

**BEFORE THE INDIANA BOARD
OF PHARMACY
CAUSE NUMBER.: 2023IBP0010**

IN THE MATTER OF THE LICENSE OF:
PAUL'S PHARMACY
LICENSE NO.: 60006286A

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HEARING NOTICE AND CASE MANAGEMENT ORDER

Pursuant to Ind. Code § 4-21.5-3-20, the Indiana Board of Pharmacy (“Board”) issues the following Hearing Notice:

- 1) On February 18, 2025 a petition for probation withdrawal was filed before the Board by the above-captioned practitioner (“Respondent”).
- 2) A final administrative hearing on this petition is scheduled on April 14, 2025 at 8:30 a.m. EST in W064, 402 W. Washington Street, Indianapolis, IN 46204. This hearing is to determine whether the terms of probation on the Respondent’s license should be withdrawn/modified.
- 3) The Board will be presiding as administrative law judge in this matter. The Board is empowered to hold this administrative hearing pursuant to the authority of Ind. Code ch. 25-1-9 and Ind. Code art. 4-21.5. et seq.
- 4) In preparation for the hearing, the parties shall adhere to the following dates:

4/7/2025	On or before this date, the parties shall file with the Board a joint stipulation as to all facts, witnesses, and exhibits not reasonably in dispute. If a party fails to stipulate to any exhibit, it shall file with the
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	Board a statement of its objections to that exhibit. The parties shall label any joint exhibits with roman numerals (e.g., Ex. I).
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- 5) Communications regarding hearing schedules and procedures shall be sent via e-mail to Clerk@pla.in.gov.
- 6) Any party may be represented by counsel at the party's own expense.
- 7) A party who fails to attend or participate in a pre-hearing conference, hearing, or other later stage of this proceeding may be held in default or have the proceeding dismissed under Ind. Code § 4-21.5-3-24.
- 8) Any matters containing confidential material shall be marked "NOT FOR PUBLIC ACCESS" and submitted without redaction. Concurrent with such a filing, a version with all confidential information redacted shall be filed and marked "PUBLICLY ACCESSIBLE".

SO ORDERED this 18th day of March 2025.

By: Kimberly Snyder for
Steve Anderson, R.Ph., Chair
Indiana Board of Pharmacy

DISTRIBUTION

I certify that a copy of this Case Management Order has been duly served upon:

Paul's Pharmacy
2345 W Franklin St.
Evansville, IN 47712
Service by Email and U.S. Mail

Stephanie Eckerle
Krieg DeVault LLP
One Indiana Square, Ste 2800
Indianapolis, IN 46204
seckerle@kdlegal.com
Service by Email and U.S. Mail

Ryan Eldridge
Office of the Attorney General
Indiana Government Center South, 5th Floor
302 West Washington Street
Indianapolis, IN 46204
Ryan.Eldridge@atg.in.gov
Service by Email

03/18/2025

Date

Sydney Baylis

Sydney Baylis, Litigation Specialist

Indiana Professional Licensing Agency
Indiana Government Center South
402 West Washington St., Room W072
Indianapolis, IN 46204
Phone: 317-232-2960
Fax: 317-233-4236
Email: Clerk@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.

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



1. Respondent has kept the Board informed of its facility contact information including address and telephone number.
2. Respondent has kept the Board informed of its facility's management of the pharmacy.
3. Respondent provided, within one (1) month of the Final Order, a plan detailing all steps taken to remediate any violations (the "Remediation Plan") and at all such times made the Remediation Plan available for Board inspection. The Remediation Plan is attached hereto as Exhibit B.

4. Respondent submitted bi-monthly summaries to the Board detailing remediation actions taken, in accordance with the Remediation Plan. These bi-monthly summaries are attached hereto as Exhibit C.
5. Per the terms of the Final Order, Respondent is required to pass two (2) Indiana Professional Licensing Agency inspections – one (1) inspection within the first year of probation, and a second inspection within thirty (30) days of filing this Motion. Respondent passed one (1) Indiana Professional Licensing Agency inspection on October 31, 2024. A copy of the inspection report is attached hereto as Exhibit D. Respondent will undergo another Indiana Professional Licensing Agency inspection and will supplement this Motion with documentation of such passed second inspection.
6. Respondent paid a fee of five dollars (\$5.00), pursuant to Ind. Code § 4-6-14-10(b), to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund.
7. Respondent paid a fine in the amount of four thousand dollars (\$4,000.00), payable to the Indiana Professional Licensing Agency.
8. Respondent has understood and complied with all terms of the Final Order, and respectfully requests that the Board release it from indefinite probation.
9. Pursuant to the terms of the Final Order, Respondent hereby additionally requests the scheduling of a Board inspection within thirty (30) days of this Motion.

Respectfully submitted,

/s/ Stephanie T. Eckerle

Stephanie T. Eckerle (#27091-49)

KRIEG DEVAULT LLP

One Indiana Square, Suite 2800

Indianapolis, Indiana 46204

Phone: (317) 238-6373

Fax: (317) 636-1507

Email: seckerle@kdlegal.com

Attorney for Respondent

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing has been served by mail, with courtesy copy by email, this 18th day of February 2025 to the following:

Kim Snyder, Board Director
Indiana Professional Licensing Agency
Attn: Indiana Board of Pharmacy
402 West Washington St., Rm. W072
Indianapolis, Indiana 46204
pla4@pla.in.gov

Ryan P. Eldridge, Deputy Attorney General
Office of the Attorney General
Indiana Government Center South
302 West Washington St., 5th Floor
Indianapolis, Indiana 46204
ryan.eldridge@atg.in.gov

Caitlin Cress, Ass't Board Director
Indiana Professional Licensing Agency
Attn: Indiana Board of Pharmacy
402 West Washington St., Rm. W072
Indianapolis, Indiana 46204
cacress@pla.in.gov

/s/ Stephanie T. Eckerle
Stephanie T. Eckerle

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)

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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:

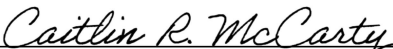
Paul’s Pharmacy
2345 W Franklin Street
Evansville, IN 47712
Service by U.S. Mail & Email

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.

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))

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

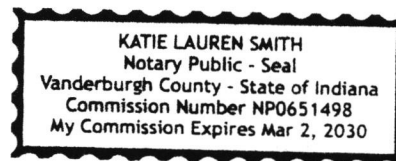
Ryan Eldridge

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

Paul's Pharmacy Remediation Plan

License No. 60006286A

The Paul's Pharmacy Remediation Plan consists of four core elements:

1. Policies and Procedures: Paul's Pharmacy has created new and updated policies to the address the issues raised in the Administrative Complaint filed with the Indiana Board of Pharmacy, Cause No. 2023 IBP 0010.
2. Continuing Education and Training: Paul's Pharmacy is requiring pharmacists, lead pharmacy technicians, and compounding pharmacy technicians to complete continuing education (CE) programs with a focus on compliance, regulatory issues, and compounding. In addition, Paul's Pharmacy is undertaking in-house training on its new and updated policies referenced above. This will empower employees with targeted training to address identified areas of improvement and stay abreast of industry developments.
3. Comprehensive Gap Analysis: Paul's Pharmacy has put into place a comprehensive Gap Analysis that allows for heightened monitoring. The Gap Analysis began with internal audits occurring three times a week and once all inspections are passed consecutively, will eventually result in inspections occurring one time per month throughout the probation period unless issues are found, in which case more frequent inspections will begin again. The Gap Analysis audits issues that were raised in the Administrative Complaint. The Gap Analysis will provide crucial insights to tailor strategies effectively and allow for enhanced training for the pharmacist and pharmacy technicians.
4. Chief Compliance Officer/Chief Operations Officer: Paul's Pharmacy has hired Deborah Larison, PharmD, CPh as its Chief Compliance Officer and Chief Operating Officer. Dr. Larison will oversee all aspects of compliance and daily operations. Dr. Larison has over twenty years of experience with a focus on compounding and compliance.

Through these measures, Paul's Pharmacy aims to foster resilience, meet compliance requirements, and drive long-term success. A copy of this Remediation Plan will be kept onsite at the Paul's Pharmacy located at 2345 West Franklin Street, Evansville, Indiana and will be made available to the Board of Pharmacy during any inspection.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 11/13/2023

Date Due to IN BOP: 11/18/2023

Next Summary Due Date: 01/18/2023

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Dear Board of Pharmacy:

Enclosed is the bimonthly report for November 2023, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy is committed to providing comprehensive reports outlining the remediation progress aligned with the Plan of Remediation submitted on September 27, 2023. The remediation plan encompasses four core elements 1) Policies and Procedures, 2) Continuing Education and Training, 3) Comprehensive Gap Analysis, and 4) Chief Compliance Officer/Chief Operation Officer. Each element is thoughtfully addressed within this report. I have included 2 attachments with evidence of completion of remediation activities discussed herein.

- 1) **Policies and Procedures**: In adherence to the Remediation Plan, Paul's Pharmacy has made significant strides in implementing new policies and procedures carefully tailored to address the concerns outlined in the Administrative Complaint. These Policies and Procedures are listed in the Gap Analysis document, attached herewith.
- 2) **Continuing Education and Training**: Aligned with the stipulations in the Remediation Plan, Paul's Pharmacy has engaged in continuing education and training related to compliance, regulatory issues, and compounding, which has included the following:
 - a) ***Pharmacist-in-Charge Boot Camp from CE Impact***: the pharmacy manager, owner, and chief compliance officer for the location associated with this remediation plan were mandated complete *Pharmacist-in-Charge Boot Camp* from CE Impact. This comprehensive 15-hour certificate encompasses 12 modules, listed below.
 - (1) A Legal Case Study of Unmet PIC Responsibility
 - (2) State Boards of Pharmacy: Background, Role, and Discretionary Authority
 - (3) Disciplinary Action by State Boards of Pharmacy—Discretionary Justice
 - (4) Compliance with FDA Requirements
 - (5) Compliance with DEA Requirements
 - (6) Compliance with Patient Education Requirements
 - (7) Compliance with Drug Use Review Requirements
 - (8) Compliance with Patient Confidentiality Requirements
 - (9) Compliance with Technician Supervision Requirements
 - (10) Compliance with Drug Product Selection Requirements
 - (11) Compliance with Extemporaneous Compounding Requirements
 - (12) Compliance with Pharmacy System Quality Requirements

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

- b) Additionally, Paul's Pharmacy extended the opportunity for voluntary participation in the "Bootcamp" to pharmacy managers at other locations not included in the administrative complaint, as well as all full-time pharmacists. Given their voluntary participation, the deadline for completion has been extended for these team members.

