

**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


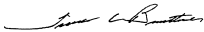
With a copy to:
Ice Miller LLP
250 West Street, 7th Floor
Columbus, OH 43215
Attn. Kristina Dahmann
Kristina.Dahmann@IceMiller.Com

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;

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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



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

IN THE MATTER OF:

**CASE NO. A-2022-0533
A-2022-0671**

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

License No. 02-2014300

August 2, 2023

Dear CVS Pharmacy #2528:

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

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to section 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
2. CVS Pharmacy #2528 located at 2801 Far Hill Ave., Dayton, Ohio, has an active TDDD license with the Board under license number 02-2014300, which lists Jesse Keller as the Responsible Person.

ALLEGATIONS

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

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

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

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55(D) of the ORC, effective March 22, 2020 and March 31, 2021, each punishable by a maximum penalty of \$1,000: Adequate safeguards are assured to carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.
2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
 - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
 - c. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or
 - d. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).
3. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729:5-5-02(G)(1) of the OAC, Minimum Standards for an Outpatient Pharmacy, as effective December 1, 2020: Personnel, The pharmacy shall be appropriately staffed to operate in a safe

and effective manner pursuant to section 4729.55 of the Revised Code, each violation punishable by a maximum penalty of \$1,000.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14 of the OAC, as effective March 1, 2020, each punishable by a maximum penalty of \$1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to:
 - a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
 - b. Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).
5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017, each punishable by a maximum penalty of \$1,000: All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion, OAC Rule 4729-9-05(A).
6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, each punishable by a maximum penalty of \$1,000:
 - a. The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(A)(2); and/or
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and/or
 - c. For all locations licensed as a terminal distributor of dangerous drugs: A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC Rule 4729:5-2-01(E)(1); and/or
 - d. When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code, OAC Rule 4729:5-2-01(E)(2); and/or

- e. A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs, OAC 4729:5-2-01(E)(3); and/or
 - f. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or
 - g. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).
7. Such conduct as set forth in the Allegation Section, if proven, each constitutes a violation of section Rule 4729-5-27(C) of the OAC, Record Keeping, All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours, as effective January 20, 2015, each violation punishable by a maximum penalty of \$1,000.
 8. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
 - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
 - c. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or
 9. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
 - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
 - c. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or

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

The Board is in receipt of your request for a hearing dated February 24, 2023; no additional request for a hearing is necessary.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY


Steven W. Schierholt, Esq., Executive Director

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