October 9, 2025

Crosby's Drugs, Inc.
c/o Christina Gonyeau, RPh
2609 N. High Street
Columbus, OH 43202

Re: License No. 02-0173000
Case(s): A-2021-0591, A-2023-0433

Dear Crosby's Drugs, Inc:

This letter is to confirm that the probationary period outlined in the Settlement Agreement dated September 6, 2024, is now concluded as of September 6, 2025, as Crosby's Drugs, Inc has satisfied all the terms of their probation. Crosby's Drugs, Inc's license number 02-0173000 is now deemed in good standing. The Board would like to acknowledge your diligence in meeting this goal.

If you have any questions or concerns, please contact the Board of Pharmacy at 614-466-4143.

Respectfully,

Richelle Johnson
Ohio Board of Pharmacy
Legal Administrative Assistant

IN THE MATTER OF:

CASE NOS. A-2021-0591
A-2023-0433

Crosby's Drugs, Inc.
c/o Cynthia Kryc, RPh
2609 N. High Street
Columbus, Ohio 43202

License No. 02-0173000

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Crosby's Drugs, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of Crosby Drugs, Inc.'s errors in dispensing and follow-up inspection. Together, the Board and Crosby's Drugs, Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. Crosby's Drugs, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 02-0173000.

FACTS

1. The Board initiated an investigation of Crosby's Drugs, Inc., Terminal Distributor of Dangerous Drugs license number 02-0173000, related to Crosby's Drugs, Inc.'s errors in dispensing and follow-up inspection.

2. On or about May 22, 2024, the Board sent a Notice of Opportunity for Hearing to Crosby's Drugs, Inc., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. On or about June 6, 2024, Crosby's Drugs, Inc., through counsel Douglas Graff, timely requested an administrative hearing, which was subsequently scheduled for October 5, 2024.

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

TERMS

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

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Crosby's Drugs, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 22, 2024; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Crosby's Drugs, Inc. agrees to pay to the Board a monetary penalty the amount of $2,500. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Crosby's Drugs, Inc. agrees to a one-year probationary period beginning the effective date of this Agreement. During the probationary period, any violation of this Agreement is also a violation of probation and could result in additional discipline.

5. The Board hereby imposes a written reprimand on Crosby's Drugs, Inc.'s TDDD license, number 02-0173000.

6. Crosby's Drugs, Inc. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

7. Crosby's Drugs, Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Crosby's Drugs, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Crosby's Drugs, Inc. by the Board and will NOT discharge Crosby's Drugs, Inc. from any obligation under the terms of this Agreement.

8. Crosby's Drugs, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

9. Crosby's Drugs, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

10. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Crosby's Drugs, Inc. will operate.

11. Crosby's Drugs, Inc. explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

12. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

13. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

14. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

15. 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.

16. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

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

Approved by:

Cynthia Kryc

Cynthia Kryc, RPh, on behalf of,
Crosby's Drugs, Inc., Respondent

9.4.24

Date of Signature

Douglas Graff, Attorney for Respondent

9/4/24

Date of Signature

Mindy Ferris

Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

09.06.2024

Date of Signature

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

IN THE MATTER OF: **CASE NO. A-2021-0591**
A-2023-0433

Crosby's Drugs, Inc. **License No. 02-0173000**
c/o Cynthia Kryc, RPh
2609 N. High Street
Columbus, OH 43202

May 22, 2024

Dear Crosby's Drugs and Ms. Kryc:

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. Crosby's Drugs Inc., located at 2609 N. High Street, Columbus, Ohio, has an active TDDD license with the Board under license number 02-0173000, which lists Cynthia Kryc as the Responsible Person since 2017.

ALLEGATIONS

1. On or about August 2, 2021, a prescription for 30 10 mg baclofen suppositories, prescription #2785668, was compounded for Patient 1 at Crosby Drugs, located at 2609 N. High Street, Columbus, Ohio. The compounding log did not reflect which staff member compounded this prescription. On or about August 3, 2021, Candice Siegenthaler, RPh, performed the final check for prescription #2785668. The compounded prescription should have yielded 60 suppositories; however, only 48 were made due to

an incorrect mold being used. Although the suppositories were compounded incorrectly when the incorrect mold was used, yielding approximately 30% more drug than prescribed, no patient harm was reported.