Role	Pharmacist	Certificate	Deadline
West Manager	Jonathan Garvey	Attached	10/15/2023
CCO	Deborah Larison	Attached	11/30/2023
Owner	Jacob Mayer	Pending	
Other Store Managers (voluntary)	Ryan Anslinger Jon Robb Brandt Kolb	Attached Attached Voluntary - Pending	12/30/2023
Pharmacists (voluntary)	Laura Ziliak Ashley Gibson Scott Schutte	Attached Voluntary - Pending Voluntary - Pending	12/30/2023

- c) ***Compounding Competency Assessment Center*** offered by ASHP:
Compounding personnel at the location referenced in the administrative complaint were mandated to participate in the *Compounding Competency Assessment Center* Training Program offered by ASHP.
- i) This extensive 6-hour skills assessment program covers skills associated with non-sterile compounding, sterile compounding, and the handling of hazardous drugs. The aim is to facilitate strict adherence to USP standards for personnel engaged in compounding. Each competency within the program incorporates a learning activity, an assessment exam, and a competency assessment checklist.
- ii) While compounding in accordance with USP <797> has never taken place at this facility, and it has been voluntarily suspended at Paul's Pharmacy Long Term Care facility, several concepts addressed in the USP <797> modules – such as calculations, cleaning, certificates of analysis, safety data sheets, etc – are pertinent to our USP <795> compounding best practices. Therefore, we have opted to include these topics in our training program despite the specific focus on USP <795>.
- iii) In addition, Paul's Pharmacy has opted to integrate training in USP <800>. While this inclusion is not mandated in the Plan of Remediation or specifically addressed in the administrative complaint, the aim is to further align with standards and guidelines for the secure handling of hazardous drugs. This measure is taken to foster a culture of safety and compliance while safeguarding compounders, staff, patients, and the environment from potential risks associated with the handling of hazardous drugs.
- iv) This program encompasses the 26 modules, listed below.
- (a) USP <795>: Overview
 - (b) USP <795>: Hand Hygiene and Garbing
 - (c) USP <795>: Cleaning and Sanitizing

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

- (d) USP <795>: Handling Compounded Nonsterile Preparations, Components, and Use of Equipment
 - (e) USP <795>: Master Formulation and Compounding Records
 - (f) USP <795>: Interpreting Certificates of Analysis and Safety Data Sheets
 - (g) USP <797>: Overview
 - (h) USP <797>: Calculations, Measuring and Mixing
 - (i) USP <797>: Movement within the Compounding Area
 - (j) USP <797>: Hand Hygiene and Garbing
 - (k) USP <797>: Principles of HEPA Filtration
 - (l) USP <797>: Use of Primary Engineering Controls
 - (m) USP <797>: Use of Equipment
 - (n) USP <797>: Aseptic Technique and Maintaining Sterility
 - (o) USP <797>: Immediate-Use Preparations
 - (p) USP <797>: Master Formulation and Compounding Records
 - (q) USP <797>: Cleaning and Disinfecting Agents and Supplies
 - (r) USP <797>: Cleaning and Disinfecting the PEC and SEC
 - (s) USP <800>: Overview
 - (t) USP <800>: Types of Exposure
 - (u) USP <800>: Hazardous Drug List and Risks
 - (v) USP <800>: Proper Use of PPE
 - (w) USP <800>: Use of Devices and Equipment
 - (x) USP <800>: Cleaning Process
 - (y) USP <800>: Response to Exposures and Spills
 - (z) USP <800>: Disposal of Hazardous Drugs and Trace Contaminated Materials
- v) Similar to the boot camp experience, Paul's Pharmacy has extended this offer to pharmacists at locations not referenced in the administrative complaint.

Role	Pharmacist	Certificate	Deadline
Compounding Pharmacy Manager	Jonathan Garvey	Pending	12/30/2023
Compounding Pharmacist	Ashley Gibson	Pending	12/30/2023
Compounding Technician	Joy	Pending	12/30/2023
Chief Compliance Officer	Deborah Larison	Pending	12/30/2023
Other Pharmacists (voluntary)	Ryan Anslinger Jon Robb Brandt Kolb Laura Ziliak Scott Schutte	Pending Pending Pending Pending Pending	02/28/2023

- 3) Comprehensive Gap Analysis: I have continued to undertake a comprehensive Gap Analysis at periodic intervals. The most recent Gap Analysis was completed by me on 11/09/2023. The results of that Gap Analysis and auditing are included at the end this report.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

- 4) Chief Compliance Officer/Chief Operations Officer: I continue to serve as the Chief Compliance Officer and Chief Operating Officer at Paul's Pharmacy. In this capacity, I have actively overseen the development and implementation of our comprehensive remediation plan, which includes integrating mandatory and non-mandatory training for various teammates, updating and creating policies and procedures, periodic internal audits, executing the heightened monitoring program, and more. My responsibility is to ensure that Paul's Pharmacy practices align with the highest standards and guidelines and oversee continuous quality improvement within the organization.

I would like to acknowledge and appreciate Paul's Pharmacy owner, Jacob Mayer, for his unwavering commitment to achieving best practices in these matters. Jacob's dedication to excellence is evident in his proactive support of the steps we have implemented, especially by extending relevant measures to locations not related to the administrative complaint. This proactive approach underscores our dedication to fostering a culture of safety and compliance, with a primary focus on the well-being of our patients, compounders, and colleagues.

In our continued efforts to implement strategies encompassing the 4 core elements outlined in the plan of remediation, the ongoing support and collaboration from the Indiana Board of Pharmacy are truly invaluable. Should you have any questions or require further information, please feel free to contact me by phone at 812-426-5033 x-308 or via email at deborah@paulsrx.com. Your continued partnership is indispensable to the success of our collective efforts.

Sincerely,

Deborah Larison, Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 11/09/2023

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

- ☒ All products on active inventory shelves in the pharmacy area
 - ☒ are in date (not expired).
 - ☒ expiring within the current calendar year have a month sticker prominently affixed.
 - ☒ expiring within the next calendar year have a year sticker prominently affixed.

- Note: Medications appear organized and have prominently affixed labels for the year 2023.
- Note: Audited 25 products in active pharmacy shelves. (A-Z, OTC, controlled substance). All are in date; the team is working though placing the month and year stickers per new policy.
- Note: I “quizzed” pharmacy personnel about the process, to which each explained the current policy and procedure for labeling incoming inventory prior to being put away on active inventory shelves clearly and completely.
- Personnel verbalize the current expectations related to managing Expiration Dates in active inventory, point out the location of the quarantine bins, and describe proper quarantine procedures.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Count 3 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS
 - USP <795> Establishing Beyond-Use Dates: The day that the preparation is compounded is considered Day 1. BUD by type of preparation in absence of a USP-NF compounded preparation monograph or CNSP specific monograph:
 - Non-preserved aqueous 14 days refrigerator
 - Preserved aqueous 35 days controlled room temperature.
 - Non-aqueous 90 days controlled room temperature.
 - Solid 180 days controlled room temperature.
 - USP <796> Extending BUD's for CNSP's: if USP-NF compounded preparation monograph has BUD for CNSP, then BUD stays
 - CNSPs with Stability Information: Exceptions:
 - Aqueous and nonaqueous CNSPs may be extended to max 180 days if there is a stability study (published or unpublished) using a stability-indicating assay for the API's, CNSP, and type of container-closure that will be used.
 - If the BUD of the CNSP is extended beyond the BUDs in USP <795> 10.3, a aqueous CNSP should be submitted for antimicrobial effectiveness testing (AET). The compounder may rely on AET that is:
 - Conducted once for each formulation in the container-closure system packaged in or
 - Provided by an FDA-registered facility or published in a peer-reviewed literature sources if the CNSP formulation (including any preservatives) and container-closure system are exactly the same as those tested unless a bracketing study is performed.
- ☒ All compounded products on the active inventory shelves
- ☒ comply with the USP <795> BUDs.
- Note: Audited all products in active inventory – compounding shelves. All have appropriate BUD's per USP 795.
 - NOTE: In the previous audit I noted two products that are liquids and being stored on the shelves that are stored appropriately and suggested to the pharmacy manager, that we label them with "store at room temperature" or "refrigerate" as appropriate for clarity for such liquids prepared with anhydrous bases. He reached out to the supplier and obtained said labels, and these are being used appropriately at the time of this audit.
 - NOTE: I am currently addressing some areas of improvement in our compounding processes. Specifically, I am working with Jonathan, with the approval of Jacob, to review our master formulas one by one. We are exploring the possibility of implementing a different compounding software to ensure that all formulations align with the most current USP guidelines and have appropriate Beyond-Use Dates (BUDs). This proactive approach will contribute to a more streamlined and compliant compounding process. I will continue to work on this over time and advise when pertinent in future audits.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.
- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible whenever possible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>
- NOTE: I have audited all compounded products in active inventory. All have prominently affixed month stickers on the exterior containers, there are only products on the shelves with 6 weeks or longer BUD, and all have BUD's compliant with USP 795.
- NOTE: There is a small, handwritten, quick reference tool for BUDs on various bases, I suggest that a more formal document be prepared, laminated, and used as a reminder of the USP approved BUD's.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 draft USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES

- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
- NOTE: The script pro policy is lengthy and detailed. Although the team is still pending formal education and read and sign documents covering this P&P, the process has been rolled out, evaluated, and is being fine-tuned. It is being followed; we have been auditing this process for several months. No bottles are being returned to the SPM cartridges per the pharmacists and technicians.
- NOTE: I audited the SPM return procedure, evaluating 10 cartridges on the shelves with matching return to stock bottles, cartridges have less than 12-month expiration date, bottles and cartridges match, bottles have been initialed by a pharmacist, and a barcode label is placed (after verification by the pharmacist) covering up HIPAA information.
- Technicians and pharmacist verbalize the policy correctly and are able to demonstrate the procedures to me with clarity today.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.
Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

☒ All products with an extended BUD have appropriate documentation on file, either a peer-reviewed study, or stability study, or documentation from a compounding agency like PCCA.
NOTE: This is Not applicable. There are no products with extended BUD's being compounded.

☒ Training completed by compounding pharmacist supervising compounding at least annually:

☒ USP 797 labeling.

☒ USP 797 Assigning BUDs.

NOTE: This was completed in 2023.

☐ Training completed by compounding technician at least annually:

☐ Re: USP 797 labeling.

☐ USP 797 Assigning BUDs.

- NOTE: I'm currently working with Jonathan to enhance our documentation process to demonstrate that the technician(s) have received training on this specific matter within the past year. While the current ASHP training that we have implemented does not specifically address this topic, I've taken the initiative to print out USP <7> Labeling, utilizing it as a temporary training tool until I identify a suitable Continuing Education (CE) program.
- NOTE: Simultaneously, I've conducted positive and engaging verbal discussions with the compounding team, ensuring their clear understanding and commitment to the rules associated with this topic. This proactive measure reflects Paul's Pharmacy's dedication to continuous improvement and sets the groundwork for a more comprehensive and formalized training in the near future.
- NOTE: While not mandated in the remediation plan, I have conducted a comprehensive audit of the full labeling, specifically pertaining to USP <7> . The labeling aligns with Paul's Pharmacy's current conventions. Moving forward, addressing the naming convention will be a particular focus as we consider a new compounding software.

☒ USP 795 Figure 1 posted in plain view for compounding team.

- NOTE: As mentioned above, there is a handwritten chart, we will formalize this.

☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

- NOTE: I will specifically locate the documentation of the read and sign page for these policies and have them on hand if requested to view at the time of inspection.

Cover Sheet

Attachment 2 – Certificates for Completed Continuing Education

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2023



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Bimonthly Report for Indiana Board of Pharmacy – November 2023

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 01/15/2024

Date Due to IN BOP: 01/18/2024

Next Summary Due Date: 03/2024

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Dear Board of Pharmacy:

Enclosed is the bimonthly report for January 2024, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy is committed to providing comprehensive reports outlining the remediation progress aligned with the Plan of Remediation submitted on September 27, 2023. The remediation plan encompasses four core elements 1) Policies and Procedures, 2) Continuing Education and Training, 3) Comprehensive Gap Analysis, and 4) Chief Compliance Officer/Chief Operation Officer. Each element is thoughtfully addressed within this report. I have included 2 attachments with evidence of completion of remediation activities discussed herein.

