ORDER OF THE OHIO BOARD OF PHARMACY
Case Numbers A-2025-0032; A-2025-0034; A-2025-0036

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 12/15/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

In The Matter Of:

Schwieterman's Drug Store, Inc. (Coldwater)
Case No. A-2025-0032
404 W. North St.
Coldwater, OH 45828
License No. 02-0165150

Schwieterman's Drug Store, Inc. (New Bremen)
Case No. A-2025-0034
2 North Washington St.
New Bremen, OH 45869
License No. 02-0125900

Schwieterman's Drug Store, Inc. (Minster)
Case No. A-2025-0036
324 N. Main St.
Minster, OH 45865
License No. 02-0598000

INTRODUCTION

On April 28, 2025, the Ohio Board of Pharmacy ("Board") issued Notices of Opportunity for Hearing to Schwieterman's Drug Store (Coldwater), Schwieterman's Drug Store (New Bremen, and Schwieterman's Drug Store (Minster) ("Respondents"). The Notice was served on Respondents' owner Dale Bertke via traceable electronic mail on or about May 22, 2025. Pursuant to Ohio Revised Code Section 119.07, Respondent had a right to a hearing if requested within thirty days of service of the Notice. Respondent failed to request a hearing by the thirtieth and final day. Accordingly, as no hearing was requested, the matter came before the Board under the authority of *Goldman v. State Med. Bd. of Ohio*, 110 Ohio App.3d 124, 129 (10th Dist.1996) on December 9, 2025, before the following members of the Ohio Board of Pharmacy (Board): Jeff Huston, RPh, *Presiding*; Jason George, RPh, *Vice President*; Anthony Buchta, Sr., RPh; Trina Buettner, RPh; Mindy Ferris, RPh; T.J. Grimm, RPh; Leonard Hubert, *Public Member*; Rich Miller, RPh; and Thomas Whiston, RPh.

Respondent was not present. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Sarah Nash, Board Compliance Specialist

Respondent's Witnesses:

1. None.

State's Exhibits:

1a. Notice Letter #1 -- Schwieterman's Drug Store (Coldwater)

1b. Confidential Patient Key (*filed under seal)

1c. Notice Letter #2 -- Dale Bertke

1d. Confidential Patient Key (*filed under seal)

2. First Inspection (June 2023)

3. Records for Patients 1 and 2 (*filed under seal)

4. Email -- 8-8-2023

5. Email -- 8-24-2023

6. Second Inspection (August 2023)

7. Third Inspection (October 2023)

8. Response to Third Inspection

9. Records for Patient 3 (*filed under seal)

10. Records for Patient 4 (*filed under seal)

11. Records for Patient 5 (*filed under seal)

12. Records for Patient 6 (*filed under seal)

13. Fourth Inspection (August 2024)

14. Fifth Inspection (September 2024)

15. Sixth Inspection (October 2024)

16. E-mail 9/6/2023

17. Omitted

18. Omitted

19. Omitted

20a. Notice Letter #3 -- Dale Bertke

20b. Notice Letter #4 -- Schwieterman's Drug Store (Coldwater)

20c. Notice Letter #5 -- Schwieterman's Drug Store (Minster)

20d. Notice Letter #6 -- Schwieterman's Drug Store (New Bremen)

20e. Service for Notice Letters #3-#6

21. Facebook Post -- 12-17-2024

22. Facebook Post -- 12-25-2024

23. Discontinuation of Business Notice (New Bremen)

24. Discontinuation of Business Notice (Minster)

25. E-mail -- 12-26-2024.

Respondent's Exhibits:

A. None.

FINDINGS OF FACT

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds and adopts as its Findings of Fact:

1. Allegations 1 through 3, inclusive, as set forth in the Notice of Opportunity for Hearing, dated April 28, 2025, in Case No. A-2025-0032;

2. Allegation 1, as set forth in the Notice of Opportunity for Hearing, dated April 28, 2025, in Case No. A-2025-0034;

3. Allegation 1, as set forth in the Notice of Opportunity for Hearing, dated April 28, 2025, in Case No. A-2025-0036.

CONCLUSIONS OF LAW

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds and adopts as its Conclusions of Law:

1. Violations of law 1 through 4, inclusive, as set forth in the Notice of Opportunity for Hearing, dated April 28, 2025, in Case No. A-2025-0032;

2. Violations of law 1 through 4, inclusive, as set forth in the Notice of Opportunity for Hearing, dated April 28, 2025, in Case No. A-2025-0034;

3. Violations of law 1 through 4, inclusive, as set forth in the Notice of Opportunity for Hearing, dated April 28, 2025, in Case No. A-2025-0036.

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and after consideration of the record as a whole, the Ohio Board of Pharmacy imposes a written reprimand and a monetary penalty in the amount of $500.00 on each of Respondent TDDD license nos. 02-0165150 (Coldwater), 02-0125900 (New Bremen), and 02-0598000 (Minster).

These fines will be attached to Respondents' license record and must be paid no later than six months from the effective date of this Order. To pay this fine Respondents must login to www.elicense.ohio.gov and process the items in the cart of the owner, Dale Bertke.

Ms. Ferris moved for Findings of Fact; Mr. Grimm seconded the motion. Motion passed (Yes-8/No-0).

Ms. Ferris moved for Conclusions of Law; Mr. Grimm seconded the motion. Motion passed (Yes-8/No-0).