2. On or about September 8, 2021, Candice Siegenthaler, RPh, while working as a pharmacist at Crosby's Drugs, compounded prescription #6163134, clonidine 20 mcg/mL oral suspension, 30 mL, with directions to "take 1 mL by mouth once daily". The medication was prescribed for Patient 2, a 3-year-old with a medical history of tracheomalacia and developmental delay. The electronic prescription included a note that stated: "Notes to Pharmacy: To help prevent medication errors, do not change concentration prescribed". The bottle dispensed to Patient 2 on September 16, 2021 contained clonidine; however, during compounding, Candice Seigenthaler, RPh used clonidine HCL USP powder instead of clonidine tablets, as required by the master formula. As a result, the compounded product was calculated to contain approximately 1,000 times the concentration of clonidine than prescribed.

    a. On September 17, 2021, Patient 2 was administered 1 mL of the compounded medication. He became bradycardic and unresponsive within fifteen minutes of the administration. Patient 2 was transported to Nationwide Children's Hospital via emergency squad where emergency medications were administered, such as Narcan (as a clonidine antidote) and atropine; Patient 2 was hospitalized for five days.

    b. Upon investigation, it was discovered that the master formula #1217 was used and the compounding log was generated at 2:41pm on September 8, 2021. However, the formula was modified at 2:58pm. Investigation revealed that during compounding, Ms. Siegenthaler, RPh used clonidine HCL USP powder and measured out 0.703 grams. The log instructions and master formula indicate the compound is to be made from clonidine tablets. When changing the tablets to powder, the quantity would have required a manual change to 0.0007 grams. However, 0.7 grams was weighed, documented and used. The initials of Candice Siegenthaler were notated on the compounding log and dated September 8, 2021. She was the only compounding employee in the lab on September 8, 2021; she did not have a compounding technician to assist with this product.

    c. The Board submitted prescription #6163134 to a laboratory for analysis. The results confirmed the concentration of clonidine was 16 mg (+/- 1.2 mg) per mL versus the prescribed 20 mcg per mL.

    d. On or about September 17, 2021, pharmacist Bryant called Crosby's Drugs and inquired about what was used for Patient 2's prescription. Shortly after the call, Candice Siegenthaler created a formula for clonidine suspension using powder. The formula was not completed and included a note, "Clonidine (do not use- use powder)". The PCCA triturate formula was printed along with Patient 2's refill label for prescription #6163134. It appeared this was prepared in anticipation of preparing the compound using powder and to complete the formula. The error in dispensing was discovered prior to the compound being made.

3. On or about October 28, 2021, an agent of the Board conducted an inspection of the non-sterile compounding lab at Crosby's Drugs. As a result, 15 written warnings/written responses required were issued, including but not limited to:

    a. Employees responsible for compounding lacked documented training. The training records were incomplete and not adequate, pursuant to U.S. Pharmacopeia (USP) 795 and 797 standards.

    b. Policies and Procedures were vague, lacking processes, and unorganized. It was difficult for the Board inspector to follow the policies because the USP 795, USP 797 and general policies were comingled.

    c. The policies did not appear to be updated nor signed by the Responsible Person.

    d. The PK Software (the compounding software) and compounding logs did not document positive ID except at final product check. The compounding logs and software documented names of personnel not involved in the compounding process and in some cases, no longer employed by Crosby's Drugs.

    e. There was not an audit trail available for changes made within the PK Software, nor was there a way to identify who made the changes.

    f. Crosby's Drugs did not require positive ID for the technician preforming compounding, in violation of OAC Rule 4729:7-2-04

    g. An FDA inspection on or about September 9-30, 2021 resulted in a report that found eight violations regarding sterile compounding. Note: Crosby's Drugs has ceased sterile compounding.