- 1) **Policies and Procedures**: In adherence to the Remediation Plan, Paul's Pharmacy previously implemented new policies and procedures carefully tailored to address the concerns outlined in the Administrative Complaint. We have continued to evaluate these Policies and Procedures for efficiency and effectiveness. Additional information is available in the Gap Analysis document, attached herewith.
- 2) **Continuing Education and Training**: Aligned with the stipulations in the Remediation Plan, Paul's Pharmacy has engaged in continuing education and training related to compliance, regulatory issues, and compounding, which has included the following:
 - a) ***Pharmacist-in-Charge Boot Camp from CE Impact***: The pharmacy manager, pharmacist, COO, and owner have completed this CE. Please, see attachment 2 for certificates of completion.

Role	Pharmacist	Certificate
West Manager	Jonathan Garvey	Previously Attached
West Pharmacist	Ashley Gibson	Pending
Paul's Pharmacy CCO/COO	Deborah Larison	Previously Attached
Paul's Pharmacy Owner	Jacob Mayer	Attached

- a) Additionally, Paul's Pharmacy extended the opportunity for voluntary participation in the "Bootcamp" to pharmacy managers at other locations not included in the administrative complaint, as well as all full-time pharmacists. Given their voluntary participation, the deadline for completion has been extended for these team members. Please, see attachment 2 for certificates of completion.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Role	Pharmacist	Certificate
Other Store Managers (voluntary)	Ryan Anslinger Jon Robb Brandt Kolb	Previously Attached Previously Attached Voluntary - Pending
Other Pharmacists (voluntary)	Laura Ziliak Scott Schutte	Previously Attached Voluntary - Pending

- b) ***Compounding Competency Assessment Center*** offered by ASHP:
- Compounding personnel at the location referenced in the administrative complaint were mandated to by Paul's Pharmacy to participate in the *Compounding Competency Assessment Center* Training Program offered by ASHP.
- i) This extensive 6-hour skills assessment program covers skills associated with non-sterile compounding, sterile compounding, and the handling of hazardous drugs. The aim is to facilitate strict adherence to USP standards for personnel engaged in compounding. Each competency within the program incorporates a learning activity, an assessment exam, and a competency assessment checklist.
 - ii) While compounding in accordance with USP <797> has never taken place at the facility referred to in the administrative complaint, several concepts addressed in the USP <797> modules – such as calculations, cleaning, certificates of analysis, safety data sheets, etc – are pertinent to our USP <795> compounding best practices. Therefore, we have opted to include these topics in our training program despite the specific focus on USP <795>.
 - iii) In addition, Paul's Pharmacy has opted to integrate training in USP <800>. While this inclusion is not mandated in the Plan of Remediation or specifically addressed in the administrative complaint, the aim is to further align with standards and guidelines for the secure handling of hazardous drugs. This measure is taken to foster a culture of safety and compliance while safeguarding compounders, staff, patients, and the environment from potential risks associated with the handling of hazardous drugs.
 - iv) This program encompasses the 26 modules, listed below.
 - (a) USP <795>: Overview
 - (b) USP <795>: Hand Hygiene and Garbing
 - (c) USP <795>: Cleaning and Sanitizing
 - (d) USP <795>: Handling Compounded Nonsterile Preparations, Components, and Use of Equipment
 - (e) USP <795>: Master Formulation and Compounding Records
 - (f) USP <795>: Interpreting Certificates of Analysis and Safety Data Sheets
 - (g) USP <797>: Overview
 - (h) USP <797>: Calculations, Measuring and Mixing
 - (i) USP <797>: Movement within the Compounding Area
 - (j) USP <797>: Hand Hygiene and Garbing
 - (k) USP <797>: Principles of HEPA Filtration
 - (l) USP <797>: Use of Primary Engineering Controls
 - (m) USP <797>: Use of Equipment

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

- (n) USP <797>: Aseptic Technique and Maintaining Sterility
- (o) USP <797>: Immediate-Use Preparations
- (p) USP <797>: Master Formulation and Compounding Records
- (q) USP <797>: Cleaning and Disinfecting Agents and Supplies
- (r) USP <797>: Cleaning and Disinfecting the PEC and SEC
- (s) USP <800>: Overview
- (t) USP <800>: Types of Exposure
- (u) USP <800>: Hazardous Drug List and Risks
- (v) USP <800>: Proper Use of PPE
- (w) USP <800>: Use of Devices and Equipment
- (x) USP <800>: Cleaning Process
- (y) USP <800>: Response to Exposures and Spills
- (z) USP <800>: Disposal of Hazardous Drugs and Trace Contaminated Materials

- v) Similar to the boot camp experience, Paul's Pharmacy has extended the offer to participate in this CE program to pharmacists at locations not referenced in the administrative complaint.

Role	Pharmacist	Certificate	Completed
Compounding Pharmacy Manager	Jonathan Garvey	Completed	Attached
Compounding Pharmacist	Ashley Gibson	Completed	Attached USP <800> pending
Compounding Technician	Joy Caldwell	Completed	Will attach to next report
Chief Compliance Officer	Deborah Larison	Completed	Attached
Other Pharmacists (voluntary)	Ryan Anslinger Jon Robb Brandt Kolb Laura Ziliak Scott Schutte	Pending Pending Pending Pending Pending	

- 2) Comprehensive Gap Analysis: I have continued to undertake a comprehensive Gap Analysis at periodic intervals. The most recent Gap Analysis was completed by me on 01/15/2024. The results of that Gap Analysis and auditing are included at the end of this report in attachment 1.
- 3) Chief Compliance Officer/Chief Operations Officer: I continue to serve as the Chief Compliance Officer and Chief Operating Officer at Paul's Pharmacy. In this capacity, I have actively overseen the development and implementation of our comprehensive remediation plan, which includes integrating mandatory and non-mandatory training for various teammates, updating, and creating policies and procedures, periodic internal audits, executing the heightened monitoring program, and more. My responsibility is to ensure that Paul's Pharmacy practices align with the highest

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

standards and guidelines and oversee continuous quality improvement within the organization.

I would like to acknowledge and appreciate Paul's Pharmacy owner, Jacob Mayer, for his unwavering commitment to achieving best practices in these matters. Jacob's dedication to excellence is evident in his proactive support of the steps we have implemented, especially by extending relevant measures to locations not related to the administrative complaint. This proactive approach underscores our dedication to fostering a culture of safety and compliance, with a primary focus on the well-being of our patients, compounders, and colleagues.

In our continued efforts to implement strategies encompassing the 4 core elements outlined in the plan of remediation, the ongoing support and collaboration from the Indiana Board of Pharmacy are truly invaluable. Should you have any questions or require further information, please feel free to contact me by phone at 812-426-5033 x-308 or via email at deborah@paulsrx.com. Your continued partnership is indispensable to the success of our collective efforts.

Sincerely,

Deborah Larison, Chief Compliance Officer/Chief Operating Officer

Paul's Pharmacy

Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 1/15/2024

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

- ☒ All products on active inventory shelves in the pharmacy area
 - ☒ are in date (not expired).
 - ☒ expiring within the current calendar year have a month sticker prominently affixed.
 - ☒ expiring within the next calendar year have a year sticker prominently affixed.

- Note: Medications are organized and have prominently affixed labels for the year 2024, 2025, and 2026.
- Note: Over two days, with a pharmacy technician from another store, I audited the entirety of products in active pharmacy shelves in the pharmacy. Month and year stickers were prominently affixed. No expired products were found. No products with expirations dates within the next 90 days were found.
- Personnel verbalize the current expectations related to managing Expiration Dates in active inventory, point out the location of the quarantine bins, and describe proper quarantine procedures.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Count 3 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
- ☒ comply with the USP <795> BUDs.

- NOTE: I audited all products in active inventory on compounding shelves on 1/15/2024. All have appropriate BUD's per USP 795 or supporting literature. I am in the process of reviewing all supporting literature for each formulation; this is a longitudinal project.
- NOTE: Per previous report, and per current best practice guidelines at Paul's Pharmacy, there are "do not refrigerate" and "refrigerate" stickers on appropriate liquids.
- NOTE: Per previous report, I have evaluated and obtained pricing for various compounding software options that we believe will help us manage BUDs, and all compounding compliance matters more efficiently and effectively. This proactive approach will contribute to a more streamlined and compliant compounding process. We will focus on the implementation of this software platform between now and the next report.
- NOTE: the following BUD reference charts have been prominently posted near the compounding area: Table 1 of the USP guidelines for BUD management.

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.
- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible whenever possible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>
- NOTE: I have audited all compounded products in active inventory on 1/15/2024. All have prominently affixed month stickers on the exterior containers, there are only products on the shelves with 6 weeks or longer BUD, and all have BUD's compliant with USP 795.
- NOTE: There is a small, typed (formerly handwritten), quick reference tool for BUDs on various bases, posted and used as a reminder of the USP approved BUD's. I will explore the possibility of replacing it with something commercially prepared when one is located in the literature.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 draft USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
 - 5.060 MAINTENANCE OF INVENTORIES
-
- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
-
- NOTE: The script pro policy is lengthy and detailed. The staff have been educated on the policy and have signed a "Read and Understood" form for the policy. The policy has been regularly evaluated for appropriateness and it is being followed; we have been auditing this process for several months and continue to audit it 2-3 times a month. No bottles are being returned to the SPM cartridges per the pharmacists and technicians, and per my observations.
 - NOTE: I audited the SPM return procedure, evaluating all cartridges on the shelves with matching return to stock bottles, cartridges have less than 12-month expiration date, bottles and cartridges match, bottles have been initialed by a pharmacist.
 - Technicians and pharmacists verbalize the policy correctly and can demonstrate the procedures to me with clarity today.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.
Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

- ☒ All products with an extended BUD have appropriate documentation on file, either a peer-reviewed study, or stability study, or documentation from a compounding agency like PCCA.

NOTE: This is Not applicable. There are no products with extended BUD's being compounded.

- ☒ Training completed by compounding pharmacist supervising compounding at least annually:

☒ USP 797 labeling.

☒ USP 797 Assigning BUDs.

NOTE: This was completed in 2023.

- ☒ Training completed by compounding technician at least annually:

☒ Re: USP 797 labeling.

☒ USP 797 Assigning BUDs.

- NOTE: Staff has read and understood the USP <7> Labeling chapter that was printed and used in lieu of a commercially available CE on labeling which I have not been able to find. See Attachment 3 for the RAU form.
- NOTE: While not mandated in the remediation plan, I have conducted a comprehensive audit of the full labeling, specifically pertaining to USP <7>. Moving forward, as we implement the new software platform, we will address the naming convention used at Paul's Pharmacy for compounded products. This is a longitudinal project.
- NOTE: the following training has been completed: ASHP compounding training on USP 795, 800, and 797 for Deborah Larison (CCO), Jonathan Garvey (Pharmacy Manager), Ashley Gibson (Pharmacist) pending the USP 800 chapter, and Joy Caldwell, Technician. See attachment 2 for certificates of completion.

- ☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

- NOTE: I will have the read and sign page for these policies and have them on hand if requested to view at the time of inspection.

Cover Sheet

Attachment 2 – Certificates for Completed Continuing Education

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024



Paul's Pharmacy - West

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Paul's Pharmacy - West

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STATEMENT OF COMPLETION

provided by

American Society of Health-System Pharmacists®

Name: Deborah Larison
ASHP Customer #: 04122657|0
Activity Date: 1/15/2024
Activity Name: 2024 USP <795> Pharmaceutical Compounding - Nonsterile Preparations

Completion Hours: 1.500
Transcript ID: USP795

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
This statement is for documentation of participation only.



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STATEMENT OF COMPLETION

provided by

American Society of Health-System Pharmacists®

Name: Deborah Larison
ASHP Customer #: 04122657|0
Activity Date: 1/15/2024
Activity Name: 2024 USP <797> Pharmaceutical Compounding- Sterile Preparations

Completion Hours: 3.000
Transcript ID: USP797

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
This statement is for documentation of participation only.

STATEMENT OF COMPLETION

provided by

American Society of Health-System Pharmacists®

Name: Deborah Larison
ASHP Customer #: 04122657|0
Activity Date: 1/15/2024
Activity Name: 2024 USP <800> Hazardous Drugs- Handling in Healthcare Settings

Completion Hours: 2.000
Transcript ID: USP800

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024



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STATEMENT OF COMPLETION
provided by
American Society of Health-System Pharmacists®

Name: Jonathan Garvey
ASHP Customer #: 08411943|0
Activity Date: 12/6/2023
Activity Name: 2023 USP <797> Pharmaceutical Compounding- Sterile Preparations

Completion Hours: 3.000
Transcript ID: USP797

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
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STATEMENT OF COMPLETION
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Name: Jonathan Garvey
ASHP Customer #: 08411943|0
Activity Date: 11/14/2023
Activity Name: 2023 USP <795> Pharmaceutical Compounding - Nonsterile Preparations

Completion Hours: 1.500
Transcript ID: USP795

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
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Name: Jonathan Garvey
ASHP Customer #: 08411943|0
Activity Date: 11/28/2023
Activity Name: 2023 USP <800> Hazardous Drugs- Handling in Healthcare Settings

Completion Hours: 2.000
Transcript ID: USP800

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
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Name: Deborah Larison
ASHP Customer #: 04122657|0
Activity Date: 1/15/2024
Activity Name: 2024 USP <800> Hazardous Drugs- Handling in Healthcare Settings

Completion Hours: 2.000
Transcript ID: USP800

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
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STATEMENT OF COMPLETION

provided by

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Name: Ashley Gibson
ASHP Customer #: 08442089|0
Activity Date: 11/29/2023
Activity Name: 2023 USP <797> Pharmaceutical Compounding- Sterile Preparations

Completion Hours: 3.000

Transcript ID: USP797

This Statement acknowledges only the completion of this activity:
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STATEMENT OF COMPLETION

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Name: Deborah Larison
ASHP Customer #: 04122657|0
Activity Date: 1/15/2024
Activity Name: 2024 USP <795> Pharmaceutical Compounding - Nonsterile Preparations

Completion Hours: 1.500

Transcript ID: USP795

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
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STATEMENT OF COMPLETION

provided by

American Society of Health-System Pharmacists®

Name: Deborah Larison
ASHP Customer #: 04122657|0
Activity Date: 1/15/2024
Activity Name: 2024 USP <797> Pharmaceutical Compounding- Sterile Preparations

Completion Hours: 3.000

Transcript ID: USP797

This Statement acknowledges only the completion of this activity:
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STATEMENT OF COMPLETION

provided by

American Society of Health-System Pharmacists®

Name: Ashley Gibson
ASHP Customer #: 08442089|0
Activity Date: 11/21/2023
Activity Name: 2023 USP <795> Pharmaceutical Compounding - Nonsterile Preparations

Completion Hours: 1.500

Transcript ID: USP795

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
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Bimonthly Report for Indiana Board of Pharmacy – January 2024



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STATEMENT OF COMPLETION

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Name: Ashley Gibson
ASHP Customer #: 08442089|0
Activity Date: 1/17/2024
Activity Name: 2024 USP <800> Hazardous Drugs- Handling in Healthcare Settings

Completion Hours: 2.000
Transcript ID: USP800

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
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STATEMENT OF COMPLETION

provided by
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Name: Joy Caldwell
ASHP Customer #: 08442083|0
Activity Date: 11/16/2023
Activity Name: 2023 USP <797> Pharmaceutical Compounding- Sterile Preparations

Completion Hours: 3.000
Transcript ID: USP797

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
This statement is for documentation of participation only.

STATEMENT OF COMPLETION

provided by
American Society of Health-System Pharmacists®

Name: Joy Caldwell
ASHP Customer #: 08442083|0
Activity Date: 11/15/2023
Activity Name: 2023 USP <795> Pharmaceutical Compounding - Nonsterile Preparations

Completion Hours: 1.500
Transcript ID: USP795

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
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STATEMENT OF COMPLETION

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Name: Joy Caldwell
ASHP Customer #: 08442083|0
Activity Date: 11/16/2023
Activity Name: 2023 USP <800> Hazardous Drugs- Handling in Healthcare Settings

Completion Hours: 2.000
Transcript ID: USP800

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
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Bimonthly Report for Indiana Board of Pharmacy – January 2024

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Cover Sheet

Attachment 3 – Policy and Procedure RAU forms

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Bimonthly Report for Indiana Board of Pharmacy – January 2024

Paul's Pharmacy RAU – USP <7> Labeling

Jonathan <i>Jonathan</i>	Pharmacy Manager <i>Pharmacy Manager</i>
Trainer Printed Name	Title

By signing below, I acknowledge I have been trained regarding the USP <7> Labeling chapter and understand how it applies as appropriate to my job function. Through the Training I understand the importance of ensuring that all Paul's Pharmacy medications Labels and Labeling contain the proper information.

If I have any questions, I will direct them to my Supervisor, the Pharmacy Manager, or the Chief Compliance Officer as appropriate. (Heather, Jonathan, or Deb)

TRAINING DOCUMENTATION

This training was performed at the West location during the month of November, 2023.

Employee Name	Role	Requirement to be informed of	Date & Employee Signature	Type of training: Annual, Supplemental, Retraining	Pharmacy Manager or CCO Signature
			<i>Month of November</i>		
Bacon, Kaylee	Clerk – W	No	<i>11/12/23</i>	Seasonal See Individual Training Documentation	
Baehl, Carmen	Technician – W	Yes	<i>11/12/23 Carmen Baehl</i>	Annual	<i>JD</i>
Bragin, Al	Technician, Sales – W	Yes	NA	NA	NA
Caldwell, Joy	Compounding Tech – W	Yes	<i>11/23 J Caldwell</i>	Annual	<i>JD</i>
Delano Jr, Richard (Rick)	Driver – W	No	NA	NA	NA
Garvey, Jonathan	Pharmacy Manager – W	Yes	<i>11/23 Jonathan</i>	Annual	<i>JD</i>
Gibson, Ashley	Pharmacist – W	Yes	<i>11/23 Ash Gibson</i>	Annual	<i>JD</i>
Lockwood, McKinzy	Tech In Training – W	Yes		Seasonal See Individual Training Documentation	
Macke, Emma	Technician – W	Yes		Seasonal See Individual Training Documentation	
Miller, Nancy	Clerk – W	No	NA	NA	NA
Pyle, Seth	Technician – W	Yes	<i>11/23 Seth Pyle</i>	Annual	<i>JD</i>
Scheiler, Susan	Compounding Tech – W	Yes		Annual	
Ruth, Jane	Driver – W	No		Seasonal See Individual Training Documentation	
Wilson, Kevin	Driver – W	No	NA	NA	NA

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2024

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Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 03/13/2024

Date Due to IN BOP: 03/18/2024

Next Summary Due Date: 05/2024

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Dear Board of Pharmacy:

Enclosed is the bimonthly report for March 2024, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy is committed to providing comprehensive reports outlining the remediation progress aligned with the Plan of Remediation submitted on September 27, 2023. The remediation plan encompasses four core elements 1) Policies and Procedures, 2) Continuing Education and Training, 3) Comprehensive Gap Analysis, and 4) Chief Compliance Officer/Chief Operation Officer. Each element is thoughtfully addressed within this report. I have included attachments with evidence of completion of remediation activities discussed herein.

- 1) **Policies and Procedures**: In adherence to the Remediation Plan, Paul's Pharmacy previously implemented new policies and procedures carefully tailored to address the concerns outlined in the Administrative Complaint. We have continued to evaluate these Policies and Procedures for efficiency and effectiveness. Additional information is available in the Gap Analysis document, attached herewith.
- 2) **Continuing Education and Training**: Aligned with the stipulations in the Remediation Plan, Paul's Pharmacy has engaged in continuing education and training related to compliance, regulatory issues, and compounding, which has included the following:
 - a) ***Pharmacist-in-Charge Boot Camp from CE Impact***: The pharmacy manager, pharmacist, COO, and owner have completed this CE. Please, see Attachment 2.

Role	Pharmacist	Certificate
West Manager	Jonathan Garvey	Previously Attached
West Pharmacist	Ashley Gibson	Attached
Paul's Pharmacy CCO/COO	Deborah Larison	Previously Attached
Paul's Pharmacy Owner	Jacob Mayer	Previously Attached

- a) Additionally, Paul's Pharmacy extended the opportunity for voluntary participation in the "Bootcamp" to all full-time pharmacists who have completed this course. Please, see Attachment 2 for certificates of completion.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

b) ***Compounding Competency Assessment Center offered by ASHP:***

Compounding personnel at the location referenced in the administrative complaint were mandated by Paul's Pharmacy to participate in the *Compounding Competency Assessment Center* Training Program offered by ASHP.

- i) This extensive 6-hour skills assessment program covers skills associated with non-sterile compounding, sterile compounding, and the handling of hazardous drugs. The aim is to facilitate strict adherence to USP standards for personnel engaged in compounding. Each competency within the program incorporates a learning activity, an assessment exam, and a competency assessment checklist.
- ii) While compounding in accordance with USP <797> has never taken place at the facility referred to in the administrative complaint, several concepts addressed in the USP <797> modules – such as calculations, cleaning, certificates of analysis, safety data sheets, etc – are pertinent to our USP <795> compounding best practices. Therefore, we have opted to include these topics in our training program despite the specific focus on USP <795>.
- iii) In addition, Paul's Pharmacy has opted to integrate training in USP <800>. While this inclusion is not mandated in the Plan of Remediation or specifically addressed in the administrative complaint, the aim is to further align with standards and guidelines for the secure handling of hazardous drugs. This measure is taken to foster a culture of safety and compliance while safeguarding compounders, staff, patients, and the environment from potential risks associated with the handling of hazardous drugs.
- iv) This program encompasses 26 modules, detailed in previous reports.
- v) See Attachment 2 for certificates of completion.