Ms. Ferris moved for Action of the Board; Mr. Grimm seconded the motion. Motion passed (Yes-8/No-0).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin county. Such notices of appeal shall be filed within fifteen (15) days after the service of the notice of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE OHIO BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **December 15, 2025**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/zas/rlj

ORDER OF THE OHIO BOARD OF PHARMACY
Case Numbers A-2024-0014; A-2024-0023

In The Matter Of:

Schwieterman's Drug Store, Inc.
404 W. North St.
Coldwater, OH 45828
License No. 02-0165150

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 12/15/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

INTRODUCTION

On December 23, 2024, the Ohio Board of Pharmacy ("Board") issued a Notice of Opportunity for Hearing to Schwieterman's Drug Store (Coldwater) ("Respondent"). The Notice was served on Respondent's owner Dale Bertke via traceable electronic mail on or about March 14, 2025. Pursuant to Ohio Revised Code Section 119.07, Respondent had a right to a hearing if requested within thirty days of service of the Notice. Respondent failed to request a hearing by the thirtieth and final day. Accordingly, as no hearing was requested, the matter came before the Board under the authority of *Goldman v. State Med. Bd. of Ohio*, 110 Ohio App.3d 124, 129 (10th Dist.1996) on December 9, 2025, before the following members of the Ohio Board of Pharmacy (Board): Jeff Huston, RPh, *Presiding*; Jason George, RPh, *Vice President*; Anthony Buchta, Sr., RPh; Trina Buettner, RPh; Mindy Ferris, RPh; T.J. Grimm, RPh; Leonard Hubert, *Public Member*; Rich Miller, RPh; and Thomas Whiston, RPh.

Respondent was not present. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Sarah Nash, Board Compliance Specialist

Respondent's Witnesses:

1. None.

State's Exhibits:

1a. Notice Letter #1 -- Schwieterman's Drug Store (Coldwater)

1b. Confidential Patient Key (*filed under seal)

1c. Notice Letter #2 -- Dale Bertke

1d. Confidential Patient Key (*filed under seal)

2. First Inspection (June 2023)

3. Records for Patients 1 and 2 (*filed under seal)

4. Email -- 8-8-2023

5. Email -- 8-24-2023

6. Second Inspection (August 2023)

7. Third Inspection (October 2023)

8. Response to Third Inspection

9. Records for Patient 3 (*filed under seal)

10. Records for Patient 4 (*filed under seal)

11. Records for Patient 5 (*filed under seal)

12. Records for Patient 6 (*filed under seal)

13. Fourth Inspection (August 2024)

14. Fifth Inspection (September 2024)

15. Sixth Inspection (October 2024)

16. E-mail 9/6/2023

17. Omitted

18. Omitted

19. Omitted

20a. Notice Letter #3 -- Dale Bertke

20b. Notice Letter #4 -- Schwieterman's Drug Store (Coldwater)

20c. Notice Letter #5 -- Schwieterman's Drug Store (Minster)

20d. Notice Letter #6 -- Schwieterman's Drug Store (New Bremen)

20e. Service for Notice Letters #3-#6

21. Facebook Post -- 12-17-2024

22. Facebook Post -- 12-25-2024

23. Discontinuation of Business Notice (New Bremen)

24. Discontinuation of Business Notice (Minster)

25. E-mail -- 12-26-2024.

<u>Respondent's Exhibits:</u>

A. None.

FINDINGS OF FACT

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds and adopts as its Findings of Fact, Allegations 1 through 13, inclusive, as set forth in the Notice of Opportunity for Hearing, dated December 23, 2024, in Case Nos. A-2024-0014 and A-2024-0023.

CONCLUSIONS OF LAW

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds and adopts as its Conclusions of Law, violations of law 1 through 20, inclusive, as set forth in the Notice of Opportunity for Hearing, dated Dec. 23, 2024, in Case Nos. A-2024-0014 and A-2024-0023.

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and after consideration of the record as a whole, the Ohio Board of Pharmacy imposes a written reprimand and a monetary penalty in the amount of $500.00 on Respondent's TDDD license. This fine will be attached to Respondent's license record and must be paid no later than six months from the effective date of this Order. To pay this fine Respondent must login to www.elicense.ohio.gov and process the items in the cart of the owner, Dale Bertke.

Ms. Ferris moved for Findings of Fact; Mr. Grimm seconded the motion. Motion passed (Yes-8/No-0).

Ms. Ferris moved for Conclusions of Law; Mr. Grimm seconded the motion. Motion passed (Yes-8/No-0).

Ms. Ferris moved for Action of the Board; Mr. Grimm seconded the motion. Motion passed (Yes-8/No-0).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin county. Such notices of appeal shall be filed within fifteen (15) days after the service of the notice of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE OHIO BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **December 15, 2025**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/zas/rlj

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 4/28/2025
-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-2025-0032**

Schwieterman's Drug Store, Inc. **License No. 02-0165150**
404 W. North St.
Colwater, OH 45828

April 28, 2025

Dear Schwieterman's Drug Store (Coldwater):

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the 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. Schwieterman's Drug Store, located at 404 W. North St., Coldwater, Ohio 45828, has an inactive TDDD license with the Board under license number 02-0165150, which lists Dale Bertke, RPh, as the owner and Responsible Person (RP).

