

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

IN THE MATTER OF THE LICENSE OF:)
)
PAUL'S PHARMACY)
)
LICENSE NO: 60006286A (ACTIVE))

ADMINISTRATIVE COMPLAINT

FILED
MAR 30 2023

Indiana Professional
Licensing Agency

Petitioner, the State of Indiana, by counsel, Deputy Attorney General Ryan P. Eldridge, pursuant to Ind. Code § 25-1-7-7 and Ind. Code ch. 4-21.5-3, brings this Administrative Complaint before the Indiana Board of Pharmacy against the pharmacy license of Paul's Pharmacy ("Respondent") for violations of Ind. Code § 25-1-9-4. In support, Petitioner states and alleges the following:

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, and, accordingly, a copy of that consumer complaint is being submitted to the Board herewith as Exhibit A.

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.

Respondent’s Misconduct

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 numerous 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 were labeled incorrectly or 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.

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 of one (1) year or more to compounded medications, which is outside the scope of USP 795.
- b. Failure to have documentation to support BUDs that exceeded six (6) months.

13. IPLA also found in October 2022 that Respondent failed to have 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 medical freezer.
- b. Expired dietary supplement found on the active pharmacy shelf.
- c. Seven (7) vessels found with BUDs beyond USP 795 recommendations or failed to have a BUD or proper labeling.

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 maintain

technician files. At the time, Respondent was unable produce compounding formula sheets and had no policies or procedures for compounding formula sheets.

CHARGES

16. Paragraphs one (1) through fifteen (15) are incorporated by reference.

Count 1

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

17. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

18. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

19. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

20. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

21. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

22. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

23. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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)

24. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question 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 consistently 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

25. Respondent's conduct constitutes a violation of Ind. Code § 25-1-9-4(a)(4)(B) in that Respondent has continued to practice although Respondent has become unfit to practice due to failure to keep abreast of current professional theory or practice. Specifically, Respondent violated Ind. Code § 25-1-9-4(a)(4)(B) by Respondent's failure to follow USP 795 standards, failure to maintain essential documentation, failure to consistently label medications with appropriate BUDs, and failure to create necessary policies and procedures.

REQUESTED RELIEF

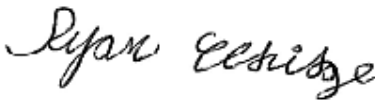
ACCORDINGLY, Petitioner requests that the Board issue an order against Respondent that:

- I. Imposes one or more of the disciplinary sanctions authorized by Ind. Code § 25-1-9-9;
- II. Directs Respondent to pay all of the costs incurred in the prosecution of this case, as authorized by Ind. Code § 25-1-9-15;
- III. Directs Respondent to pay a fee of Five Dollars (\$5.00) to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund pursuant to Ind. Code § 4-6-14-10(b); and,
- IV. Provides any other relief the Board deems just and proper.

Respectfully submitted,

THEODORE E. ROKITA
Indiana Attorney General
Attorney No. 18857-49

By:


Ryan Eldridge
Deputy Attorney General
Attorney No. 34578-49

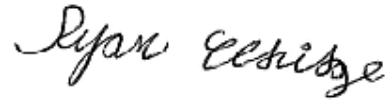
Office of Attorney General Todd Rokita
302 West Washington Street
Indiana Government Center South, 5th Floor
Indianapolis, Indiana 46204-2770
Email: ryan.eldridge@atg.in.gov

CERTIFICATE OF SERVICE

I hereby certify that on the 30th day of March, 2023, a true and correct copy of this Administrative Complaint was served upon the below-listed party or parties:

Paul's Pharmacy
2345 W. Franklin Street
Evansville, Indiana 47712

By:

A handwritten signature in black ink that reads "Ryan Eldridge". The signature is written in a cursive, flowing style.

Ryan Eldridge
Deputy Attorney General
Attorney No. 34578-49



CONSUMER COMPLAINT
Office of the Indiana Attorney General
(R5 / 12-17)

State Ex. A

INSTRUCTIONS: To prevent delay, please be sure to complete **both sides** of this form in full. Please print clearly or type. **Do not include your Social Security Number** on this form or in any accompanying documents. **Please note:** If you have already obtained a judgment, or there is pending litigation, we may be limited or unable to take further action on your complaint.

Section 1: Your Information

Salutation ☒ Mr. ☐ Mrs. ☐ Ms. ☐ Dr. ☐ Miss ☐ Rev.		Street Address 402 W. Washington St.	
Full Name or Organization/Agency Professional Licensing Agency		City Indianapolis	State IN
If an Organization/Agency provide a Primary Contact Name Ronald Hinderliter		County Marion	Zip Code 46204
Age Group ☐ 18-24 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 55-59 ☐ 60+		Daytime Phone [REDACTED]	
		Email Address [REDACTED]	
		May we contact you by email? If yes, we will not contact you by regular mail ☒ Yes ☐ No	
		Are you or your spouse active military? ☐ Yes ☐ No	

Section 2: Who is the Complaint Against?