Role	Pharmacist	Certificate	Completed
Pharmacy Manager, Compounding Designated Person	Jonathan Garvey	Completed	Previously Attached
Pharmacist	Ashley Gibson	Completed	Attached
Compounding Technician	Joy Caldwell	Completed	Attached
Chief Compliance Officer	Deborah Larison	Completed	Previously Attached

- 2) Comprehensive Gap Analysis: I have continued to undertake regular comprehensive Gap Analyses at periodic intervals. The most recent Gap Analysis was completed by me on 03/11/2024. The results of that Gap Analysis and auditing are included at the end of this report in Attachment 1.
- 3) Chief Compliance Officer/Chief Operations Officer: I continue to serve as the Chief Compliance Officer and Chief Operating Officer at Paul's Pharmacy. In this capacity, I have actively overseen the development and implementation of our comprehensive

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

remediation plan, which includes integrating mandatory and non-mandatory training, updating, and creating policies and procedures, periodic internal audits, executing the heightened monitoring program, and more. My responsibility is to ensure that Paul's Pharmacy practices align with the highest standards and guidelines and oversee continuous quality improvement within the organization.

As mentioned in previous reports, I would like to acknowledge and appreciate Paul's Pharmacy owner, Jacob Mayer, for his continued commitment to achieving best practices in these matters. His proactive approach underscores Paul's Pharmacy's dedication to fostering a culture of safety and compliance, with a primary focus on the well-being of our patients, compounders, and colleagues.

In our continued efforts to implement strategies encompassing the 4 core elements outlined in the plan of remediation, the ongoing support and collaboration from the Indiana Board of Pharmacy are truly invaluable. Should you have any questions or require further information, please feel free to contact me by phone at 812-426-5033 x-308 or via email at deborah@paulsrx.com. Your continued partnership is indispensable to the success of our collective efforts.

Sincerely,

Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 03/11/2024

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

- ☒ All products on active inventory shelves in the pharmacy area

- ☒ are in date (not expired).

- ☒ expiring within the current calendar year have a month sticker prominently affixed.

- ☒ expiring within the next calendar year have a year sticker prominently affixed.

- NOTE: Medications are organized, and have prominently affixed labels for the years 2024, 2025, and 2026.
- NOTE: No expired products were found. No products with expirations dates within the next 90 days were found in active inventory shelves.
- NOTE: I reminded the team to stay vigilant and proactive about placing year stickers on stock bottles. The team ran out of 2025 labels, but these labels have now been reordered. Though it is not a violation of laws, rules, or regulations to leave these labels off stock bottles, we have implemented this policy and procedure to help facilitate quick and easy outdate management. This procedure has demonstrated effectiveness over the past few months, and we intend to continue enforcing this policy for the foreseeable future. The team verbalizes understanding of this expectation.
- Note: Two new technicians verbalized the current expectations related to managing Expiration Dates in active inventory, point out the location of the quarantine bins, and describe proper outdate and quarantine procedures.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Count 3 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
 - ☒ comply with the USP <795> BUDs.

- NOTE: No advanced notice is given to the owner, pharmacists, or technicians in advance of internal audits.
- NOTE: I audited all products in active inventory on compounding shelves on 03/11/2024. All containers have appropriate BUD's per USP 795 and supporting literature.
- NOTE: Regarding the review of supporting literature for each formulation (mentioned in the previous report); I am finding occasional formulations put in place by the previous pharmacy manager (no longer employed at Paul's Pharmacy) which are out of date with the current standards. I have brought these to the attention of the current Pharmacy Manager, Jonathan Garvey, PharmD. We have decided to retire the old formulations and implement new ones in their places supported by PCCA which have updated literature supporting BUD's and other formulation details. As mentioned, this is an ongoing longitudinal project. I will continue to keep the board abreast of this work in progress.
- NOTE: Per previous report, we are working toward purchasing compounding software that we believe will help us manage BUDs, and all compounding compliance matters more efficiently and effectively. Since the last report we have revisited PCCA's "The Compounder" and "SiCompounding" a new platform. We have requested a trial period for "SiCompounding" and are awaiting this 14-day trial to decide the best, most cost-effective platform for Paul's Pharmacy. We will focus on making this decision shortly after the short trial period between now and the next report. Meanwhile, we continue to use PioneerRx.
- NOTE: The BUD reference charts remain posted near the compounding area: Table 1 of the USP guidelines for BUD management.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.
- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible whenever possible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>
- NOTE: As part of the unannounced visit, I audited all compounded products in active inventory on 03/11/2024. I found one product, recently compounded, and within date, that did not have a month sticker attached. I brought this to the attention of the Pharmacy Manager, Jonathan Garvey, and the Compounding Operator, Joy Caldwell, who immediately applied the correct sticker and verbalized the procedure to ensure understanding. Given that this is a new finding, I will continue to monitor this closely between now and the next audit. All other preparations have prominently affixed month stickers on the exterior containers, and all have BUD's compliant with USP 795.
- NOTE: I reminded the compounding team to stay vigilant and proactive about placing month stickers on the exterior of compounded preparation containers. Though it is not a violation of laws, rules, or regulations to leave these stickers off, we have implemented this policy and procedure to help facilitate quick and easy BUD management. This procedure has demonstrated effectiveness over the past few months, and we intend to continue enforcing this policy for the foreseeable future. The team verbalizes understanding of this expectation.
- NOTE: In order to remind the team of USP-approved BUD's, Paul's Pharmacy has historically used and posted a small, typed (formerly handwritten), quick reference tool for BUDs on various bases. I have not found a commercially available chart that is comparable to the one Paul's Pharmacy uses. So, we will leave the current quick reference tool in place for the time being.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 draft USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES

- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
- NOTE: The script pro policy has been regularly evaluated for appropriateness and it is being diligently followed; we have been auditing this process for several months and continue to audit it at least monthly.
- NOTE: According to the pharmacists and technicians, no return to stock bottles are being returned to the SPM cartridges. I have personally observed that no return to stock bottles are being returned to the SPM cartridges.
- NOTE: I audited 10 random SPM cartridges and each cartridge has less than 12-month expiration date.
- NOTE: I audited 10 random return to stock bottles for medications in the SPM. Bottles have been properly initialed by a pharmacist and were placed on a shelf for the next use.
- NOTE: Pharmacists verbalize the policy correctly and can demonstrate the procedures accurately today.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.
Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

☒ All products with an extended BUD have appropriate documentation on file by a peer-reviewed study, by stability study, or by documentation from a compounding agency like PCCA. ***(PLEASE NOTE: This is not applicable. There are no products with extended BUD's being compounded by Paul's Pharmacy).***

☒ Training completed by compounding pharmacist supervising compounding at least annually:

☒ USP 797 labeling.

☒ USP 797 Assigning BUDs.

(PLEASE NOTE: This was completed in 2023 and is no longer an ongoing issue).

☒ Training completed by compounding technician at least annually:

☒ Re: USP 797 labeling.

☒ USP 797 Assigning BUDs.

- NOTE: Staff has previously signed the read and understood for USP <7> Labeling chapter that was printed and used in lieu of a commercially available CE. See Attachment 3 in previous reports for the signed RAU form.
- NOTE: the following training has been completed: ASHP compounding training on USP 795, 800, and 797 for Deborah Larison (CCO), Jonathan Garvey (Pharmacy Manager, Qualified Person), Ashley Gibson (Pharmacist), and Joy Caldwell, Compounding Technician. See Attachment 2 for certificates of completion.

☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

- NOTE: I will have the read and sign page for these policies and have them on hand if requested to view at the time of inspection.

Cover Sheet

Attachment 2 – Certificates for Completed Continuing Education

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Mandatory Participation at West Location: Certificates of Completion:



Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Voluntary Participation at Other Locations: Certificates of Completion:



Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

Mandatory Participation at West Location: Certificates of Completion:

 4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org	 4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org	 4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org
STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®	STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®	STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®
Name: Jonathan Garvey	Name: Jonathan Garvey	Name: Jonathan Garvey
ASHP Customer #: 08411943 0	ASHP Customer #: 08411943 0	ASHP Customer #: 08411943 0
Activity Date: 11/14/2023	Activity Date: 12/6/2023	Activity Date: 11/28/2023
Activity Name: 2023 USP <795> Pharmaceutical Compounding - Nonsterile Preparations	Activity Name: 2023 USP <797> Pharmaceutical Compounding- Sterile Preparations	Activity Name: 2023 USP <800> Hazardous Drugs- Handling in Healthcare Settings
Completion Hours: 1.500	Completion Hours: 3.000	Completion Hours: 2.000
Transcript ID: USP795	Transcript ID: USP797	Transcript ID: USP800
<small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small>	<small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small>	<small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small>

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STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®	STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®	STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®
Name: Ashley Gibson	Name: Ashley Gibson	Name: Ashley Gibson
ASHP Customer #: 08442089 0	ASHP Customer #: 08442089 0	ASHP Customer #: 08442089 0
Activity Date: 11/21/2023	Activity Date: 11/29/2023	Activity Date: 1/17/2024
Activity Name: 2023 USP <795> Pharmaceutical Compounding - Nonsterile Preparations	Activity Name: 2023 USP <797> Pharmaceutical Compounding- Sterile Preparations	Activity Name: 2024 USP <800> Hazardous Drugs- Handling in Healthcare Settings
Completion Hours: 1.500	Completion Hours: 3.000	Completion Hours: 2.000
Transcript ID: USP795	Transcript ID: USP797	Transcript ID: USP800
<small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small>	<small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small>	<small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small>

Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – March 2024

 <p>4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org</p> <p>STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®</p> <p>Name: Joy Caldwell ASHP Customer #: 08442083 0 Activity Date: 11/15/2023 Activity Name: 2023 USP <795> Pharmaceutical Compounding - Nonsterile Preparations</p> <p>Completion Hours: 1.500 Transcript ID: USP795</p> <p><small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small></p>	 <p>4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org</p> <p>STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®</p> <p>Name: Joy Caldwell ASHP Customer #: 08442083 0 Activity Date: 11/16/2023 Activity Name: 2023 USP <797> Pharmaceutical Compounding- Sterile Preparations</p> <p>Completion Hours: 3.000 Transcript ID: USP797</p> <p><small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small></p>	 <p>4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org</p> <p>STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®</p> <p>Name: Joy Caldwell ASHP Customer #: 08442083 0 Activity Date: 11/16/2023 Activity Name: 2023 USP <800> Hazardous Drugs- Handling in Healthcare Settings</p> <p>Completion Hours: 2.000 Transcript ID: USP800</p> <p><small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small></p>
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 <p>4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org</p> <p>STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®</p> <p>Name: Deborah Larison ASHP Customer #: 04122657 0 Activity Date: 1/15/2024 Activity Name: 2024 USP <795> Pharmaceutical Compounding - Nonsterile Preparations</p> <p>Completion Hours: 1.500 Transcript ID: USP795</p> <p><small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small></p>

 <p>4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org</p> <p>STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®</p> <p>Name: Deborah Larison ASHP Customer #: 04122657 0 Activity Date: 1/15/2024 Activity Name: 2024 USP <797> Pharmaceutical Compounding- Sterile Preparations</p> <p>Completion Hours: 3.000 Transcript ID: USP797</p> <p><small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small></p>

 <p>4500 East-West Highway Bethesda, MD 20814 Phone: 866-279-0681 www.ashp.org</p> <p>STATEMENT OF COMPLETION provided by American Society of Health-System Pharmacists®</p> <p>Name: Deborah Larison ASHP Customer #: 04122657 0 Activity Date: 1/15/2024 Activity Name: 2024 USP <800> Hazardous Drugs- Handling in Healthcare Settings</p> <p>Completion Hours: 2.000 Transcript ID: USP800</p> <p><small>This Statement acknowledges only the completion of this activity: ACPE UAN #N/A No credits were reported to ACPE, CPE Monitor or any other accrediting body. This statement is for documentation of participation only.</small></p>

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – March 2024

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 05/17/2024

Date Due to IN BOP: 05/2024

Next Summary Due Date: 07/2024

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

Dear Board of Pharmacy:

Enclosed is the bimonthly report for May 2024, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy is committed to providing comprehensive reports outlining the remediation progress aligned with the Plan of Remediation submitted on September 27, 2023. The remediation plan encompasses four core elements 1) Policies and Procedures, 2) Continuing Education and Training, 3) Comprehensive Gap Analysis, and 4) Chief Compliance Officer/Chief Operation Officer. Each element is thoughtfully addressed within this report. I have included attachments with evidence of completion of remediation activities discussed herein.