ALLEGATIONS

1. On or about December 16, 2024, owner and RP Dale Bertke, RPh, notified pharmacy staff that Schwieterman's Drug Store (TDDD 02-020165150), located at 404 W. North St., Coldwater, Ohio, would be permanently closing on December 31, 2024. Patients were not notified by direct mail, email, or text message, within fifteen calendar days prior to closing. Notice of the closure was

only made via an online Facebook post on December 17, 2024, and when individual patients called the pharmacy.

2. On December 26, 2024, a Board Inspector spoke with owner and RP Dale Bertke, RPh.

    a. He stated they planned to move the pharmacy records to the Schwieterman's Drug Store located in New Bremen and if patients needed to access their pharmacy records, they would need to contact him on his cell or home phone.

    b. When asked about patient notification and whether they were notified via direct mail, email or text message, RP Bertke stated that patients were notified of the closure on Monday, December 16, 2024. RP Bertke stated that for most of the patients, the pharmacy did not have an email. Patients were notified by staff when they called the pharmacy, and the pharmacy had made a Facebook post.

    c. When asked if he had submitted or planned to submit a Discontinuation of Business (DCB) notice with the Board, RP Bertke stated he had not yet for any of the locations.

3. No DCB notice was ever filed with the Board for this Schwieterman's location. The TDDD license expired as of March 31, 2025.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-04 of the OAC, as effective October 1, 2024, Procedure for discontinuing business as a terminal distributor of dangerous drugs, each violation punishable by a maximum penalty of $1,000:

    a. A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the board of pharmacy. The notice shall be submitted, in a manner determined by the board, within thirty days of discontinuation of business as a terminal distributor of dangerous drugs. This notice shall include the following information:

        i. The name, address, and license number of the terminal distributor discontinuing business, OAC Rule 4729:5-2-04(A)(1); and/or

        ii. The name, address, and license number of the terminal distributor or other authorized entity where the dangerous drugs will be transferred, OAC Rule 4729:5-2-04(A)(2); and/or

        iii. The name and address of the secured location where the records of purchase and sale will be kept in accordance with this division of the Administrative Code, OAC Rule 4729:5-2-04(A)(3); and/or

        iv. The proposed date of discontinuing business, OAC Rule 4729:5-2-04(A)(4).

b. A terminal distributor of dangerous drugs licensed as a pharmacy that is permanently closing shall:

i. Provide notification, using the information on file with the pharmacy, to each patient who has filled a prescription within the previous six months. This notification must be made a minimum of fifteen calendar days prior to closing and must include:

1. The last day the pharmacy will be open, OAC Rule 4729:5-2-04(D)(1)(a); and/or

2. Name, address, and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records, OAC Rule 4729:5-2-04(D)(1)(b); and/or

3. Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice, OAC Rule 4729:5-2-04(D)(1)(c); and/or

4. The last day a transfer may be initiated, OAC Rule 4729:5-2-04(D)(1)(d);

ii. The notification shall be made via:

1. Direct mail, e-mail, or text message, OAC Rule 4729:5-2-04(D)(2)(a);

iii. Provide any new patients filling prescriptions during the fifteen-calendar day period prior to the pharmacy closing with written notification that includes:

1. The last day the pharmacy will be open, OAC Rule 4729:5-2-04(D)(3)(a); and/or

2. Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records, OAC Rule 4729:5-2-04(D)(3)(b); and/or

3. Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; OAC Rule 4729:5-2-04(D)(3)(c); and/or

4. The last day a transfer may be initiated, OAC Rule 4729:5-2-04(D)(3)(d).

2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022, Responsible person – terminal distributor, each violation punishable by a maximum penalty of $1,000:

a. The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(A)(2); and/or

b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3).

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of $1,000:

   a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or

   b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or

   c. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

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

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

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

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the 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 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 Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

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

BY ORDER OF THE OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/zas/kll

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 12/23/2024
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

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

IN THE MATTER OF: **CASE NOS. A-2024-0014**
A-2024-0023

Schwieterman's Drug Store, Inc. **License No. 02-0165150**
404 W North St.
Coldwater, OH 45828

December 23, 2024

Dear Schwieterman's Drug Store:

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

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, reprimand, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the Revised Code.

2. Schwieterman's Drug Store, Inc., located at 404 W North St., Coldwater, Ohio, has an active TDDD license with the Board under license number 02-0165150, which lists Dale Bertke, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about June 26, 2023, a Board Compliance Specialist (CS) and Board Inspector conducted an inspection at Schwieterman's Drug Store, located at 404 W North Street, Coldwater, Ohio. The inspection resulted in warnings requiring written responses for the following violations:

a. Staff were not wearing name and job title badges.

b. Outpatient prescriptions were not filed in three separate files. Over a dozen baskets of unfiled hard copy prescriptions dating back to May 2023 were observed and prescriptions for schedule II, schedule III-V, and non-controlled drugs were co-mingled in the various baskets.

c. Schedule II controlled substances were not securely stored.

d. Refrigerators for drug storage were not free of food and/or beverage.

e. Expiration dates were not placed on return to stock labels.

f. Return to stock drugs were not maintained in the container in which they were filled.

g. Expired/adulterated drugs were present in the active drug stock and were stored longer than 1 year from the date of expiration/adulteration.

h. A records request was made for the pharmacy to provide the annual controlled substance inventories from 2021 and 2022 within three (3) business days.

i. The investigation revealed an error in dispensing (EID). Patient 1's medication was sold to Patient 2 by pharmacy support personnel. The drug left the building, the error was discovered by Patient 2, and the drug was returned to the pharmacy by Patient 2. It was later sold to Patient 1 without being replaced by new drug stock. A records request was made to the Pharmacy regarding this EID.