Individual/Business Paul's Pharmacy		Name of Individual/Representative you dealt with Brian Perry #26015540A	
Street Address 2345 W Franklin St.		City Evansville	State IN
County Vanderburgh		Zip Code 47712	Daytime Phone [REDACTED]
		Email Address [REDACTED]	

Section 3: Transaction/Incident Details

3-A: Date of Transaction/Incident 10/12/2022		3-B: If a Transaction, what was the Transaction for? ☐ My business ☐ My family/household ☐ My farm ☐ Non-Profit/Church	
3-C: Where did the Transaction/Incident occur? (check box where applicable) ☐ My home ☐ By Internet/Email ☐ At the location of the business ☐ By Telephone ☐ Away from the location of the business (work, convention, etc.) ☐ By Social Media ☐ By Mail ☐ Other _____			
3-D: What was the very first contact between you and the Individual/Business? ☐ I telephoned the individual/business ☐ I received information in the mail ☐ I responded to a printed advertisement ☐ I responded to a TV/radio ad ☒ I went to the location of the business ☐ Other, describe below: ☐ A person came to my home ☐ I received a phone call from the business ☐ I received information by email ☐ I responded to an offer on the internet			
3-E: How did you Pay? ☐ Cash ☐ Credit Card/Pre-Pay ☐ Medicaid ☐ Pay-Pal ☐ Wire Transfer ☐ Check ☐ Installment Loan ☐ Medicare ☐ Private Insurance ☐ Other _____			
3-F: What, if any, is the Dollar amount associated with your loss?		\$	

Section 4 Actions Taken by Consumer

☐ Yes ☐ No	4-A: Did you sign a written agreement or contract? If yes, please attach a copy of the documentation.
☐ Yes ☐ No	4-B: Have you hired a private attorney?
☐ Yes ☐ No	4-C: Have you started a court action? If yes, please attach a copy of all court papers.
☐ Yes ☐ No	4-D: Have you sued, or have you been sued, over this incident/transaction? If yes, please attach a copy of all court papers.

Section 4 Actions Taken by Consumer - *continued*

- ☐ Yes ☐ No 4-E: Have you complained to the Individual/Business?
- ☐ Yes ☐ No 4-F: Have you filed a complaint with any other agency? If yes, list other agency:

Section 5 Transaction/Incident Details – *attach additional pages if necessary*

Please remember to attach a copy of all documentation involved (order blank, warranty, credit card receipt and statement, invoice, contract or written agreement, advertisement, cancelled check, correspondence etc). Please print clearly or type. **Do Not Include your Social Security Number.**

If you answered "Yes" to 4-E or 4-F above, please include those details also with your description of the Transaction/Incident.

Follow-Up inspection conducted on 10/12/2022 as a result of a Corrective Action Plan inspection that was conducted on 07/26/2022. This inspection was conducted by C/O Ron Hinderliter and Melissa Gresham and, after conferring with Compliance Supervisor Zaneta Nunnally and Diversion Officer, Tim Thomas, the result of this inspection was a failure. Assisting in this inspection was Pharmacist Brian Perry. The focus of this inspection was the items identified in the Corrective Action Plan.

856 IAC 4-1-1 Immunization Administration: The Pharmacy was able to secure immunization certification training of Jonathan Garvey.

IC 16-42-3 Uniform Food, Drug and Cosmetic: Nonsterile compounds were located on active shelves with assigned BUD over one (1) year. (photographs) No documentation could be produced by the pharmacy to site exceptions. Also, no policy and procedures have been established by the pharmacy.

IC 25-26-13-2, IC 16-42-3: Several bottles of tablets were located on active shelves with no labelling. The pharmacist stated they were tablets that were dropped on the floor.

21 CFR 21-1: The pharmacy is not following USP 795 guidelines when assigning BUD 's to compounds. No policy and procedures have been prepared.

IC 16-42-3.4, 21 CFR 211 RTS to Script Pro: When returning RTS to Script Pro, staff that primarily utilizes the robot are unclear of dates being assigned as BUD at the time medication is dispensed.

The pharmacy has not performed the items they identified in their plan to correct, submitted August 4, 2022. (attachment)

Extending Beyond Use Dates of nonsterile compounds for longer than six months and unable to present documentation to show stability of these compounds. (photographs)

Section 6 How would you like your Complaint resolved?

Any action the Indiana Board of Pharmacy see fit.

Section 7 WHAT HAPPENS NEXT?

The Consumer Protection Division will send a copy of your complaint to the respondent individual/business or licensed professional. This office cannot disclose your complaint against a licensed professional to the public unless this office files a disciplinary action against the licensed professional. This office represents the State of Indiana and is limited in the remedies it can pursue. You may be entitled to compensation or other rights that we cannot pursue for you. In addition to filing this complaint, you may want to consider contacting a private attorney or your local small claims court.

Section 8 Mail Completed Forms to:

Office of the Indiana Attorney General
Consumer Protection Division
Government Center South, 5th Floor
302 W. Washington Street
Indianapolis, IN 46204
317-232-6330 (phone) • 317-233-4393 (fax)
www.IndianaConsumer.com

Section 9 Consent and Verification

Do you consent to disclosing the following information to the public? →

- | | | |
|---|-----------------------------|--|
| ☒ Yes | ☐ No | The nature of the complaint and the individual/business name |
| ☒ Yes | ☐ No | Your name |
| ☒ Yes | ☐ No | Your phone number |

I affirm, under penalties for perjury, that the foregoing representations are true. I consent to the Consumer Protection Division obtaining or releasing any information in furtherance of the disposition of this complaint. I consent to the release of information included in this complaint to other public agencies attempting to discover ongoing fraudulent patterns or practices and for the purpose of law enforcement. I understand that I should not include my Social Security Number in any information submitted to the Consumer Protection Division. If I do provide my Social Security Number, I expressly consent to the disclosure of my Social Security Number in accordance with Indiana Code § 4-1-10-5(2).

Your signature

Date

10/18/2022