4. On or about October 28, 2021, and January 21, 2022, Sherry Merchant, president and owner of Crosby's Drugs, spoke with an agent of the Board. She stated:

    a. Crosby's Drugs was unaware of the error in dispensing of compounded prescription #6163134 until October 6, 2021. She explained that lead pharmacy technician Amy Hart-Edzkowski, certified pharmacy technician, spoke with Patient 2's caregiver on this date and discovered the caregiver no longer wished Crosby's Drugs to fill the clonidine prescription as the previous refill was filled incorrectly and Patient 2 had been hospitalized.

    b. After the telephone call with Patient 2's caregiver, Cynthaia Kryc, RPh, Amy Hart-Edzkowski, and Sherry Merchant, reviewed the clonidine formula used in the processing of prescription

#6163134 with Ms. Siegenthaler. Ms. Siegenthaler did not understand what she had done wrong when she changed the formula from clonidine 0.2 mg tablets to clonidine USP powder.

c. During the discussion, Ms. Siegenthaler kept denying she made the error even after she was shown her signature on the compounded master formula. Ms. Siegenthaler explained, "We do powder whenever we have a chance because we don't want that extra excipient in the compound."

5. On or about October 28, 2021, December 29, 2021, December 30, 2021, and January 21, 2022, Cynthia Kryc, RPh, Responsible Person for Crosby's Drugs, spoke with and/or emailed an agent of the Board. She stated:

   a. She recalls Nationwide Children's Hospital calling Crosby's Drugs in September and asking about mutual Patient 2 who was in the hospital. The caller asked how the clonidine prescription was compounded. After consulting the compounded master formula sheet, she informed the caller that powder was used. This is when she noticed RPh Siegenthaler's initials on the sheet and that RPh Siegenthaler had weighed the powder. At that time, she did not realize the formula was incorrect and the caller did not say why the patient was hospitalized.

   b. She recalled that the system said clonidine powder in the log, but the directions read tablets. She pulled the log and confirmed it was powder.

   c. She admitted she did not handle the incident properly and should have caught the mistake at that time.

   d. Crosby's Drugs used clonidine formula #1217 with clonidine tablets since 2016. The new formula, #2586, was created on September 17, 2021. When comparing formula #2586 and #1217, the directions do not change; therefore, whoever made the formula copied it from formula #1217. Formula #2586 does not have a master formula; whereas formula #1217 has a master formula which was created in 2016.

   e. On October 6, 2021. Ms. Siegenthaler told her, Sherry Merchant, and Ms. Hart-Edzkowski that "we as pharmacists always use raw powder because it has less excipients." Ms. Kryc responded to Ms. Siegenthaler's comment by saying, "Don't include me in that because we have always used this formula with tablets."

6. On or about October 28, 2021, and January 20-21, 2022, Amy Hart-Edzkowski, a certified pharmacy technician, spoke with an agent of the Board and provided a written, notarized statement. She stated:

   a. While examining other compounding records for potential mistakes, she located an error in the compounding of non-sterile suppositories. In regard to prescription #2785668, baclofen, 10 mg

suppositories, that occurred on August 2, 2021, she learned the incorrect mold was used. Instead of using the blue mold, the peach mold was used.

b. The compounding should have yielded #60 suppositories; however, only 48 were made, resulting in the patient receiving approximately thirty percent (30%) more drug than was prescribed. Candice Siegenthaler, RPh dispensed #30 to Patient 1. The patient was contacted and reported no side effects.

7. On or about December 15, 2021, and January 25, 2022, Candice Siegenthaler, RPh, was interviewed by agents of the Board and submitted a written statement. She stated:

a. She has been involved in compounding for about twelve years and began working for Crosby Drugs in March 2021. She was hired part-time to work on the standard operating procedures (SOPs).

b. Due to a staff shortage, she was asked to compound. She told Crosby's Drugs that she had not compounded in a while, nor has she been trained in it; however, she agreed to do the work requested. She continued to do both her pharmacy duties and split compounding duties with a certified pharmacy technician.

c. She agreed she would have been the only one to have compounded prescription #6163134, clonidine, on September 8, 2021.

d. She had no knowledge of who changed the formula from tablets to power in the master formula worksheet for clonidine suspension prescription #6163134. She also did not recall pulling the master formula for the prescription.

e. She did not read the compounding instructions at the end of the master formula sheet to ensure she didn't miss a step, and that she followed the compound. Typically, she only used the instructions for cream and ointments, and not suspensions.