2. Schwieterman's Drug Store failed to submit the required written responses resulting from the June 26, 2023, inspection for the violations and requests set forth in Allegations (1)(a) through (1)(i) above, which were due by July 26, 2023. On or about August 8, 2023, the Board CS emailed Responsible Person Dale Bertke to follow up on the required written responses; RP Bertke did not respond. On August 24, 2023, another email was sent to RP Bertke with no response. On August 28, 2023, the Board CS called the pharmacy two additional times to contact RP Bertke. RP Bertke did not return the phone calls and did not submit any written responses.

3. On or about August 29, 2023, the Board conducted a second on-site inspection at Schwieterman's Drug Store and issued warnings requiring written responses for the following violations:

   a. Staff were not wearing name and job title badges. This was a repeat warning from the 6/26/2023 inspection.

   b. Outpatient prescriptions were not filed in three separate files. This was a repeat warning from the 6/26/2023 inspection.

c. Schedule II controlled substances were not securely stored. This was a repeat warning from the 6/26/2023 inspection.

d. No annual controlled substance inventory was available for 2021 or 2022. This was previously a records request in the 6/26/2023 inspection report and is considered a repeat warning.

e. Expired/adulterated drugs were present in the active drug stock and were stored longer than 1 year from the date of expiration/adulteration. This was a repeat warning from the 6/26/2023 inspection.

f. Manufacturer stock bottles had damaged lot and/or expiration date stickers.

g. RP Bertke was directed to submit written responses for Schwieterman's Pharmacy, which were required from the 6/26/2023 inspection, as well as to provide a response regarding the failure to submit requested records and written responses.

h. RP Bertke was directed to submit written responses for Schwieterman's Pharmacy regarding the EID investigated on 6/26/2023. This was a repeat warning from the 6/26/2023 inspection.

4. On or about September 1, 2023, RP Bertke submitted a partial response to the required written responses resulting from the August 29, 2023, inspection for the violations set forth in Allegations (3)(a) through (3)(h). Despite repeated follow-up to RP Bertke, no further responses were received.

5. On or about October 19, 2023, the Board conducted a third inspection at Schwieterman's Drug Store. The following EIDs were investigated and records requests were made during the inspection:

   a. On or about March 29, 2023, Patient 3 was dispensed two prescriptions, one containing escitalopram 10 mg and one containing hydroxyzine pamoate 25 mg; however, both bottles were labeled as containing escitalopram.

   b. On or about August 24, 2023, Patient 4 was dispensed a prescription for gabapentin 100 mg instead of the prescribed gabapentin 300 mg. The prescription information was incorrectly entered into the pharmacy's dispensing software and was not caught by a pharmacist during drug utilization review. As a result of the error, Patient 4 experienced a lack of symptom control, prompting the patient to request a stronger dose.

      a. During the October 19, 2023, inspection, it was discovered that the pharmacy had corrected the error, and the dispensing software had been updated to reflect the 300 mg dose that was prescribed. However, there was no positive ID captured for the personnel who made annotations to the prescription, nor positive ID for the personnel who entered the correct information into the dispensing software.

c. On or about August 29, 2023, Patient 5 was dispensed a prescription for methylphenidate CD 20 mg instead of the prescribed methylphenidate CD 10 mg. The prescription was processed correctly through the dispensing software and the vial labeled as containing 10 mg capsules; however, the vial contained 20 mg capsules.

d. On or about June 2, 2023, Patient 6 was dispensed a prescription for amlodipine 10 mg instead of the prescribed amlodipine 5 mg. The prescription information was correctly entered into the pharmacy's dispensing software. However, the pharmacy did not have the manufacturer's product in stock, so it was later edited to a different manufacturer's product, but of the wrong strength. The pharmacist failed to identify the strength error during drug utilization review. As a result of the error and ingesting the 10 mg tablets, Patient 6 reported lower than normal blood pressure, dizziness, and lightheadedness.

e. Records were requested and warnings requiring written responses for each of the errors in dispensing for Patients 3, 4, 5 and 6, were issued during the inspection. Schwieterman's Drug Store did not submit written responses to the Board.

6. On or about October 19, 2023, during the Board's third inspection at Schwieterman's Drug Store, warnings requiring written responses were issued for the following violations:

a. RP Bertke was directed to provide a response for Schwieterman's Pharmacy for the failure to respond regarding 6/26/2023 and 8/29/2023 inspections; response requested by 10/27/2023.

b. Outpatient prescriptions were not filed in three separate files. This was a repeat warning from the 6/26/2023 an 8/29/2023 inspections.

c. Schedule II controlled substances were not securely stored. This was a repeat warning from the 6/26/2023 an 8/29/2023 inspections.

d. Refrigerators for drug storage were not maintained at proper temperatures.

e. The pharmacy was using hard copy printed end-of-day reports to capture positive ID. However, the hard copy printout did not include accurate information for the identification of pharmacy personnel responsible for activities including data entry, drug utilization review, verification by a pharmacist, dispensing, and/or changes or annotations made to a prescription.

f. The computerized record keeping system used by the pharmacy, QS1, was unable to maintain an accurate audit trail of records edited by authorized personnel.

g. No annual controlled substance inventory was available for 2021 or 2022, and the 2023 inventory was missing required elements. This was a repeat warning from the 6/26/2023 an 8/29/2023 inspections.