- 1) **Policies and Procedures**: In adherence to the Remediation Plan, Paul's Pharmacy has implemented new policies and procedures specifically designed to address the concerns outlined in the Administrative Complaint. We have continuously evaluated these policies and procedures for efficiency and effectiveness. Additional information can be found in the attached Gap Analysis document.
- 2) **Continuing Education and Training**: In alignment with the stipulations in the Remediation Plan, Paul's Pharmacy has engaged in comprehensive continuing education and training related to compliance, regulatory issues, and compounding. This includes:
 - a) ***Pharmacist-in-Charge Boot Camp from CE Impact***: The pharmacy manager, pharmacist, COO, owner, and all full-time pharmacists have successfully completed this CE.
 - b) ***Compounding Competency Assessment Center offered by ASHP***: Compounding personnel at the location referenced in the Administrative Complaint, including the pharmacy manager, pharmacist, COO, and compounding technician, have completed successfully the Compounding Competency Assessment Center Training Program offered by ASHP.
- 3) **Comprehensive Gap Analysis**: As the COO/CCO, I have conducted regular comprehensive Gap Analyses at periodic intervals. The most recent Gap Analysis was completed on May 17, 2024. The results of this analysis and accompanying audit are included in Attachment 1 at the end of this report.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

- 4) Chief Compliance Officer/Chief Operations Officer: I continue to serve as the Chief Compliance Officer and Chief Operating Officer at Paul's Pharmacy. In this capacity, I have actively overseen the development and implementation of our comprehensive remediation plan. This includes integrating mandatory and non-mandatory training, updating and creating policies and procedures, conducting periodic internal audits, executing the heightened monitoring program, and more. My responsibility is to ensure that Paul's Pharmacy practices align with the highest standards and guidelines while overseeing continuous quality improvement within the organization.

I would like to acknowledge and appreciate Paul's Pharmacy owner, Jacob Mayer, for his continued commitment to achieving best practices in these matters. His proactive approach underscores Paul's Pharmacy's dedication to fostering a culture of safety and compliance, with a primary focus on the well-being of our patients, compounders, and colleagues.

In our continued efforts to implement strategies encompassing the four core elements outlined in the Plan of Remediation, the ongoing support and collaboration from the Indiana Board of Pharmacy are truly invaluable. Should you have any questions or require further information, please feel free to contact me at 812-426-5033 ext. 308 or via email at deborah@paulsrx.com. Your continued partnership is indispensable to the success of our collective efforts.

Sincerely,

Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – May 2024

Heightened Monitoring Compliance Program – Periodic Gap Analysis Completed 03/11/2024
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Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

☒ All products on active inventory shelves in the pharmacy area

☒ are in date (not expired).

☒ expiring within the current calendar year have a month sticker prominently affixed.

☒ expiring within the next calendar year have a year sticker prominently affixed.

- **Note:** Medications are organized and have prominently affixed labels for the years 2024, 2025, and 2026. It has been noted that there are several bottles expiring in 2027 on the shelves. Consequently, I recommended to the pharmacy manager that it is an appropriate time to order labels for 2027. NOTE: No expired products were found. No products with expirations dates within the next 90 days were found in active inventory shelves.
- **Note:** One new technician present for the audit today verbalized her understanding of the current expectations related to managing expiration dates in active inventory.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

Count 3 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
 - ☒ comply with the USP <795> BUDs.

Note: No advanced notice is given to the owner, pharmacists, or technicians prior to internal audits.

Note: I audited all products in active inventory on the compounding shelves on May 17, 2024. All containers have appropriate beyond-use dates (BUDs) as per USP 795 and supporting literature.

Note: As mentioned in the previous report, we are working toward purchasing compounding software that we believe will help us manage BUDs and all compounding compliance matters more efficiently and effectively. Since the last report, we have revisited PCCA's "The Compounder" and "SiCompounding," a new platform. After careful consideration, we have ruled out SiCompounding and decided to proceed with "The Compounder." We are in the process of purchasing, implementing, and training with the new software, which will take some time before we are fully operational. We aim to complete this transition in the next 3 to 4 months. Meanwhile, we continue to use PioneerRx.

Note: The BUD reference charts, including Table 1 of the USP guidelines for BUD management, remain posted near the compounding area.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS

- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.

- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible whenever possible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>

- **Note:** All preparations have prominently affixed month stickers on the exterior containers, and all have BUD's compliant with USP 795.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 draft USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES

- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
- **Note:** The script pro policy has been regularly evaluated for appropriateness and it is being diligently followed; we have been auditing this process for several months and continue to audit it at least monthly.
- **Note:** The pharmacy manager brought to my attention that there have been some new staff rotating through this location, making supervision of many details more challenging for both the manager and the pharmacist. As the person responsible for scheduling, I am committed to minimizing the rotations of new teammates as much as possible to ensure compliance for this store.
- **Note:** I audited 12 random SPM cartridges, and each cartridge has an expiration date of less than 12 months.
- **Note:** I audited 9 random return to stock bottles for medications in the SPM. Bottles have been properly initialed by a pharmacist and were placed on a shelf for the next use.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – May 2024

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.
Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

- ☒ All products with an extended BUD have appropriate documentation on file by a peer-reviewed study, by stability study, or by documentation from a compounding agency like PCCA. ***(PLEASE NOTE: This is not applicable. There are no products with extended BUD's being compounded by Paul's Pharmacy).***
- ☒ Training completed by compounding pharmacist supervising compounding at least annually:
 - ☒ USP 797 labeling.
 - ☒ USP 797 Assigning BUDs.***(PLEASE NOTE: This was completed in 2023 and is no longer an ongoing issue).***
- ☒ Training completed by compounding technician at least annually:
 - ☒ Re: USP 797 labeling.
 - ☒ USP 797 Assigning BUDs.
- ☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

- ☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – May 2024

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 07/23/2024

Date Due to IN BOP: 07/2024

Next Summary Due Date: 09/2024

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Dear Board of Pharmacy:

Please accept this regular bimonthly report (including the latest gap analysis) for July 2024, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023, cause number Cause No. 2023 IBP 0010. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy is committed to providing comprehensive reports outlining the remediation progress aligned with the Plan of Remediation submitted on September 27, 2023.

To recap here for your reference, the remediation plan encompasses four core elements 1) Policies and Procedures, 2) Continuing Education and Training, 3) Comprehensive Gap Analysis, and 4) Chief Compliance Officer/Chief Operating Officer.

In each previous bi-monthly report, Paul's Pharmacy addressed part 3) Comprehensive Gap Analysis in some detail. Additionally, Part 4) Chief Compliance Officer/Chief Operating Officer, continues to play a large role in completion of related compliance activities.

As we approach the halfway point of the probation period, I would like to highlight Paul's Pharmacy's ongoing efforts and commitment to compliance by focusing on Part 1) Policies and Procedures, and Part 2) Continuing Education and Training.

Notably, though only our West location is mandated to participate in this settlement agreement, all our retail locations are involved in development and implementation of the revised policies and procedures.

- 1) **Policies and Procedures**: In adherence to the Remediation Plan, Paul's Pharmacy implemented new policies and procedures beginning in 2023, specifically designed to address the concerns outlined in the Administrative Complaint. We have continuously evaluated these policies and procedures for efficiency and effectiveness.

The following Policies and Procedures (P&P) have been either established or revised:

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION
- 4.290 USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES
- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

During this reporting period Paul's Pharmacy leadership team has reviewed and, in most cases, revised these P&P to ensure they reflect both the best practices, and actual conduct at Paul's Pharmacy. The revised P&P are undergoing the "RAU" process where they are circulated among the staff, and each relevant staff member is required to sign the Read and Understood Form (RAU).

Since the last report, Paul's Pharmacy has changed the RAU to electronic documentation through our electronic communication tool that was implemented this year. ConnectTeam® is an asset that helps us disseminate information more quickly to the right teams and obtain real-time verification of who has read and signed off on important information.

- 2) **Continuing Education and Training:** In alignment with the stipulations in the Remediation Plan, Paul's Pharmacy has engaged in comprehensive continuing education and training related to compliance, regulatory issues, and compounding. This includes:
- a) ***Compounding Competency Assessment Center offered by ASHP:*** We have hired and trained an additional compounding technician for non-sterile compounding. Her certificates of achievement are attached in Attachment 3 at the end of this document.
 - b) ***CORE Compounding Training by PCCA:*** We have enrolled one compounding pharmacist and one compounding technician in this 4-day hands on live workshop at the PCCA laboratory in Texas September 10-13, 2024. This comprehensive program covers both USP <795> and <800> and includes the following topics:
 - USP 795 and 800 overviews
 - Formulation considerations in compounding
 - Quality assurance, quality control and workflow resources and tools
 - HRT, veterinary, dermatology compounding
 - Calculations workshop
 - Standard Operating Procedures and required USP documentation

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

- Role of the Designated Person (DP)

Laboratory sessions include:

- Understanding different bases
- Suppositories and rectal rockets
- Capsules and suspensions
- Lollipops and troches
- Equipment use: Ointment Mill, Electronic Mortar & Pestle (EMP), Capsule Machine and more
- Equipment maintenance and cleaning
- Cleaning procedures
- End product verification and documentation
- Instructors also observe gowning, hand washing and workflow technique within the powder containment enclosure.

As you can see, Paul's Pharmacy has been diligently adhering to the details of our settlement agreement and our commitment to excellence, while taking action to improve communication, compliance, and patient care. As mandated in the settlement agreement, I will also address components 3 and 4.

- 3) **Comprehensive Gap Analysis:** As the COO/CCO, I have conducted regular comprehensive Gap Analyses, and I am conducting spot checks and regular bi-monthly documentation currently. The most recent Gap Analysis was completed on July 10, 2024. The results of this analysis and accompanying audit are included in Attachment 1 at the end of this report. I am proud to report that our new compounding team under the leadership of Jonathan Garvey is doing an outstanding job! Our compounding department has never been as clean, organized, compliant, and aligned with the rules and regulations as it is today.

That said, Paul's Pharmacy is still addressing a few matters including compounding software updates (which is taking longer than expected), updating the master formula database for the most updated formulations (also a longitudinal project), and additional PCCA training which, as I mentioned previously, is scheduled for September 2024.