f. Each ingredient was weighed per the calculations of the formula for the quantity prepared. She was now aware the formula she compounded was 0.7 grams versus 0.7 milligrams, resulting in the medication being 1000 times higher in concentration. She filled what the computer told her to fill; she knows the difference between micrograms and milligrams.

g. She was unaware the prescription was for a child, she had never filled this prescription before. She did not review the patient profile.

h. If she is performing the final check on a compound that she does not know how to compound, she relies on the pharmacy technician's knowledge of the compounding process.

i. She performed pharmacist and technician roles on a daily basis and even worked 10 to 15 hours more a week than scheduled to help because they were so short staffed and behind in work and maintenance. (Sterile, nonsterile, and hazardous).

j. In regard to other names being on the compounding log, if someone was already logged in to the PK software, then it would stay that way for the remainder of the day.

k. She reviewed a piece of paper that had the work telephone number and name of a pharmacist from Nationwide Children's Hospital written on it and agreed it was in her handwriting; however, she said she was unaware of what it was in regard to. She has no recollection of speaking to anyone about Patient 2.

l. She admitted she created formula #2586 on September 17, 2021, at 11:49 A.M. for clonidine 20 mcg/mL which was used to create formula #1217 clonidine 20 mcg/mL (from tabs) to clonidine (do not use- use powder). She stated she had only started the formula and it was not complete because she didn't have a triturate. She stated the formula looks correct.

m. She denied creating the formula for Patient 2 on September 8, 2021, which had her signature and initials on the log and showed that powder was used. She said she did not touch or change this formula; she only filled the prescription.

n. She did not edit the compound log used for Patient 2's prescription even though she was the only person working on September 8, 2021.

o. The FDA conducted a 3-week inspection in September 2021, and mentioned that the compounding staff was not enough for the number of prescriptions being prepared.

p. In regard to the error in dispensing of prescription #2785668, baclofen suppositories, the technicians do the compounding and she checks the ingredients. She had never made a suppository from beginning to end. She would compound only wet and dry products as she was not comfortable with capsules. She added that she usually verified the color of the mold; however, she could not recall if she verified the color of mold for this particular prescription.

8. On or about October 25, 2023, an agent of the Board conducted a follow-up inspection of the non-sterile compounding lab at Crosby's Drugs. The inspection revealed the pharmacy does not require positive ID (manual signature) on compounding records for the pharmacy personnel responsible for preparing the compounded drug preparation. This violation was identified at the October 28, 2021 inspection, and had not been corrected as of the follow-up inspection.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52(A) of the ORC, the adulteration or misbranding of any food, drug, device, or cosmetic, a misdemeanor of the fourth degree, punishable by a maximum penalty of $2,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.64(A)(1), as effective March 21, 2017, Misbranded drug – its labeling is false or misleading in any particular, punishable by a maximum penalty of $1,000.

3. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of divisions (A)(10) of section 3715.64 of the ORC, as effective March 21, 2017, Misbranding, each violation punishable by a maximum penalty of $1,000: It is a drug and its container is so made, formed, or filled as to be misleading, ORC Section 3715.64(A)(10)(a).

4. Such conduct as set forth in the Allegations Section, if proven, also constitutes a violation of Rule 4729:5-5-08(A)(5) of the OAC, as effective December 1, 2020, Incorrect drug dosage, punishable by a maximum penalty of $1,000.

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:7-2-03(A) of the OAC, as effective July 1, 2021, Drugs compounded in a pharmacy, punishable by a maximum penalty of $1,000: For all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>. This paragraph does not apply to non-sterile compounded preparations exempted from the requirements of this chapter in accordance with paragraph (C) of rule 4729:7-2-01 of the Administrative Code.

6. Such conduct as set forth in the Allegations Section, if proven, also constitutes a violation of Rule 4729:7-2-04(A) of the OAC, as effective July 1, 2021, Pharmacy Compounding, Record keeping, punishable by a maximum penalty of $1,000:

    a. In addition to the pharmacy record keeping requirements of agency 4729 of the Administrative Code, a pharmacy shall maintain records of all drugs compounded that include, at a minimum, all the following:
        i. The positive identification of the following:
            1. The pharmacy personnel responsible for preparing the compounded drug preparation, OAC 4729:7-2-04(A)(11)(a); and
            2. The pharmacist conducting the final check of the compounded drug preparation, OAC 4729:7-2-04(A)(11)(b); and
            3. The pharmacist who dispenses the compounded drug preparation, OAC 4729:7-2-04(A)(11)(c); and/or

ii. All other drug compounding records as required by USP 795, USP 797, and USP 800, OAC 4729:7-2-04(A)(12).

