 4729:5-5-01.
- b. The Board agrees to forego issuing notice letters against CVS Pharmacy numbers 3455, and 5364 for Covered Conduct.

5. **Representations and Warranties.**

- a. CVS represents and warrants that:
 - i. It has completely read the agreement and fully understands all such terms, and has been represented by counsel of its choice in the negotiation of this Agreement;
 - ii. It has the full right, power, and authority to enter into this Agreement and to perform all obligations thereunder;
 - iii. It has obtained in writing, as of the Effective Date of this Agreement, consent or permission required from any third party; and
 - iv. The individual executing this Agreement on behalf of CVS has the requisite power and authority to cause this matter to be settled on its own behalf, and on behalf of each and every Releasor and each and every CVS Settlement Store, in accordance with the terms of this Agreement.

6. **Releases.**

- a. The Board agrees to release the Released Claims and any liabilities, causes of action, fees (including attorney fees), costs, expenses, or damages (including consequential or incidental damages) arising directly or indirectly from the Released Claims. Releasors agree to release the Board from any liabilities, causes of action, fees (including attorney fees), costs, expenses, or damages (including consequential or incidental damages) arising directly or indirectly from the Released Claims.
- b. Notwithstanding anything in this Agreement, CVS has the right to defend against any lawsuit or administrative action that the State of Ohio or the Board, or that any other claimant or plaintiff without limitation, may bring against it after the Effective Date of this Agreement.
- c. Notwithstanding anything in this Agreement, CVS has the right to defend against any lawsuit or administrative action that the State of Ohio or the Board, or that any other claimant or plaintiff without limitation, may bring against it with respect to any investigation or civil, criminal, or administrative action against CVS or any CVS Settlement Store based on an alleged violation of any state or federal law or rule other than Covered Conduct.
- d. Nothing in this Agreement binds the State of Ohio or any other state agency, department, board, commission, or other state entity.
- e. Nothing in this Agreement prevents, impairs, or affects the Board's ability or authority to bring any investigation or civil, criminal, or administrative action against CVS or any CVS Settlement Store based on an alleged violation of any

state or federal law or rule other than Covered Conduct.

7. **Inadmissibility**. This Agreement is not, and is not intended to be, admissible against CVS in any suit or action, in any judicial, administrative or other forum, by any claimant or plaintiff other than in an action by the Board to enforce this Agreement.
8. **Binding Agreement**. This Agreement shall be binding upon, and insure to the benefit of, the successors and assigns of the Board, CVS, and each and every CVS Settlement Store.
9. **Fees and Costs**. Each party to this Agreement hereby waives all rights to seek attorney fees and/or costs in connection with Covered Conduct and agrees to pay its own court fees, expenses, and other costs it incurred as a result of, or that may have arisen out of, the administrative hearings.
10. **Notices**. All notices provided under this Agreement shall be in writing. Notice shall be provided either by: i) email; ii) hand delivery; or iii) registered or certified mail, return receipt requested, postage prepaid, and shall be addressed to the following:

If to the Board:

Attn: The State of Ohio Board of Pharmacy
c/o Legal Department
77 S. High St., 17th Floor
Columbus, OH 43215
Legal@pharmacy.ohio.gov

If to CVS, any Selected Pharmacies, and/or any CVS Settlement Store:

Attn: Ohio CVS Stores, LLC
c/o Thomas S. Moffatt, President
1 CVS Drive
Mail Code 2325
Woonsocket, RI 02895
RxRegulatory@CVSHelath.Com
Thomas.Moffatt@CVSHealth.Com


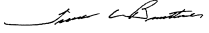
With a copy to:
Ice Miller LLP
250 West Street, 7th Floor
Columbus, OH 43215
Attn. Kristina Dahmann
Kristina.Dahmann@IceMiller.Com

11. **Choice of Law and Venue**. This Agreement shall be construed and interpreted in accordance with the laws of the State of Ohio, without regard to whether another result

would otherwise be required by application of choice-of-law principles. Any action regarding the enforcement or breach of this Agreement shall be filed as a breach of contract action in a court of competent jurisdiction in Franklin County, Ohio.