- 4) **Chief Compliance Officer/Chief Operations Officer:** I continue to serve as the Chief Compliance Officer and Chief Operating Officer at Paul's Pharmacy. In this capacity, I have actively overseen the development and implementation of our comprehensive remediation plan. This includes integrating mandatory and non-

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

mandatory training, updating and creating policies and procedures, conducting periodic internal audits, executing the heightened monitoring program, and more.

My responsibility is to ensure that Paul's Pharmacy's practices align with the highest standards and guidelines while overseeing continuous quality improvement within the organization.

I would like to acknowledge and appreciate Paul's Pharmacy owner, Jacob Mayer, for his continued commitment to achieving best practices in these matters. His proactive approach underscores Paul's Pharmacy's dedication to fostering a culture of safety and compliance, with a primary focus on the well-being of our patients, compounders, and colleagues.

In our continued efforts to implement strategies encompassing the four core elements outlined in the Plan of Remediation, the ongoing support and collaboration from the Indiana Board of Pharmacy are truly invaluable. Should you have any questions or require further information, please feel free to contact me at 812-426-5033 ext. 308 or via email at deborah@paulsrx.com. Your continued partnership is indispensable to the success of our collective efforts.

Sincerely,

Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – July 2024

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 07/10/2024

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

☒ All products on active inventory shelves in the pharmacy area

☒ are in date (not expired).

☒ expiring within the current calendar year have a month sticker prominently affixed.

☒ expiring within the next calendar year have a year sticker prominently affixed.

- **Note:** Medications are organized and have prominently affixed labels for the years 2024 (month and year), 2025, 2026, and 2027.
- **Note:** No expired products were found on active inventory shelves. No products with expirations dates within the next 90 days were found on active inventory shelves.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 3 Adulterated Drugs: BUDs (Beyond Use Dates) beyond USP (United States Pharmacopeia) 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
 - ☒ comply with the USP <795> BUDs.

Note: No advanced notice is given to the owner, pharmacists, or technicians prior to internal audits.

Note: I audited all products in active inventory on the compounding shelves on July 10, 2024. All containers have appropriate beyond-use dates (BUDs) as per USP 795. It is noted that there are some older formulas still in use, we are sorting through these as they are encountered, and changing to newer formulas from PCCA whenever a similar formulation is available.

Note: As mentioned in the previous report, we are working toward purchasing compounding software that we believe will help us manage BUDs and all compounding compliance matters more efficiently and effectively. We aim to complete this transition before January 1, 2025. Meanwhile, we continue to use PioneerRx.

Note: The BUD (Beyond Use Dates) reference charts, including Table 1 of the USP guidelines for BUD management, remain posted near the compounding area.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS

- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.

- ☒ All compounded products on active inventory shelves
 - ☒ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible whenever possible.
 - ☒ expiring within the current calendar month are removed from the active inventory shelves.
 - ☒ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>

- **Note:** All preparations have prominently affixed month stickers on the exterior containers, and all have BUD's compliant with USP 795.
- **Note:** All preparations have BUD compliant with USP 795.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES

- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
- **Note:** The script pro policy has been regularly evaluated for appropriateness and it is being diligently followed; we have been auditing this process for several months and continue to audit the process at least every other month. I have attached the policy at the end of this document. It has been updated, added to the ConnecTeam® platform.
- **Note:** I audited 12 random SPM cartridges, and each cartridge has an expiration date of less than 12 months.
- **Note:** I audited 10 random returns to stock bottles for medications in the SPM. Bottles have been properly initialed by a pharmacist and were placed on a shelf for the next use.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

- ☒ All products with an extended BUD have appropriate documentation on file by a peer-reviewed study, by stability study, or by documentation from a compounding agency like PCCA. ***(PLEASE NOTE: This is not applicable. There are no products with extended BUD's being compounded by Paul's Pharmacy).***
- ☒ Training completed by compounding pharmacist supervising compounding at least annually:
- ☒ USP 797 labeling.
 - ☒ USP 797 Assigning BUDs.
- (PLEASE NOTE: This was completed in 2023 and is no longer an ongoing issue).***
- ☒ Training completed by compounding technician at least annually:
- ☒ Re: USP 797 labeling.
 - ☒ USP 797 Assigning BUDs.
- ☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

- ☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

Cover Sheet

Attachment 2 – Related Policy and Procedures

(none attached today, undergoing the RAU process)

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Cover Sheet

Attachment 3 – New Training Certificates

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024



4500 East-West Highway
Bethesda, MD 20814
Phone: 866-279-0681
www.ashp.org

STATEMENT OF COMPLETION

provided by
American Society of Health-System Pharmacists®

Name: Jessica Nickens
ASHP Customer #: 08485499|0
Activity Date: 6/10/2024
Activity Name: 2024 USP <795> Pharmaceutical Compounding - Nonsterile Preparations

Completion Hours: 1.500

Transcript ID: USP795

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
This statement is for documentation of participation only.



4500 East-West Highway
Bethesda, MD 20814
Phone: 866-279-0681
www.ashp.org

STATEMENT OF COMPLETION

provided by
American Society of Health-System Pharmacists®

Name: Jessica Nickens
ASHP Customer #: 08485499|0
Activity Date: 6/10/2024
Activity Name: 2024 USP <800> Hazardous Drugs- Handling in Healthcare Settings

Completion Hours: 2.000

Transcript ID: USP800

This Statement acknowledges only the completion of this activity:
ACPE UAN #N/A
No credits were reported to ACPE, CPE Monitor or any other accrediting body.
This statement is for documentation of participation only.

Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – July 2024

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 09/16/2024

Date Due to IN BOP: 09/2024

Next Summary Due Date: 11/2024

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Dear Board of Pharmacy:

Please accept this regular bimonthly report (including the latest gap analysis) for July 2024, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023, cause number Cause No. 2023 IBP 0010. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy is committed to providing comprehensive reports outlining the remediation progress aligned with the Plan of Remediation submitted on September 27, 2023.

To recap here for your reference, the remediation plan encompasses four core elements 1) Policies and Procedures, 2) Continuing Education and Training, 3) Comprehensive Gap Analysis, and 4) Chief Compliance Officer/Chief Operating Officer.

- 1) **Policies and Procedures**: In adherence to the Remediation Plan, Paul's Pharmacy implemented new policies and procedures beginning in 2023, specifically designed to address the concerns outlined in the Administrative Complaint. We have continuously evaluated these policies and procedures for efficiency and effectiveness.
- 2) **Continuing Education and Training**: In alignment with the stipulations in the Remediation Plan, Paul's Pharmacy has engaged in comprehensive continuing education and training related to compliance, regulatory issues, and compounding. This includes:
 - a) ***Compounding Competency Assessment Center offered by ASHP***: We currently have four pharmacists and two compounding technicians who have completed this training.
 - b) ***CORE Compounding Training by PCCA***: We now have two compounding pharmacists and one compounding technician who has completed this intensive 4-day hands on live workshop at the PCCA laboratory in Texas. This comprehensive program covers both USP <795> and USP <800>.
- 3) **Comprehensive Gap Analysis**: I have conducted regular comprehensive Gap Analyses, and I am conducting spot checks and regular bi-monthly documentation. The results of the most recent gap analysis are included in Attachment 1 at the end of this report. I am proud to report that our new compounding team under the leadership of Jonathan Garvey is doing an outstanding job! Paul's Pharmacy is still addressing a few matters including compounding software (which is taking longer

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

than expected), updating the master formula database for the most updated formulations (also a longitudinal project).

- 4) **Chief Compliance Officer/Chief Operations Officer**: I continue to serve as the Chief Compliance Officer and Chief Operating Officer at Paul's Pharmacy. In this capacity, I have actively overseen the development and implementation of our comprehensive remediation plan. This includes integrating mandatory and non-mandatory training, updating and creating policies and procedures, conducting periodic internal audits, executing the heightened monitoring program, and more.

My responsibility is to ensure that Paul's Pharmacy's practices align with the highest standards and guidelines while overseeing continuous quality improvement within the organization.

I would like to acknowledge and appreciate Paul's Pharmacy owner, Jacob Mayer, for his continued commitment to achieving best practices in these matters. His proactive approach underscores Paul's Pharmacy's dedication to fostering a culture of safety and compliance, with a primary focus on the well-being of our patients, compounders, and colleagues.

In our continued efforts to implement strategies encompassing the four core elements outlined in the Plan of Remediation, the ongoing support and collaboration from the Indiana Board of Pharmacy are truly invaluable. Should you have any questions or require further information, please feel free to contact me at 812-426-5033 ext. 308 or via email at deborah@paulsrx.com. Your continued partnership is indispensable to the success of our collective efforts.

Sincerely,

Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 09/11/2024

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

☒ All products on active inventory shelves in the pharmacy area

☒ are in date (not expired).

☒ expiring within the current calendar year have a month sticker prominently affixed.

☒ expiring within the next calendar year have a year sticker prominently affixed.

- **Note:** No advanced notice is given to the owner, pharmacists, or technicians prior to internal audits.
- **Note:** Medications are organized and have prominently affixed labels for the years 2024 (month and year), 2025, 2026, and 2027. Some bottles for 2027 and beyond did not have labels. Though this is not a violation of the law, it is not according to Paul's Pharmacy Best Practice. This was brought to the attention of the pharmacy manager, Jonathan.
- **Note:** No expired products were found on active inventory shelves. No products with expirations dates within the next 90 days were found on active inventory shelves.
- **Note:** A training was launched today on ConnectTeam® on applying Year and Month labels to products called "Labeling – Annual Review". It has been assigned to the following groups: pharmacists, compounding, lead technicians.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 3 Adulterated Drugs: BUDs (Beyond Use Dates) beyond USP (United States Pharmacopeia) 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
- ☒ comply with the USP <795> BUDs.

Note: I audited all products in compounding active inventory. All containers have appropriate beyond-use dates (BUDs) as per USP 795.

Note: As mentioned in the previous report, we are working toward purchasing compounding software that we believe will help us manage BUDs and all compounding compliance matters more efficiently and effectively. We aim to complete this transition before January 1, 2025. Meanwhile, we continue to use PioneerRx.

Note: The BUD (Beyond Use Dates) reference charts, including Table 1 of the USP guidelines for BUD management, remain posted near the compounding area.

Note: A training was launched today on ConnectTeam® on BUD and Expirations Dates called "Labeling – Annual Review". It has been assigned to the following groups: pharmacists, compounding, lead technicians.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.
- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves and placed in quarantine.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>

Note: All preparations have prominently affixed month stickers on the exterior containers.

Note: All preparations have BUD compliant with USP 795.

Note: A training was launched today on ConnectTeam® called "Labeling – Annual Review". It has been assigned to the following groups: pharmacists, compounding, lead technicians.

Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
 - 5.060 MAINTENANCE OF INVENTORIES
-
- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
-
- **Note:** The script pro policy has been regularly evaluated for appropriateness and it is being diligently followed; we have been auditing this process for months and continue to audit the process at least every other month.
 - **Note:** I audited 10 random SPM cartridges, and each cartridge has an expiration date of less than 12 months.
 - **Note:** I audited 10 random return to stock bottles for medications in the SPM. Bottles have been properly initialed by a pharmacist and were placed on a shelf for the next use.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – July 2024

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

☒ All products with an extended BUD have appropriate documentation on file by a peer-reviewed study, by stability study, or by documentation from a compounding agency like PCCA. **(PLEASE NOTE: This is not applicable. There are no products with extended BUD's being compounded by Paul's Pharmacy).**

☒ Training completed by compounding pharmacist supervising compounding at least annually:

- ☒ USP 797 labeling.
- ☒ USP 797 Assigning BUDs.

