

BEFORE THE INDIANA BOARD
OF PHARMACY
CAUSE NUMBER: 2023 IBP 0010

IN THE MATTER OF THE LICENSE OF:)
)
PAUL’S PHARMACY)
)
LICENSE NUMBER: 60006286A (ACTIVE))



FINAL ORDER ACCEPTING PROPOSED SETTLEMENT AGREEMENT

The State of Indiana (“Petitioner”), by counsel, Deputy Attorney General Ryan P. Eldridge, on behalf of the Office of the Indiana Attorney General, and Paul’s Pharmacy (“Respondent”), by Counsel Stephanie Eckerle, signed a Proposed Settlement Agreement (“Agreement”), which purports to resolve all issues involved in the action regarding the Respondent’s license before the Indiana Board of Pharmacy (“Board”), and which Agreement has been submitted to the Board for approval.

The Board, after reviewing the Agreement at its August 14, 2023 meeting, now finds it has been entered into fairly and without fraud, duress, or undue influence, and was fair and equitable between the parties. The Board hereby incorporates the Agreement, which is attached hereto and incorporated herein as Exhibit A and approves and adopts in full the Agreement as a resolution of this matter. The Board approved this Agreement by a vote of 6-0-0. Incorporated into the Agreement was the consensus of both parties to Stipulated Facts, Stipulated Conclusions of Law, and Agreed Disposition.

WHEREFORE, the Board hereby accepts and approves the Agreement, settling all matters in this case consistent with the terms of the Agreement between the parties, and Respondent is hereby **ORDERED** to abide by all the terms of the Agreement.

SO ORDERED, this 18th day of September 2023.

INDIANA BOARD OF PHARMACY

By:  for
Mark Bunton, R.Ph.
Board President

CERTIFICATE OF SERVICE

I certify that a copy of the “Final Order Accepting Proposed Settlement Agreement” has been duly served upon:

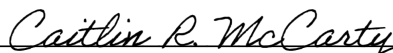
Paul’s Pharmacy
2345 W Franklin Street
Evansville, IN 47712
Service by U.S. Mail & Email

Stephanie Eckerle
Krieg DeVault LLP
One Indiana Square, Ste 2800
Indianapolis, IN 46204
Service by U.S. Mail & Email

Ryan P. Eldridge
Deputy Attorney General
Indiana Government Center South, Fifth Floor
302 West Washington Street
Indianapolis, Indiana 46204-2770
Ryan.eldridge@atg.in.gov
Service by Email

9.18.2023

Date



Caitlin R. McCarty, Litigation Specialist

Indiana Board of Pharmacy
Indiana Government Center South
402 West Washington St., Room W072
Indianapolis, IN 46204
Phone: 317-234-2067
Fax: 317-233-4236
Email: pla4@pla.in.gov

Explanation of Service Methods

Personal Service: by delivering a true copy of the aforesaid document(s) personally.

Service by U.S. Mail: by serving a true copy of the aforesaid document(s) by First Class U.S. Mail, postage prepaid.

Service by Email: by sending a true copy of the aforesaid document(s) to the individual’s electronic mail address.

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FILED

AUG 14 2023

Indiana Professional
Licensing Agency

PROPOSED SETTLEMENT AGREEMENT

The State of Indiana ("Petitioner"), by counsel, Deputy Attorney General Ryan P. Eldridge, on behalf of the Office of the Indiana Attorney General, and Paul's Pharmacy ("Respondent"), by Counsel Stephanie Eckerle, hereby execute this Agreement as a disposition of the Administrative Complaint filed in this cause with the Indiana Board of Pharmacy ("Board"). This Agreement is subject to the review and approval of the Board pursuant to Ind. Code § 25-1-9 *et seq.* and the Administrative Orders and Procedures Act, Ind. Code § 4-21.5-3 *et seq.*

STIPULATED FACTS

Parties

1. The Office of the Attorney General ("OAG") is empowered under Ind. Code § 25-1-7-7 to prosecute this action on behalf of Petitioner against Respondent's license.
2. Respondent is a pharmacy and holds license number 60006286A, which was issued by the Board on January 5, 2012, and expires on December 31, 2023.
3. Respondent's address on file with the Indiana Professional Licensing Agency ("IPLA") is 2345 W. Franklin Street, Evansville, Indiana 47712.

Jurisdiction

4. On October 18, 2022, the OAG received a consumer complaint filed against Respondent, and an investigation was then conducted as authorized by Ind. Code § 25-1-7-5(b)(4).
5. After investigation, the OAG determined that the complaint had merit.

6. The OAG having tendered a meritorious complaint, the Board has jurisdiction to hear this matter under Ind. Code § 25-1-7-5(b)(1).

7. Further, at all times relevant, Respondent was a “practitioner” as that term is defined by Ind. Code § 25-1-9-2. Respondent is also a “person” as that term is defined by Ind. Code § 25-26-13-2.