12. **Binding Effect.** This Agreement shall be binding upon the parties and their respective personal representatives, heirs, executors, successors and assigns and the parties agree that the Agreement and its terms are supported by full and adequate consideration.
13. **Entire Agreement.** This Agreement represents the sole and entire agreement between the parties and supersedes all prior written and oral negotiations, agreements, and understandings between the parties related to the Covered Conduct. No party to this Agreement has been induced to enter into this Agreement by any representation or inducement except those expressly set forth in this Agreement. This Agreement may be modified or amended only by a written instrument executed by all of the parties to this Agreement.
14. **Severability.** 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. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties so the transactions contemplated can be consummated as originally contemplated to the greatest extent possible.
15. **No Party Deemed to be the Drafter.** Neither of the parties hereto shall be deemed to be the drafter of this Agreement or any provision hereof for the purpose of any statute, case law or rule of interpretation or construction that would or might cause any provision to be construed against the drafter hereof.
16. **Amendment; Waiver.** This Agreement shall not be modified in any respect except by a writing executed by CVS and the Board. The waiver by any party of any breach of this Agreement shall not be deemed or construed to be a waiver of any other breach, whether prior, subsequent, or contemporaneous, of this Agreement.
17. **Public Record.** All parties to this Agreement understand that this document is a public record pursuant to R.C. 149.43.
18. **Effective Date.** This Agreement becomes effective immediately on the date of the last signature below.
19. **Counterparts.** This Agreement may be signed in counterparts which, taken together, shall constitute a single binding and enforceable agreement. Copies of signatures that are transmitted electronically via PDF are acceptable in lieu of original signatures.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the dates shown below.

Ohio CVS Stores, L.L.C.	The State of Ohio Board of Pharmacy
 Thomas S. Moffatt President	 Trina Buettner, R.Ph., President The State of Ohio Board of Pharmacy
2/28/24 Date	02.29.2024 Date

4729:5-5-02.1

Provision of Ancillary Services in an Outpatient Pharmacy.

- (A) As used in this rule, “ancillary services” are those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs. Examples of such services include, but are not limited to, immunizations, drug administration, medication therapy management, disease state management, and refill reminders.
- (B) In accordance with division (D) of section 4729.55 of the Revised Code, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not establish any productivity or production quotas relating to the provision of ancillary services.
- (1) For purposes of this rule, “quota” means a fixed number or formula related to the duties of pharmacy personnel, against which the pharmacy or its agent measures or evaluates the number of times either an individual performs tasks or provides services while on duty.
- (2) For purposes of this rule, “quota” does not mean any of the following:
- (a) A measurement of the revenue earned by a pharmacy not calculated in relation to, or measured by, the tasks performed, or services provided by pharmacy personnel.
 - (b) Any evaluation or measurement of the competence, performance, or quality of care provided to patients of pharmacy personnel if the evaluation does not use quotas.
 - (c) Any performance metric required by state or federal regulators.
- (C) This rule does not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies).

4729:5-5-02.1

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Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	4729.26
Rule Amplifies:	4729.54, 4729.55

4729:5-5-02.3**Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy.**

- (A) An outpatient pharmacy shall develop a process for pharmacy staff to communicate requests for additional staff or reports of staffing concerns. Requests for additional staff or reports of staffing concerns shall be communicated and documented by the responsible person or pharmacist on duty to the terminal distributor.
- (B) Executed requests for additional staffing or reports of staffing concerns shall be provided to the immediate supervisor of the responsible person or pharmacist on duty, with one copy maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.
- (C) Outpatient pharmacies licensed as terminal distributors of dangerous drugs shall review all requests and reports of concern submitted in accordance with this rule and shall resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff as required by section 4729.55 of the Revised Code. A written response to the request or report of concern shall occur within fourteen business days of submission and be communicated to the responsible person or pharmacy staff who submitted the request for additional staffing or report of concern. A copy of this response shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.
- (D) An outpatient pharmacy shall not retaliate or discipline a pharmacist who, in good faith, makes a request for additional staff or reports staffing concerns in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:
- (1) Removing or suspending the employee from employment;
 - (2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
 - (3) Transferring or reassigning the employee;
 - (4) Denying the employee a promotion that otherwise would have been received;
 - (5) Reducing the employee in pay or position.

4729:5-5-02.3

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Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	4729.26
Rule Amplifies:	4729.54, 4729.55

4729:5-5-02.4

Significant Delays in the Provision of Pharmacy Services.

(A) An outpatient pharmacy has a duty to properly dispense lawful prescriptions for dangerous drugs or devices without significant delay.

(1) For purposes of this rule, "significant delay" means a prescription that was submitted to the pharmacy for processing by a prescriber, patient, or caregiver and has yet to be dispensed (e.g., final verification) by a pharmacist as follows:

(a) For new prescriptions: within three business days of receiving the prescription.

(b) For refill prescriptions not generated by a pharmacy auto-refill program: within three business days of receiving the prescription.

(c) For refill prescriptions generated by a pharmacy auto-refill program: within five business days of receiving the prescription.

(2) Receipt of the prescription as described in paragraph (A)(1) of this rule is said to occur:

(a) For new prescriptions: receipt occurs on the day when the prescription is transmitted or submitted to the pharmacy.

(b) For refills on existing prescriptions: receipt occurs on the day when a refill request is submitted to the pharmacy by a patient, caregiver, or prescriber or when a refill request is generated as part of a pharmacy's auto-refill program.

(3) For purposes of this rule, "significant delay" does not mean any of the following:

(a) A prescription that has been submitted to the pharmacy but where there is a documented drug shortage, or the pharmacy documents the drug is not available from the pharmacy's drug distributor.