7. Such conduct as set forth the Allegations Section, if proven, constitutes a violation of section 4729.55(D) of the ORC, as effective March 31, 2021, 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.

8. Such conduct as set forth in the Allegations Section, if proven, also constitutes a violation of Rule 4729-5-20(A)(5) of the OAC, as effective March 1, 2017, prospective drug utilization review, punishable by a maximum penalty of $1,000: Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying: Incorrect drug dosage.

9. Such conduct as set forth in the Allegations Section, if proven, also constitutes a violation of Rule 4729-5-21 of the OAC, as effective March 1, 2017, manner of processing a prescription, punishable by a maximum penalty of $1,000: A pharmacist when dispensing a prescription must: Ensure that patient information is profiled pursuant to rule 4729-5-18 of the Administrative Code, OAC Rule 4729-5-21(B)(1).

10. Such conduct as set forth in the Allegations section, if proven, constitutes a violation of each of the following divisions of Rule 4729:5-2-01 of the OAC, as effective March 1, 2019, 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 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 4729:5-2-01(A)(3); and/or

    c. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC 4729:5-2-01(E)(4); and/or

    d. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate

safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC 4729:5-2-01(E)(6).

11. Such conduct as set forth in the Allegations Section, if proven, also constitutes a violation of Rule 4729:7-2-03(A) of the OAC, as effective February 15, 2016, For all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>. This paragraph does not apply to non-sterile compounded preparations exempted from the requirements of this chapter in accordance with paragraph (C) of rule 4729:7-2-01 of the Administrative Code, punishable by a maximum penalty of $1,000.

12. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, each violation punishable by a maximum penalty of $1,000:

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

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

    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).

13. 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. 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/alg/kll

Enclosure: Patient ID Key

Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. 2015-1428

License No. 02-0173000

Crosby's Drugs, Inc.
c/o Kirk Betteridge, RPh
2609 N. High Street
Columbus, Ohio 43202

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Crosby's Drugs, Inc., for the purpose of resolving all issues between the parties relating to the OSBP investigation of the pharmacies failure to create and implement corrective action plan as required by the Board. Together, OSBP and Crosby's Drugs, Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.55 of the Ohio Revised Code to practice pharmacy the state of Ohio.

2. Crosby's Drugs, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 02-0173000.

FACTS

1. On or about May 20, 2015, the OSBP initiated an investigation of Crosby's Drugs, Inc., Terminal Distributor of Dangerous Drugs license number 02-0173000, related to Crosby's Drugs, Inc.'s failure to create and implement corrective action plan as required by the Board.

2. On or about December 11, 2015, the OSBP sent a Notice of Opportunity for Hearing to Crosby's Drugs, Inc., which outlined the allegations and provided notice of their right to a hearing, their rights in such hearing, and their right to submit contentions in writing.

3. On or about December 29, 2015, Crosby's Drugs, Inc. timely requested an administrative hearing, which was subsequently scheduled for September 13, 2016.

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

TERMS

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

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Crosby's Drugs, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated December 11, 2015; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same.

3. Crosby's Drugs, Inc. agrees to pay to the OSBP the amount of $1,000.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the OSBP, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Crosby's Drugs, Inc. and its Responsible Person as that term is used in Ohio Administrative Code 4729-5-11 agree and acknowledge that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Crosby's Drugs, Inc. currently holds a professional license, including the OSBP on renewal applications or applications for a new license.

5. Crosby's Drugs, Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Crosby's Drugs, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Crosby's Drugs, Inc. by the OSBP and will NOT discharge Crosby's Drugs, Inc. from any obligation under the terms of this Agreement.

6. Crosby's Drugs, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Crosby's Drugs, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Crosby's Drugs, Inc. will operate.