h. The pharmacy had a perpetual inventory binder for tracking the inventory of schedule II controlled substances, but the binder was not started until September 2023. A warning requiring written response was issued regarding the EID being investigated, and Schwieterman's Drug Store provided an unsatisfactory response, which stated a perpetual inventory had been initiated in September but did not address the pharmacy's manner of compliance prior to September 2023.

i. Oral prescriptions received by the pharmacy were missing required elements.

j. Expiration dates were not placed on return to stock labels. This was a repeat warning from the 6/26/2023 inspection.

k. Manufacturer stock bottles had damaged lot and/or expiration date stickers. This was a repeat warning from the 6/26/2023 and 8/29/2023 inspections.

l. Expired/adulterated drugs were stored longer than 1 year from the date of expiration/adulteration. This was a repeat warning from the 6/26/2023 and 8/29/2023 inspections.

7. Schwieterman's Drug Store and RP Bertke failed to submit the required written responses from the October 19, 2023 inspection regarding either the EIDs investigated, as set forth in Allegations (5)(a) through (5)(e), or the multiple other identified violations, as set forth in Allegations (6)(a) through (6)(l). On October 29, 2023, RP Bertke submitted a late, partial, and incomplete response regarding the October 19, 2023 inspection. The response did not include specific corrective actions and failed to include responses regarding multiple violations. Despite repeated follow-up by Board staff, no further responses were submitted by Schwieterman's Drug Store or RP Bertke.

8. On or about August 1, 2024, the Board conducted a fourth inspection. Violations from the pharmacy's three 2023 inspections were re-inspected and warnings requiring written response were issued for the following violations:

   a. The pharmacy failed to respond to written warnings issued during OBP inspections on 6/26/2023, 8/29/2023, and 10/19/2023. The pharmacy also failed to provide a policy on the sale and refunding of prescriptions based on another EID which was investigated during the 6/26/2023 inspection.

   b. Manufacturer stock bottles in the pharmacy's active drug stock had damaged labels, which rendered the expiration date illegible. This was a repeat violation for which written warnings were also issued on 6/26/2023, 8/29/2023, and 10/19/2023.

   c. The pharmacy did not capture Positive Identification (positive ID) for personnel responsible for Data Entry, refilled prescriptions, or prescriptions entered but not yet dispensed (pulled from an on-hold status). These were repeat violations, for which written warnings were issued on 10/19/2023.

d. The pharmacy maintained a tamper-evident log book, but it only captured the information for prescription production and was not compliant for documenting activities requiring positive ID.

e. Oral prescriptions reduced to writing did not contain the full name of the prescriber's agent or positive ID of the pharmacy personnel transcribing the prescription. This was a repeat violation, for which a written warning was issued on 10/19/2023.

f. Drugs returned to stock did not have expiration dates indicated on the bottles. This was a repeat violation, for which written warnings were issued on 6/26/2023 and 10/19/2023.

g. Expired schedule II controlled substances were found in an unlocked cabinet labeled "CII Outdates." This was a repeat violation, for which written warnings were issued on 6/26/2023, 8/29/2023, and 10/19/2023.

h. Food and beverage were found in the medication refrigerator where immunizations and drugs were stored. This was a repeat violation, for which a written warning was issued on 6/26/2023.

i. Temperature logs for the medication refrigerators were incomplete. This was a repeat violation, for which a written warning was issued on 10/19/2023.

j. An EID occurred where a misbranded prescription was dispensed to a patient. The pharmacy was to respond with a plan to ensure errors of the same nature were not repeated.

k. 19 expired medications were located in the active drug stock. One of the expired products expired on 9/30/2022 – more than 18 months prior to the inspection. These were repeat violations, for which a similar warning was issued on 6/26/2023 and written warnings were issued on 8/29/2023 and 10/19/2023.

l. Loose pills were observed on the floor of the pharmacy along with dusty shelving and manufacturer bottles. This was a repeat violation, for which a warning was issued during the 10/19/2023 inspection.

m. Records were requested with a due date of 8/6/2024 for the pharmacy's records of HME sales from 1/1/2023 to 8/1/2024. The pharmacy's HME license expired effective 6/30/2024 and RP Bertke indicated during the inspection that HME sales had continued after the HME license expiration date.

9. Schwieterman's Drug Store and RP Bertke failed to submit the required responses to either the ten warnings requiring written responses that were issued during the 8/1/2024 inspection, or to the records request for the pharmacy's records of HME sales. Board staff followed up with RP Berke but still failed to receive any required responses.

10. Due to the lack of responses from Schwieterman's Drug Store, the Board conducted a fifth follow-up, partial inspection on or about September 18, 2024. Warnings requiring written response were issued for the following violations:

    a. The pharmacy's controlled substance safe was ajar. This was a repeat violation, for which written warnings were issued during inspections on 6/26/2023, 8/29/2023, 10/19/2023, and 8/1/2024.

    b. The pharmacy failed to respond to written warnings issued by the OBP during the inspection on 8/1/2024 and failed to provide the requested HME records by 8/6/2024. This was a repeat violation, due to the lack of responses from the 2023 inspections.

    c. Records of the pharmacy's HME sales from 1/1/2023 through 9/18/2024 were re-requested, to be provided by 9/23/2024. These records were initially requested on 8/1/2024, to be provided by 8/6/2024. However, due to the failure to provide records, the request was escalated to a written warning in the inspection report.