8. As such, the Board has authority to hear this case and to impose any of the sanctions enumerated under Ind. Code § 25-1-9-9.

Prior Discipline

9. On February 12, 2014, Respondent was placed on indefinite probation by this Board for a minimum of two (2) years based on expired medications being found in the pharmacy area.

10. On December 6, 2016, Respondent successfully petitioned this Board for probation withdrawal.

Recent IPLA Inspections

11. On July 26, 2022, IPLA conducted an inspection of Respondent’s facility, which resulted in a Corrective Action Plan. The following violations were noted:

- a. Expired medications found in a random search of active pharmacy shelves.
- b. Nonsterile compounded medications were given Beyond Use Dates (BUDs) outside the scope of United State Pharmacopeia (USP) 795.
- c. Medications in the compounding area and active shelves contained inappropriate BUDs.

- d. Return-to-Stock medications were being returned to the ScriptPro cabinet, and cells were not being changed to reflect the original medication dispensed date.
- e. Failed to produce immunization certification (training) for a pharmacist at this location at the time of the July 26, 2022 inspection.

12. On October 12, 2022, IPLA conducted an inspection of Respondent's facility, which resulted in a fail. The following violations were noted:

- a. Respondent was assigning BUDs beyond those permitted in USP 795.
- b. Failure to have documentation to support BUDs that exceeded the USP 795 standards at the time of inspection.

13. IPLA also found in October 2022 that Respondent failed to produce written procedures for USP 795.

14. On February 1, 2023, IPLA conducted an inspection of Respondent's facility, which resulted in a fail. The following violations were noted:

- a. A container of ice cream was located in the pharmacy freezer.
- b. Expired dietary supplement found on the active pharmacy shelf.
- c. Seven (7) vessels found with BUDs beyond USP 795 recommendations.

15. IPLA also found in February 2023 that Respondent failed to maintain maintenance and cleaning policies for the Eyecon scanner/counter and ScriptPro robot, and failed to produce technician files. At the time, Respondent was unable produce compounding formula sheets and policies or procedures for compounding formula sheets.

STIPULATED CONCLUSIONS OF LAW

Count 1

Adulterated Drugs: Expired Drugs in the Pharmacy (July 26, 2022)

16. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-3(1). Specifically, Respondent violated Ind. Code § 16-42-3-3(1) by the pharmacy having expired medications in the pharmacy area at the time of the July 26, 2022 inspection.

Count 2

Adulterated Drugs: Expired Drugs in the Pharmacy (February 1, 2023)

17. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-3(1). Specifically, Respondent violated Ind. Code § 16-42-3-3(1) by the pharmacy having expired medication in the pharmacy area at the time of the February 1, 2023 inspection.

Count 3

Adulterated Drugs: BUDs beyond USP 795 standards (July 26, 2022)

18. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-3(3). Specifically, Respondent violated Ind. Code § 16-42-3-3(3) by the pharmacy having medications with BUDs beyond USP 795 standards without having documentation to support such BUDs at the time of the July 26, 2022 inspection.

Count 4

Adulterated Drugs: BUDs beyond USP 795 standards (October 12, 2022)

19. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-3(3). Specifically, Respondent violated Ind. Code § 16-42-3-3(3) by the pharmacy having medications with BUDs beyond USP

795 standards without having documentation to support such BUDs at the time of the October 12, 2022 inspection.

Count 5

Adulterated Drugs: BUDs beyond USP 795 standards (February 1, 2023)

20. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-3(3). Specifically, Respondent violated Ind. Code § 16-42-3-3(3) by the pharmacy having medications with BUDs beyond USP 795 standards without having documentation to support such BUDs at the time of the February 1, 2023 inspection.

Count 6

Misbranded Medication (July 26, 2022)

21. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-4(1). Specifically, Respondent violated Ind. Code § 16-42-3-4(1) by assigning BUDs beyond USP 795 standards, failure to consistently label medications, and inappropriate return-to-stock procedures for the ScriptPro machine, as witnessed at the time of the July 26, 2022 inspection.

Count 7

Misbranded Medication (October 12, 2022)

22. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-4(1). Specifically, Respondent violated Ind. Code § 16-42-3-4(1) by assigning BUDs beyond USP 795 standards, as witnessed at the time of the October 12, 2022 inspection.

Count 8
Misbranded Medication (February 1, 2023)

23. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) as evidenced by Respondent's violation of Ind. Code § 16-42-3-4(1). Specifically, Respondent violated Ind. Code § 16-42-3-4(1) by assigning BUDs beyond USP 795 standards, and failure to adequately label medications, as witnessed at the time of the February 1, 2023 inspection.

Count 9
Failure to Keep Abreast of Current Professional Theory and Practice

24. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(4)(B). Specifically, Respondent violated Ind. Code § 25-1-9-4(a)(4)(B) by Respondent's failure to keep abreast of current professional theory or practice regarding USP 795 standards and Indiana pharmacy regulations.