(b) A prescription that has been submitted to the pharmacy that requires clarification or consultation by the issuing prescriber.

(c) A prescription that has been submitted to the pharmacy that requires prior authorization or is otherwise delayed because of the patient's prescription insurance coverage.

4729:5-5-02.4

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- (d) A prescription that is for a compounded drug product.
 - (e) A prescription that the pharmacist, using their professional judgement, determines is of questionable, doubtful, or suspicious origin.
 - (f) A prescription that, in the pharmacist's professional judgment, if dispensed, cannot be safely provided or may negatively impact patient care.
 - (g) A prescription where the prescriber indicates a "do not fill until" date or similar designation.
 - (h) A prescription where the patient, caregiver, or issuing prescriber has communicated to the pharmacy that dispensing may occur beyond the period described in paragraph (A)(1) of this rule.
 - (i) A prescription where the patient, caregiver, or issuing prescriber has requested a transfer to another pharmacy.
 - (j) A prescription where the pharmacy has experienced any of the following:
 - (i) A natural disaster (fire, flood, etc.), civil unrest, or human made disaster;
 - (ii) An outbreak of a pandemic illness or the declaration of a state or federal public health emergency;
 - (iii) A loss of power; or
 - (iv) An unplanned information technology system outage.
 - (k) Any other circumstance as determined by the board.
- (B) Each prescription that experiences a significant delay, as defined in paragraph (A) of this rule, shall be considered a violation of this rule and shall subject the outpatient pharmacy to disciplinary action in accordance with rule 4729:5-4-01 of the Administrative Code.
- (C) Immediately upon discovery or at the request of an agent, inspector, or employee of the board, a pharmacy experiencing a significant delay shall implement one or more of the following remediation measures to dispense all prescriptions that are experiencing a significant delay:
- (1) Limiting pharmacy hours (e.g., dark hours);
 - (2) Transferring prescriptions to another pharmacy, upon patient consent;

4729:5-5-02.4

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(3) Increasing pharmacy staff; or

(4) Any other strategy that is mutually agreed upon by the outpatient pharmacy and the agent, inspector, or employee of the board.

(D) As part of the remediation process required in paragraph (C) of this rule, the outpatient pharmacy shall implement a process that triages lifesaving and life-sustaining medications that are experiencing a significant delay.

(E) As used in this rule, "business day" means any day, excluding holidays, where the pharmacy is open for business.

(F) An outpatient pharmacy shall only provide auto-refills of a prescription upon the authorization of the patient or the patient's caregiver.

(1) The pharmacy shall maintain documentation indicating the patient or the patient's caregiver has enrolled in the pharmacy's auto-refill program.

(2) Consent for enrollment in the pharmacy's auto-refill program may be captured electronically, verbally by pharmacy staff, or in writing.

(3) The pharmacy shall maintain a record of consent in the patient's profile, or another system maintained by the pharmacy, in a readily retrievable manner. As part of this record, the pharmacy shall document the date the patient or caregiver consented to enrollment in the pharmacy's auto-refill program.

(4) The pharmacy shall discontinue enrollment in an auto-refill program upon the request of the patient or the patient's caregiver.

4729:5-5-02.4

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Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	4729.26
Rule Amplifies:	4729.54, 4729.55



-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: 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 NO. A-2023-0419

CVS Pharmacy #10246

License No. 02-2348950

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.

ALLEGATIONS

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.

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- 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, 2023 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.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
- a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or
 - b. A pharmacist, licensed health professional authorized to prescribe drugs, or other person authorized by the board, animal shelter or county dog warden licensed under section 4729.531 of the Revised Code, or a laboratory will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or
 - d. Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns

employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC 4729.55(D).

2. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective 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).

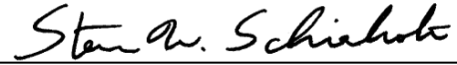
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

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 legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll

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



**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.

ALLEGATIONS

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 an 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.

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- 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.
 - l. 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 an 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 an 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 an 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 an 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.
 - l. 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 an 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.
 - i. 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 an 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.
 - l. 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 medications 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.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
 - a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or
 - b. A pharmacist, licensed health professional authorized to prescribe drugs, or other person authorized by the board, animal shelter or county dog warden licensed under section 4729.531 of the Revised Code, or a laboratory will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or
 - d. Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns

employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC 4729.55(D).

2. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 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 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).
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
 - 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); 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).

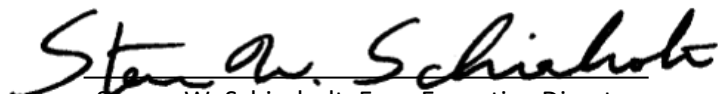
10. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020, each violation punishable by a maximum penalty of \$1,000:
 - a. All terminal distributors 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 legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY


Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll

CMRRR: 9414 7118 9956 2097 3433 83

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