11. Schwieterman's Drug Store and RP Bertke failed to submit the required responses resulting from the 9/18/2024 inspection, one of which was a repeat records request for the pharmacy's HME sales.

12. Due to the continued lack of responses from Schwieterman's Drug Store, the Board conducted a sixth inspection on or about October 8, 2024. Warnings requiring written response were issued for the following violations:

    a. The pharmacy failed to respond to written warnings issued by the OBP during inspections on 8/1/2024 and 9/18/2024. Additionally, Schwieterman's Drug Store failed to provide the twice-requested HME records by 8/6/2024 and 9/23/2024. This was a repeat violation, for which a warning was issued during the 8/1/2024 inspection and a written warning was issued on 9/18/2024.

    b. In the inspection report, a third request for records of the pharmacy's HME sales from 1/1/2023 to 10/8/2024 was issued, with a due date of 10/11/2024. The pharmacy's HME license expired effective 6/30/2024 and RP Bertke indicated during the 8/1/2024 inspection that HME sales had continued after the HME license expiration date.

    c. 29 expired medications were located in the pharmacy's active drug stock, rather than stored in a separate, secure area. Two other manufacturer packages had damage to the expiration date on the labels and were illegible. These were repeat violation, for which similar written warnings were issued on 6/26/2023, 8/29/2023, 10/19/2023, and 8/1/2024.

    d. Positive identification issues were observed:

        a. 14 prescriptions had no positive ID of the personnel performing Data Entry. This was a repeat violation. The pharmacy did not have any form of positive ID for Data Entry during previous OBP inspections, and written warnings were issued during the

10/19/2023 and 8/1/2024 inspections. During the inspection on 10/8/2024, inspectors observed improvement but only partial compliance with positive ID.

b. 12 prescriptions had no positive ID of the pharmacist performing Data Entry Verification.

c. 11 prescriptions had no positive ID of the pharmacist responsible for Dispensing. This was a repeat violation for which written warnings were issued during inspections on 10/19/2023 and 8/1/2024.

d. 11 prescriptions had no positive ID of the pharmacy personnel who transcribed telephoned prescriptions.

e. Inspectors observed oral prescriptions transcribed to paper which were missing the full name of the prescriber. This was a repeat violation for which written warnings were issued on 10/19/2023 and 8/1/2024.

f. Refrigerator temperature logs were missing documented temperatures on various dates. Additionally, the pharmacy had a Covid-19 vaccine freezer with no temperature monitoring; the vaccines were expired and staff explained the pharmacy was no longer offering these vaccines. This was a repeat violation for which written warnings were issued during the 10/19/2023 and 8/1/2024 inspections.

g. Schwieterman's Drug Store had no policy regarding refrigerator temperature excursions or policy stating food/beverage may not be stored inside. This was a repeat violation for which a written warning was issued during the 8/1/2024 inspection.

h. Schwieterman's Drug Store had not submitted a written policy on the prevention of dispensing errors regarding the EID investigated during the 8/1/2024 inspection. This was a repeat violation. A written warning was issued concerning the EID during the 8/1/2024 inspection.

13. Schwieterman's Drug Store and RP Bertke failed to submit the required responses from the 10/8/2024 inspection, one of which was a repeat records request for the pharmacy's HME sales.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022, Responsible person – terminal distributor, each violation punishable by a maximum penalty of $1,000:

   a. The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(A)(2); and/or

b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and/or

c. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC 3729:5-2-01(E)(4); and/or

d. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required OAC 3729:5-2-01(E)(6).

2. Such conduct as set forth in paragraphs (1)(a), (3)(a), (8)(l) of the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-5-02 of the OAC, as effective December 1, 2020, Minimum standards for an outpatient pharmacy, each violation punishable by a maximum penalty of $1,000:

   a. Space and fixtures – 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, OAC Rule 4729:5-5-02(E)(2); and/or

   b. Personnel – An employee of a pharmacy must be identified by a name tag that includes the employee's job title, OAC Rule 4729:5-5-02(G).

3. Such conduct as set forth in paragraphs (1)(g), (3)(e), (6)(l), (8)(k), (12)(c) the Allegations section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective March 1, 2019, Storage of adulterated drugs, each violation punishable by a maximum penalty of $1,000:

   a. To prevent their use, 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, OAC Rule 4729:5-3-06(A).

4. Such conduct as set forth in paragraphs (1)(b), (3)(b) and (6)(b) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-03 of the OAC, as

effective December 1, 2020, Filing and storage of prescriptions, each violation punishable by a maximum penalty of $1,000:

a. All original outpatient prescriptions shall be filed in the following manner:

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

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

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

5. Such conduct as set forth in paragraphs (5)(b)(i), (6)(e), (6)(f), (8)(c), (8)(d), (12)(d)(i), (12)(d)(ii), (12)(d)(iii), and (12)(d)(iv) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-04 of the OAC, as effective December 1, 2020, Record keeping, each violation punishable by a maximum penalty of $1,000:

a. There shall be positive identification of the licensed or registered individuals responsible for performing the following activities authorized under Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code, OAC Rule 4729:5-5-04(A):

i. Prescription information entered into the record keeping system. This provision shall take effect one-year from the effective date of this rule, OAC Rule 4729:5-5-04(A)(1); and/or

ii. Prospective drug utilization review, which shall be captured as a standalone action or as part of either:

1. The pharmacist verification of prescription information in paragraph (A)(2) of this rule, OAC Rule 4729:5-5-04(A)(3)(a); and/or

