IN THE MATTER OF: **CASE NO. A-2022-0267**

Hock's Tipp City Pharmacy **License No. 02-2293300**
c/o James Leonard, RPh
5175 South County Road 25-A
Tipp City, OH 45371

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Hock's Tipp City Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of drug security and record keeping. Together, the Board and Hock's Tipp City Pharmacy 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. Hock's Tipp City Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2293300.

FACTS

1. The Board initiated an investigation of Hock's Tipp City Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-2293300, related to Hock's Tipp City Pharmacy's drug security and record keeping.

2. On or about April 9, 2024 the Board sent a Notice of Opportunity for Hearing to Hock's Tipp City Pharmacy, 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 April 15, 2024, Hock's Tipp City Pharmacy, through counsel Steven P. Goodin, timely requested an administrative hearing, which was subsequently scheduled for December 10, 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. Hock's Tipp City Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 9, 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. Hock's Tipp City Pharmacy 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. The Board hereby imposes a written reprimand on Hock's Tipp City Pharmacy's TDDD license, number 02-2293300.

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

6. Hock's Tipp City Pharmacy 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 Hock's Tipp City Pharmacy 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 Hock's Tipp City Pharmacy by the Board and will NOT discharge Hock's Tipp City Pharmacy from any obligation under the terms of this Agreement.

7. Hock's Tipp City Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Hock's Tipp City Pharmacy understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Hock's Tipp City Pharmacy will operate.

10. Hock's Tipp City Pharmacy explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

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

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

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

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

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

[SIGNATURE PAGE FOLLOWS]

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

Approved by:

James Leonard, RPh, on behalf of,
Hock's Tipp City Pharmacy, Respondent

10-30-24
Date of Signature

Steven P. Goodin
Attorney for Respondent

10-30-24
Date of Signature

Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

11.07.2024
Date of Signature

-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: Apr 09, 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-2022-0267**

Hock's Tipp City Pharmacy **License No. 02-2293300**
c/o James Leonard, RPh
5175 South County Road 25-A
Tipp City, OH 45371

April 09, 2024

Dear Hock's Tipp City Pharmacy and James Leonard, RPh

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

JURISDICTION

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

2. Hock's Tipp City Pharmacy, located at 5175 South County Road 25-A, Tipp City, Ohio, has an active TDDD license with the Board under license number 02-2293300, which lists James Leonard as the Responsible Person.

ALLEGATIONS

1. On or about May 16, 2020, Hock's Tipp City Pharmacy, located at 5175 South County Road 25-A, Tipp City, Ohio, filed a Theft and Loss Report with the Board for the loss of a partial bottle of acetaminophen/codeine, 300/30mg, a Schedule III controlled substance, containing approximately 92 tablets. The report states an additional loss of 790 tablets of acetaminophen/codeine, 300/30mg over the past year was discovered as a result of their internal investigation.

2. On or about August 26, 2020, agents of the Board performed counts for audit purposes for the date range of December 30, 2018, through August 26, 2020, at Hock's Tipp City Pharmacy. The results are as follows:

    a. Shortage of 6,167 tablets of acetaminophen/codeine 300/30mg, a Schedule III controlled substance.

    b. Shortage of 2,661 tablets of acetaminophen/codeine 300/60mg, a Schedule III controlled substance.

    c. Shortage of 50 capsules of butalbital/aspirin/caffeine 50/325/40mg, a Schedule III controlled substance.

    d. Overage of one film buprenorphine/naloxone 8/2mg.

3. On or about June 17, 2021, agents of the Board conducted an inspection at Hock's Tipp City Pharmacy. The following issues were found:

    a. Records of ordering, receiving, inventory, and/or dispensing were not sufficient to determine how the losses were occurring.

    b. The pharmacists ignored the electronic perpetual inventory and ordered more dangerous drugs to fill prescriptions while their inventory showed plenty on hand.

    c. Expired drugs were found in the active drug stock, including flavoring agents for compounds and drugs which had been returned to stock.

    d. Multiple Return to Stock bottles were found to be expired and/or with the expiration date on bottle more than one year past the date the drug was originally dispensed and placed in the prescription vial.

    e. Customized medication packaging label(s) which included Beyond Use Dates (BUD) of one year after packaging were observed.

    f. The pharmacy had not performed and documented an annual query of eLicense prior to purchasing dangerous drugs at wholesale.