MITIGATING FACTORS

1. Respondent has hired a full-time Chief Operations and Chief Compliance Officer ("CCO") with extensive experience in pharmacy compliance, including compounding and compliance with USP 795 standards, and the goal of the CCO is to oversee and optimize day-to-day operations while ensuring a strong culture of compliance with laws, regulations, and industry standards.

2. Respondent has created and is implementing an audit and gap analysis that includes a heightened monitoring plan to verify compliance with laws, regulations, and Respondent's policies and procedures, and which addresses each violation alleged in the administrative complaint tendered by the OAG.

3. Respondent has created, educated, and implemented new policies, as well as updated old policies, addressing all issues alleged in the administrative complaint tendered by the OAG.

4. Respondent is requiring increased training and continuing education for its owner, pharmacy manager, pharmacist, and pharmacist technicians with a focus on regulatory compliance and USP 795.

AGREED DISPOSITION

It is now therefore agreed by Respondent and Petitioner as follows:

1. The Board has jurisdiction over Respondent and the subject matter in this disciplinary action.

2. The parties execute this Agreement voluntarily.

3. Both parties voluntarily waive their rights to a public hearing on the Complaint and all other proceedings in this action to which either party may be entitled by law, including judicial review.

4. Petitioner agrees the terms of this Agreement will resolve any and all pending claims or allegations relating to disciplinary action against Respondent's pharmacy license.

5. Respondent's pharmacy license shall be placed on **INDEFINITE PROBATION** for **NOT LESS THAN EIGHTEEN (18) MONTHS** from the date of the final order. While on probation:

- a. Respondent shall **pass at least two (2) IPLA inspections. The Board shall complete** one (1) inspection within the first year of probation, and another inspection within thirty (30) days of Respondent's withdrawal petition. Respondent shall have no violations in any noted inspection. If **any violations**

are noted, the Board shall determine whether an Order to Show Cause is appropriate.

- b. Respondent shall keep the facility's contact information up to date with the Board.
- c. Respondent shall keep the Board informed of the facility's management of the pharmacy.
- d. Respondent shall provide **bimonthly reports to the Board** detailing remediation taken in accordance with the plan of remediation referenced in Section 5(e) below, which shall include bimonthly audits addressing the alleged violations in this case. These reports shall be **typed and sent to** pla4@pla.in.gov with all relevant documentation. The **first report** will be due two (2) months after the issuance of the final order.
- e. Respondent shall provide a **plan of remediation** within one (1) month of the issuance date of the final order. The plan shall detail all steps taken to remediate any violations in this case and any other relevant policies and procedures created or updated. In addition, Respondent shall make the plan available for inspection at all IPLA inspections while on probation.

6. Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE of FIVE DOLLARS (\$5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Executive Assistant, Consumer Protection
302 West Washington Street, 5th Floor
Indianapolis, IN 46204

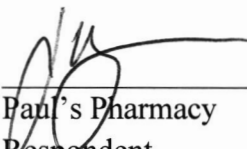
7. Respondent shall pay a **FINE** of **four thousand dollars (\$4,000)** to the Indiana Professional Licensing Agency. The full fine amount shall be paid within ninety (90) days of the Final Order Accepting Settlement. Payment shall be made payable to the State of Indiana by personal check, cashier's check, or money order, and sent to the following address:

Indiana Professional Licensing Agency
Attn: Indiana Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, Indiana 46204

8. Respondent has carefully read and examined this agreement and fully understands its terms and that, subject to a final order issued by the Board, this Agreement is a final disposition of all matters and not subject to further review.

9. Respondent further understands that a violation of the Final Order, any non-compliance with the statutes or regulations regarding the practice of pharmacy, or any violation of this Settlement Agreement may result in Petitioner requesting a summary suspension of Respondent's license, an Order to Show Cause as may be issued by the Board, or a new cause of action pursuant to Ind. Code § 25-1-9-4, any or all of which could lead to additional sanctions, up to and including a revocation of Respondent's license.

10. The parties agree to the continuing jurisdiction of the Board.



Paul's Pharmacy
Respondent



Date



Counsel for Respondent

8/11/2023

Date

Ryan Eldridge

Ryan P. Eldridge
Deputy Attorney General
Attorney No.: 34578-49

8/11/2023

Date

STATE OF Indiana)
COUNTY OF Vanderburgh) SS:



Before me a Notary Public for said County and State, personally appeared Jacob Mayer, on behalf of Paul's Pharmacy, first duly sworn by me upon his oath, says that the facts alleged in the foregoing instrument are true.

Signed and sealed this 11 day of August, 2023.

Katie Smith
Signature

Katie Smith
Printed

My Commission Expires: March 2, 2030
County of Residence: Vanderburgh