9. Crosby's Drugs, Inc. waives its right to an appeal and an opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code and specifically withdraws its request for a hearing in this matter.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

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

Approved by:

Crosby's Drugs, Inc., Respondent — Date of Signature: 10/14/2016

Douglas Graff, Attorney for Respondent — Date of Signature: 10/19/2016

Michael A. Mone, R.Ph., President, Ohio State Board of Pharmacy — Date of Signature: 11/7/2016

~~Matthew J. Lampke~~, Ohio Assistant Attorney General — Date of Signature: 11/8/2016

Steven R. Kochheiser

Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO BOARD OF PHARMACY

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

IN THE MATTER OF: **CASE NO. 2015-1428**

Crosby's Drugs, Inc.
c/o Kirk Betteridge, R.Ph.
2609 N. High Street
Columbus, OH 43202

License No. 02-0173000

-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: 12/11/15
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

December 11, 2015

Dear Crosby Drugs, Inc. and Kirk Betteridge,

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

JURISDICTION

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

2. Crosby Drugs, Inc. has a current TDDD license with the Board under license number 02-0173000 which is valid through March 31, 2016 and lists Kirk Betteridge as the Responsible Person.

ALLEGATIONS

1. On or about January 14, 2013, February 13, 2013, and October 27, 2014 you were issued a written warning and required to submit a corrective action plan outlining the policy and procedures for the operation of your compounding facility. A corrective action plan was submitted on or about March 04, 2013 and November 15, 2015 that stated a policy and procedure manual will be created and implemented. During the most recent inspection on May 14, 2015, a Compliance Specialist discovered that the policy and procedures for the operation of the compounding facility were not created or implemented.

2. While conducting the inspection, the Compliance Specialist observed at a minimum thirty-six (36)

different adulterated drugs with outdated beyond use dates stated by the manufacturer. The drugs that were outdated are as follows:

Name & Strength	Quantity	Beyond Use Date
Cisapride 2.5mg capsules	60	05-04-2015
Triest 1.5mg SR capsules	10	04-29-2015
Stanozolol 4mg capsules	40	05-04-2015
T4 75mcg capsules	10	04-30-2015
Triest 1.5mg SR Capsules	30	01-23-2015
Progesterone 200mg SR capsules	30	04-21-2015
Budesonide 1mg capsules	5	04-24-2015
Naltrexone 1.25mg capsules	10	05-01-2015
PRG/E3/E2 100/1.5/0.3mg SR Capsules	20	05-06-2015
Estriol/Testosterone cream 3/0.5/ml	large container	05-07-2015
Testosterone 3mg/ml cream	large container	05-07-2015
Testosterone 50mg/ml gel	large container	04-19-2015
Estriol 0.5% (5mg/ml) HRT	Medium container	04-24-2015
Progesterone/Triest 100/2.5mg (80/10/10) HRT	Medium container	05-11-2015
Estriol 0.5mg/ml HRT	Medium container	04-23-2015
Testosterone prop 2mg/ml	Medium container	05-23-2015
Testosterone 4mg/ml cream	Medium container	04-26-2015
Tri-est 3mg (60/20/20) HRT cream	Medium container	05-06-2015
E2/Test (0.01/0.1%) cream	large container	05-10-2015
Estradiol 0.5mg/ml cream	large container	04-27-2015
Estradiol/test 2/1mg/ml	large container	05-10-2015
Clomipramine 2.5mg/0.1ml	Small container	04-26-2015
Metronidazole 30mg/0.1ml	Small container	05-05-2015
Testosterone 4% cream	Small container	04-26-2015
Clindamycin 30mg/0.1ml LPD	Small container	04-16-2015
DHEA/E3/Test 25/1/10mg/ml	Small container	05-16-2015
Diltiazem 15mg/0.1ml	Small container	04-17-2015
Triest 3mg (60-20-20) ml	2-10ml's	05-06-2015
Biest (80/20) 3mg	large container	04-21-2015
Biest (50/50) 4mg HRT	large container	04-23-2015
E2/E2/TST 06/1.4/1mg/ml	medium container	04-16-2015
Prog/E3/E2/TST 30/0.3/1.2/1.5mg	medium container	05-3-2015
Biest 2.5mg (50/50)	small container	04-21-2015
Amitriptyline 20mg/0.1ml LPD	small container	04-26-2015
Calcitrol 14mg/0.1ml	small container	05-07-2015
Itraconazole 30mg capsules	40 capsules	04-30-2015