2. The dispensing process in paragraph (A)(4) of this rule, OAC Rule 4729:5-5-04(A)(3)(b); and/or

iii. Dispensing, OAC Rule 4729:5-5-04(A)(4); and/or

iv. Prescription information transcribed from an order received by telephone, facsimile, or recording device, OAC Rule 4729:5-5-04(A)(8); and/or

v. Any changes or annotations made to a prescription, OAC Rule 4729:5-5-04(A)(9); and/or

b. A pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to electronically document positive identification in accordance with paragraph (A) of this

rule shall be required to maintain hard copy documentation. Hard copy documentation shall be provided by each registered or licensed individual who makes use of such system by one of the following methods:

i. A hard copy printout of each day's prescription data, OAC Rule 4729:5-5-04(D)(1);

1. The printout shall include, at a minimum, the following data:

a. Date of dispensing, OAC Rule 4729:5-5-04(D)(1)(a)(i);

b. Prescription number, OAC Rule 4729:5-5-04(D)(1)(a)(ii);

c. Patient name, OAC Rule 4729:5-5-04(D)(1)(a)(iii);

d. Name, strength, and quantity of drug dispensed, OAC Rule 4729:5-5-04(D)(1)(a)(iv);

e. Identification of the pharmacist or pharmacy personnel responsible for any activity described in paragraph (A) of this rule, OAC Rule 4729:5-5-04(D)(1)(a)(v);

f. Identification of the pharmacy, OAC Rule 4729:5-5-04(D)(1)(a)(vi);

g. Identification of controlled substances; OAC Rule 4729:5-5-04(D)(1)(a)(vii); and/or

2. The printout must be verified, dated, and signed by each individual responsible for any activity described in paragraph (A) of this rule. The printout must be verified and manually signed by the individual within a reasonable timeframe to ensure the accuracy of the record, OAC Rule 4729:5-5-04(D)(1)(b); and/or

3. If the printout is prepared at a location other than where the drug was dispensed, the printout must be provided to the licensed location within three business days of the date on which the drugs were dispensed. Such printouts must be verified and signed by each individual responsible for any activity described in paragraph (A) of this rule within twenty-four hours of the date the printout is received by the individual, OAC Rule 4729:5-5-04(D)(1)(c); and/or

4. The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing, OAC Rule 4729:5-5-04(D)(1)(d); and/or

5. The signed printout may be stored electronically in accordance with paragraph (E) of this rule, OAC Rule 4729:5-5-04(D)(1)(e); and/or

ii. A tamper evident log book, OAC Rule 4729:5-5-04(D)(2;

1. Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book the following data for each prescription dispensed:

    a. Date of dispensing, OAC Rule 4729:5-5-04(D)(2)(a)(i);

    b. Prescription number, OAC Rule 4729:5-5-04(D)(2)(a)(ii);

    c. Patient name, OAC Rule 4729:5-5-04(D)(2)(a)(iii);

    d. Name, strength and quantity of drug dispensed, OAC Rule 4729:5-5-04(D)(2)(a)(iv);

    e. Identification of the pharmacist and pharmacy personnel responsible for any activity described in paragraph (A) of this rule, OAC Rule 4729:5-5-04(D)(2)(a)(v);

    f. Identification of controlled substances, OAC Rule 4729:5-5-04(D)(2)(a)(vi); and/or

c. In addition to the immediate retrieval and production of prescription information required by paragraph (C) of this rule, an outpatient pharmacy that utilizes a computerized record keeping system shall comply with the following: All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail, OAC Rule 4729:5-5-04(F)(3).

6. Such conduct as set forth in paragraphs (6)(i), (8)(e), and (12)(e) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-10 of the OAC, as effective December 1, 2020, Manner of processing a prescription, each violation punishable by a maximum penalty of $1,000:

    a. Oral prescriptions:

        i. A pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the source of the oral prescription, OAC Rule 4729:5-5-10(D)(1); and/or

        ii. Upon receiving a prescription from a recording device or voice mail service, a pharmacist shall transcribe the information. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the prescription removed from the recording device or voice mail service, OAC Rule 4729:5-5-10(D)(2).

7. Such conduct as set forth in paragraphs (1)(h), (3)(d) and (6)(g) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-24 of the OAC, as

effective August 19, 2022, Drug inventory records and other record keeping provisions, each violation punishable by a maximum penalty of $1,000:

a. Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code, OAC Rule 4729:5-5-24(J).

8. Such conduct as set forth in paragraphs (1)(h), (3)(d) and (6)(g) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-07 of the OAC, as effective March 1, 2019, Controlled substance inventory requirements, each violation punishable by a maximum penalty of $1,000:

a. 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

b. 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

c. 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).