4. On or about June 17, 2021, agents of the Board performed counts for audit purposes for the date range of December 1, 2019, through June 21, 2021, at Hock's Tipp City Pharmacy. Additional overages and shortages were discovered, including, but not limited, to the following:

    a. Shortage of 1,077 tablets of acetaminophen/codeine 300/30mg (40 tablets since audit on August 26, 2020), a Schedule III controlled substance.

b. Shortage of 1,358 tablets of acetaminophen/codeine 300/60mg (0 tablets since last audit), a Schedule III controlled substance.

c. Shortage of 109 tablets of alprazolam 0.5 mg, a Schedule IV controlled substance.

d. Shortage of 147 tablets of zolpidem 10 mg.

e. Shortage of 193 tablets of hydrocodone/APAP 5/325 mg, a Schedule II controlled substance.

f. Shortage of 57 tablets of oxycodone/APAP 5/325 mg, a Schedule II controlled substance.

g. Shortage of two tablets of oxycodone 10 mg, a Schedule II controlled substance.

h. Overage of 174 tablets of alprazolam 0.25 mg, a Schedule IV controlled substance.

i. Overage of 1072 tablets of alprazolam 1 mg, a Schedule IV controlled substance.

j. Overage of 255 tablets of alprazolam 2 mg, a Schedule IV controlled substance.

k. Overage of 3,491 tablets of tramadol 50 mg, a Schedule IV controlled substance.

l. Overage of 57 tablets of phentermine 37.5 mg, a Schedule IV controlled substance.

m. Overage of 861 tablets of zolpidem 5 mg, a Schedule IV controlled substance.

5. On or about January 26, 2022, Hock's Tipp City Pharmacy submitted a theft and loss report outside the thirty-day requirement. The theft and loss report was for the following losses:

a. 6,207 tablets of acetaminophen/codeine 300/30 mg.

b. 2,661 tablets of acetaminophen/codeine 300/60 mg.

c. 109 tablets of alprazolam 0.5 mg.

d. 147 tablets of zolpidem 10 mg.

e. 193 tablets of hydrocodone/APAP 5/325 mg.

f. 57 tablets of oxycodone/APAP 5/325 mg.

g. 2 tablets of oxycodone 10 mg.

h. 50 capsules of butalbital/aspirin/caffeine 50/325/40 mg.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective April 6, 2017, and March 22, 2020, and March 31, 2021, TDDD license requirements, each violation punishable by a maximum penalty of $1,000:

    a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or

    b. A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or

    c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or

    d. Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC 4729.55(D); and/or

    e. If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation, ORC 4729.55(E).

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

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

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

    c. 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

    d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or

e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or

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

3. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); and/or

e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or

f. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to other, OAC Rule 4729:5-4-01(B)(25).

4. Such conduct as set forth in paragraph (5)(a-h, inclusive) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:5-3-02(B), Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents, the theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss., effective, October 31, 2021, each violation is punishable by a maximum penalty of $1,000.

5. Such conduct as set forth in paragraph (3)(f) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04(A) of the OAC, Verification of licensure prior to sale or purchase, as effective March 1, 2019, each violation punishable by a maximum penalty of $1,000 if committed by an organization:

a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the boards online roster (available on the boards website: www.pharmacy.ohio.gov) to confirm the seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

b. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the boards online roster (available on the boards website: www.pharmacy.ohio.gov) to confirm the seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2).

6. Such conduct as set forth in paragraph (3)(f) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:5-3-04(B), Verification of licensure prior to sale or purchase, if no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of 4729.51 of the Revised Code, effective, March 1, 2019, each violation is punishable by a maximum penalty of $1,000.

7. Such conduct as set forth in paragraphs (3)(a) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-5-24 of the OAC, Drug inventory records and other record keeping provisions, all records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years, as effective December 1, 2020, each violation punishable by a maximum penalty of $1,000.

8. Such conduct as set forth in paragraphs (1), (2)(a-d, inclusive), (3)(a), (3)(b), and (4)(a-m, inclusive) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

    a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or

    b. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

9. Such conduct as set forth in paragraph (3)(c), (3)(d), and (3)(e) of the Allegations Section, if proven, constitutes a violation of the following divisions of Section 3715.52 of the ORC, constituting a misdemeanor of the fourth degree, each punishable by a maximum fine of $2,000, if committed by an organization:

    a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded, ORC 3715.52(A)(1); and/or

    b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC 3715.52(A)(2).

10. Such conduct as set forth in paragraph (3)(c), (3)(d), and (3)(e) of the Allegation Section, if proven, each constitutes a violation of section Rule 4729:5-3-06(A) of the OAC, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons. As effective March 1, 2019, each violation punishable by a maximum penalty of $1,000.

11. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible Person of a Terminal Distributor, as effective March 1, 2019, each violation punishable by a maximum penalty of $1,000:

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

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

    c. 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).

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 <u>not</u> be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to

practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

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

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

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