3. During the inspection, it was discovered that labels on twenty two (22) compounded drugs prepared in anticipation of a prescription drug order did not contain the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier. The drugs discovered with this defect were:

PRG/TRIEST 50/2.5mg SR Capsules (lot# 120114-05)- missing the identification of the re-packager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Proxicam 1.8mg capsules (lot# 121914-05) - missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Naltrexone 1.5mg capsules (lot 111914-01)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Naltrexone 3.75mg capsules (lot# 120314-07)-missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Gabapentin 50mg capsules (lot# 112614-03)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Cisapride 5mg capsules (lot# 120514-03)- missing the identification of the re-packager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Estradiol 2.5mg/ml HRT (lot# 112314-04)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Triest 1.5mg SR Capsules (lot# 102914-03)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

T4 75mcg capsules (lot#103014-05)- missing the identification of the re-packager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Itraconazole 30mg capsules (lot# 103014-03)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Budesonide 1mg capsules (lot#102414-01)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Progesterone 20mg capsules (lot#102114-03)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Estriol 0.5% (5mg/ml) HRT (lot#102414-10)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.
Estradiol 0.5mg/ml cream (lot# 102714-08)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Triest 3mg (60/20/20) HRT (lot# 112614-14)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Estriol 0.5mg/ml HRT (lot# 102314-12)-missing the identification of the re-packager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Progesterone/Triest 100/2.5mg HRT (lot# 111114-02)- missing the identification of the re-packager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Potassium Bromide 450mg (lot#111714-01) - missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Naltrexone 1.25mg capsules (lot# 103114-01)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Triest 1.5mg SR Capsules (lot# 072314-05)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Cisapride 2.5mg capsules (lot# 110414-03)-missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

Stanozolol 4mg capsules (lot#10414-101)- missing the identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any board approved identifiers.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in paragraph (1) of the Allegations section, if proven, constitutes the following violation of the OAC, punishable by a maximum fine of $1,000.
    a. Minimum Standards for compounding parenteral or sterile product prescriptions, OAC Rule 4729-19-04(B)

2. Such conduct as set forth in paragraph (2) of the Allegations section, if proven, constitutes the following violation of the ORC, a fourth degree misdemeanor, punishable by a maximum fine of $250 if committed by an individual or $2,000 if committed by an organization.

    a. The manufacture, sale, or delivery, holding or offering for sale any drug that is adulterated, ORC Section 3715.52(A)(1)
    b. The adulteration or misbranding of any drug, ORC Section 3715.52(A)(2)

3. Such conduct, as set forth in paragraph (2) of the Allegations section, if proven, also constitutes a violation of Section 3715.64(A)(1) of the ORC, adulteration or misbranding, a misdemeanor of the fourth degree, punishable by a maximum fine of $250 if committed by an individual or $2,000 if committed by an organization.

4. Such conduct as set forth in paragraph (3) of the Allegations section, if proven, constitutes the following violation of the OAC, punishable by a maximum fine of $1,000.
    a. Drugs compounded in a pharmacy, OAC Rule 4729-16-03(O)(2)

5. Such conduct as set forth in paragraphs (1) through (3) of the Allegations Section, if proven, also constitutes violation of each of the following Divisions of Section 4729.57 of the ORC, each violation being a minor misdemeanor, punishable by a maximum penalty of $150 if committed by an individual or $1,000 if committed by an organization:
        a. Violating any Rule of the Board, ORC Section 4729.57(A)(2); and/or
        b. Violating any provision of Chapter 3715 of the Revised Code, ORC 4729.57(A)(4)

6. Finally, such conduct as set forth in paragraphs (1) through (3) of the Allegations Section, if proven, constitutes a violation of OAC, each punishable by a maximum fine of $1,000:
    b. Not of good moral character and habits, OAC Section 4729-9-19(A)(4); 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 Ohio State Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 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 MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the Ohio State Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov 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/dai

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