9. Such conduct as set forth in paragraphs (1)(c), (1)(d), (3)(c), (6)(c), (6)(d), (8)(g), (8)(h), (8)(i), (10)(a), (12)(f), (12)(g) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-23 of the OAC, as effective December 1, 2020, Security, control and storage of dangerous drugs in an outpatient pharmacy, each violation punishable by a maximum penalty of $1,000:

a. All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous drugs. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs, OAC Rule 4729:5-5-23(A)(5); and/or

b. Refrigerators and freezers used for the storage of dangerous drugs shall comply with the following:

i. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

1. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-5-23(B)(1)(a); and/or

2. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-5-23(B)(1)(b); and/or

ii. The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs, OAC Rule 4729:5-5-23(B)(2); and/or

iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs, OAC Rule 4729:5-5-23(B)(3); and/or

10. Such conduct as set forth in paragraphs (1)(e), (1)(f), (1)(i), (6)(j), (8)(f) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-22 of the OAC, as effective December 1, 2020, Return to stock in an outpatient pharmacy, each violation punishable by a maximum penalty of $1,000:

a. An outpatient pharmacy may return dangerous drugs to stock shelves that have been dispensed, but have never left the pharmacy (i.e. never picked up by a patient or caregiver) or the control of a pharmacy delivery agent (i.e. never delivered to a patient or caregiver), if the pharmacy complies with all of the following:

i. The pharmacy has the capability to place the expiration date, as required by this rule, on the prescription label, OAC Rule 4729:5-5-22(B)(1); and/or

ii. The expiration date on the label shall not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging, OAC Rule 4729:5-5-22(B)(2); and/or

iii. The dangerous drug products returned to stock shelves shall be maintained in the container in which they were filled and shall maintain their original prescription label containing the original expiration date assigned. The label on the container shall not be removed, altered, or replaced with another label or have any other label added, except as follows:

1. Adding to or modifying the existing label, if the drug name, dose, and original expiration date are maintained, OAC Rule 4729:5-5-22(B)(3)(a); and/or

2. Adding a new label over the existing label on the container. In this instance, the drug shall be verified by a pharmacist or an electronic verification system following the application of the new label. The new label shall include the expiration date assigned on the original label, OAC Rule 4729:5-5-22(B)(3)(b); and/or

3. A prescription label may be removed if the prescription container is the manufacturer's original sealed packaging and the removal of the label does not

remove or otherwise cause to make unreadable the expiration date and lot number on the manufacturer's packaging, OAC Rule 4729:5-5-22(B)(3)(c).

11. Such conduct as set forth in paragraphs (5)(a) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-06 of the OAC, as effective December 1, 2020, Labeling of drugs dispensed on prescription, each violation punishable by a maximum penalty of $1,000:

    a. No drug may be dispensed by outpatient prescription unless a label is affixed to the container in which such drug is dispensed, and such label includes the proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission and such request is documented, OAC Rule 4729:5-5-06(A)(8); and/or

12. Such conduct as set forth in paragraphs (1)(g), (1)(i), (3)(e), (3)(f), (5)(a), (5)(b), (5)(c), (5)(d), (6)(k), (8)(b), (12)(c) of the Allegations Section, if proven, constitutes a violation of section 3715.52(A) of the ORC, the adulteration or misbranding of any food, drug, device, or cosmetic, a misdemeanor of the fourth degree, punishable by a maximum penalty of $2,000 if committed by an organization.

13. Such conduct as set forth in paragraphs (5)(b), (5)(c) and (5)(d) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-5-08 of the OAC, as effective November 15, 2022, Prospective drug utilization review, each violation punishable by a maximum penalty of $1,000:

    a. Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying incorrect drug dosage, OAC Rule 4729:5-5-08(A)(5).

14. Such conduct as set forth in paragraphs (1)(c), (3)(c), (6)(c) and (6)(h) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-14 of the OAC, as effective March 1, 2020, General security requirements, each violation punishable by a maximum penalty of $1,000:

    a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to:

        i. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or

        ii. 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).

15. Such conduct as set forth in paragraphs (2), (3)(g), (3)(h), (4), (5)(e), (6)(a), (7), (8)(a), (8)(j), (9), (10)(b), (11), (12)(a), (12)(h), (13) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-03 of the OAC, as effective April 1, 2018, Inspections and corrective actions, each violation punishable by a maximum penalty of $1,000:

    a. The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

        i. The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s), OAC Rule 4729:5-3-03(E)(1); and/or

        ii. An explanation disputing the observed violations, OAC Rule 4729:5-3-03(E)(2).

16. Such conduct as set forth in paragraphs (2), (3)(g), (3)(h), (4), (5)(e), (6)(a), (7), (8)(a), (8)(j), (8)(m), (9), (10)(b), (10)(c), (11), (12)(a), (12)(b), (12)(h), (13) of the Allegations Section, if proven, constitutes a violation of section 4729.19 of the ORC, as effective March 22, 2019, Cooperation in investigation, each violation punishable by a maximum penalty of $1,000:

    a. Notwithstanding division (B)(4) of section 2317.02 of the Revised Code, a pharmacist, pharmacy intern, pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, terminal distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs shall cooperate with federal, state, and local government investigations and shall divulge all relevant information when requested by a government agency.

17. Such conduct as set forth in paragraphs (8)(m), (10)(b), (10)(c), (12)(a), (12)(b) of the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-05, as effective April 1, 2018 and July 1, 2024, Confidentiality of patient records, each violation punishable by a maximum penalty of $1,000:

    a. Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released, upon request, to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug…, OAC Rule 4729:5-3-05(C).

18. Such conduct as set forth the Allegations Section, if proven, constitutes a violation of section 4729.55(D) of the ORC, as effective April 6, 2017, Terminal distributor license requirements - Adequate safeguards are assured to carry on the business of a TDDD in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, punishable by a maximum penalty of $1,000.

19. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, and April 4, 2023, Disciplinary actions – terminal distributor, 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

    a. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or

    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).

20. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, Disciplinary actions, 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. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); 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).

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 Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to 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/zas/jrn
Enclosure: Patient ID Key