☒ Training completed by compounding technician at least annually:

- ☒ Re: USP 797 labeling.
- ☒ USP 797 Assigning BUDs.

☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

Note: A training was launched today on ConnectTeam® called "Labeling – Annual Review". It has been assigned to the following groups: pharmacists, compounding, lead technicians.

Cover Sheet

Attachment 2 – Related Policy and Procedures

(nothing new attached today)

Cover Sheet

Attachment 3 – New Training Certificates



Paul's Pharmacy - West
Bimonthly Report for Indiana Board of Pharmacy – July 2024

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 11/18/2024

Date Due to IN BOP: 11/2024

Next Summary Due Date: 01/2024

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

November 25, 2025

Dear Board of Pharmacy,

Please accept this bi-monthly report (including the latest gap analysis) for November 2024, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023, Cause No. 2023 IBP 0010. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy remains committed to providing comprehensive reports outlining our progress in meeting the terms of the probationary agreement and our Plan of Remediation submitted on September 27, 2023.

Inspection Update

I am pleased to report that Paul's Pharmacy successfully passed its first of two mandatory inspections, which was conducted by Ron Hinderliter and Kim Russell on October 31, 2024. The inspection was **Passed** with no violations or remarks, and the attached inspection form provides documentation of this achievement.

I would, however, like to address the timing of the inspection as it relates to "Agreed Disposition" number 5(a) of the Settlement Agreement. According to the Final Order, the first inspection was to occur within the first year of probation, which would have been in September 2024. Unfortunately, this deadline passed before the inspection was completed. Paul's Pharmacy reached out to the Board and compliance officers multiple times in October to bring this to your attention; once the oversight was realized, the Compliance Officer promptly scheduled the inspection.

While this sequence does not strictly align with the agreement, we did make every effort to alert the Board that the inspection was overdue. We humbly request that this timing discrepancy not be held against us as we move toward our petition for withdrawal of probation. We remain committed to full compliance and are prepared to schedule the second inspection within 30 days of our petition for withdrawal. Compliance Officer, Ron Hinderliter, has kindly indicated his willingness to assist in ensuring this is completed in a timely manner.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Compliance with Terms of Final Order “Agreed Disposition”

- **Agreements 1–4:** These are administrative in nature and do not require additional documentation or action.
- **Agreement 5(a):** The first inspection has been successfully passed, and another will be scheduled in collaboration with Ron Hinderliter at the appropriate time.
- **Agreement 5(b):** There have been no changes to the contact information.
- **Agreement 5(c):** There have been no changes in management.
- **Agreement 5(d):** Bi-monthly reports, including remediation updates and documentation of bimonthly audits, have been submitted as required. This is the sixth bimonthly report, and all reports have been timely and complete. Including any additional documentation.
- **Agreement 5(e):** The required Plan of Remediation was submitted in October 2023. Gap analyses have been conducted and included in each previous bimonthly report.
- **Agreements 6 & 7:** The \$5 fee and \$4,000 fine were paid as stipulated.

Remediation Progress Summary

The remediation plan encompasses four core elements:

1. **Policies and Procedures:** Paul's Pharmacy implemented updated policies and procedures in 2023, designed to address concerns raised in the Administrative Complaint. These policies have been reviewed regularly for effectiveness and updated as needed.
2. **Continuing Education and Training:** Staff members have participated in ongoing education related to compliance, regulatory matters, and compounding.
3. **Comprehensive Gap Analysis:** Regular gap analyses have been conducted, with results submitted in each report. The latest analysis is included as Attachment 1 herewith.
4. **Chief Compliance Officer/Chief Operating Officer:** In my role as CCO/COO, I have actively overseen the implementation and execution of the remediation plan, gap analyses, communication with the Board, and as indicated in each by monthly report.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Final Remarks

Paul's Pharmacy has made every effort to comply with the conditions of probation. We are committed to upholding the highest standards of compliance and integrity. Successfully passing the first inspection is a significant milestone, and we are grateful for the Board's grace and support as we continue to meet these obligations.

Should you have any questions or require additional information, please do not hesitate to contact me at 812-426-5033 ext. 308 or via email at deborah@paulsrx.com.

Thank you for your continued partnership and collaboration.

Sincerely,

Deborah Larison, PharmD, CPh
COO/CCO
Paul's Pharmacy
Evansville, IN

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 11/06/2024

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

☒ All products on active inventory shelves in the pharmacy area

☒ are in date (not expired).

☒ expiring within the current calendar year have a month sticker prominently affixed.

☒ expiring within the next calendar year have a year sticker prominently affixed.

- **Note:** No advanced notice is given to the owner, pharmacists, or technicians prior to internal audits.
- **Note:** Medications are organized and have prominently affixed labels for the years 2024 (month and year), 2025, 2026, and 2027. There are no labels for 2028, though this is not a violation of law, I did bring it to the attention of the pharmacy manager, Jonathan.
- **Note:** No expired products were found on active inventory shelves. No products with expiration dates within the next 90 days were found on active inventory shelves.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Count 3 Adulterated Drugs: BUDs (Beyond Use Dates) beyond USP (United States Pharmacopeia) 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
 - ☒ comply with the USP <795> BUDs.

Note: I audited all products in compounding active inventory. All containers have appropriate beyond-use dates (BUDs) as per USP 795.

Note: As mentioned in the previous report, we are working toward purchasing compounding software that we believe will help us manage BUDs and all compounding compliance matters more efficiently and effectively. We aim to complete this transition before January 1, 2025. Meanwhile, we continue to use PioneerRx.

Note: The BUD (Beyond Use Dates) reference charts, including Table 1 of the USP guidelines for BUD management, remain posted near the compounding area.

Note: A training titled *"Labeling – Annual Review"* was recently launched on ConnectTeam® (our training and communication app) to address labeling, and BUD and expiration dates. This training has been assigned to the following groups: pharmacists, compounding staff, and lead technicians. To date, nine out of 14 team members have fully completed the training, including all compounding pharmacists. Follow-up emails were sent to team members who have not yet completed the training, and I will provide an update on completed training in the next report.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.
- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves and placed in quarantine.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>

Note: All preparations have prominently affixed month stickers on the exterior containers.

Note: All preparations have BUD compliant with USP 795.

Note: Note: A training titled *"Labeling – Annual Review"* was recently launched on ConnectTeam® (our training and communication app) to address labeling, and BUD and expiration dates. This training has been assigned to the following groups: pharmacists, compounding staff, and lead technicians. To date, nine out of 14 team members have fully completed the training, including all compounding pharmacists. Follow-up emails were sent to team members who have not yet completed the training, and I will provide an update on completed training in the next report.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES

- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
- **Note:** The script pro policy has been regularly evaluated for appropriateness and it is being diligently followed; we have been auditing this process for months and continue to audit the process at least every other month.
- **Note:** It was discovered that, in an effort to improve efficiency, the pharmacy manager replaced the manufacturer-provided cleaning logs for the ScriptPro machine and Eyecon with a dry-erase log containing the same required information. Upon realizing this was not an acceptable practice on 10/31/2024, he immediately reinstated the manufacturer logs, retrieved prior records as evidence of compliance, and ensured all future documentation adheres to permanent recordkeeping standards. The manager was unaware that only permanent documentation is acceptable for this purpose. While the previously used dry-erase logs resulted in a small gap in the permanent records, this was an unintended oversight that has since been fully corrected.
- **Note:** I audited every SPM cartridge, and each cartridge has an expiration date of less than 12 months.
- **Note:** I audited every return to stock bottle for medications in the SPM. Bottles have been properly initialed by a pharmacist and were placed on a shelf for the next use.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

☒ All products with an extended BUD have appropriate documentation on file by a peer-reviewed study, by stability study, or by documentation from a compounding agency like PCCA. **(PLEASE NOTE: This is not applicable. There are no products with extended BUD's being compounded by Paul's Pharmacy).**

☒ Training completed by compounding pharmacist supervising compounding at least annually:

- ☒ USP 797 labeling.
- ☒ USP 797 Assigning BUDs.

☒ Training completed by compounding technician at least annually:

- ☒ Re: USP 797 labeling.
- ☒ USP 797 Assigning BUDs.

☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

Note: See previous note regarding Labeling training in ConnectTeam ®

Cover Sheet

Attachment 2 – Related Policy and Procedures

(nothing new attached today)

Cover Sheet

Attachment 3 – New Training Certificates



Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024



Pending Completion: Ryan Anslinger, Scotte Schutte, Jon Robb, Joy Caldwell, David Smith

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Cover Sheet

Attachment 4 – Board of Pharmacy Inspection Report 10/31/2024

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072
Indianapolis, IN 46204

FACILITY
Paul's Pharmacy
2345 W Franklin St.
2345 W Franklin St
Evansville IN 47712
Phone: 8124254365
Owner:
Ownership Type:

LICENSE
License No: 60006286A
Profession: Pharmacy
License Type: Pharmacy
2345 W Franklin St
Evansville IN 47712
Phone: 8124254365

Inspection Type: Pharmacy Inspection
Inspection Date: 10/31/2024 12:00:00 AM
Result: Pass

Remarks:Rezn Pharmacy Inspection conducted on 10/31/2024 by C/O Ron Hinderliter and Kim Russell, at the direction of the Indiana Board of Pharmacy as stated in the settlement agreement. Assisting in the inspection were Managing Pharmacist, Jonathan Garvey and Chief Operating Officer/Chief Compliance Officer, Deborah Latton, PharmD, CPh. No violations were observed.

Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Facile-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation
Non-sterile Compounding

Remote Locations (Type II only)
Emergency Drug Kits/Crash Carts
Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operation of the facility and I am executing this inspection form as, or on behalf of the licensee.

This alleged violation has not been corrected. The alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall no longer pursue more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against the licensee.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PEA.Compliance@plm.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.

Signature of Inspector:  Date/Time: 11/1/2024 12:51:21 PM Signature of Owner/Representative: 

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – November 2024

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Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Paul's Pharmacy Bi-Monthly Report
License No. 60006286A
Cause No. 2023 IBP 0010

Date of Summary: 01/24/2025

Date Due to IN BOP: 01/2025

Next Summary Due Date: 03/2025

Eligible to Remove Probation 03/18/2025

Prepared by Deborah Larison, PharmD, CPh
Chief Compliance Officer/Chief Operating Officer
Paul's Pharmacy
Evansville, IN

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

January 24, 2025

Dear Board of Pharmacy,

Please accept this bi-monthly report (including the latest gap analysis) for January 2025, as mandated by the Settlement Agreement dated August 11, 2023, and the Board of Pharmacy's Final Order dated September 18, 2023, Cause No. 2023 IBP 0010. Pursuant to Paragraph 5(b) of the agreement, Paul's Pharmacy remains committed to providing comprehensive reports outlining our progress in meeting the terms of the probationary agreement and our Plan of Remediation submitted on September 27, 2023.

Pending Request to Withdraw from Probation

As previously mentioned in the November 2024, bi-monthly report, I am pleased to report that Paul's Pharmacy successfully passed its first of two mandatory inspections, on October 31, 2024. The inspection was Passed with no violations or remarks.

The second and final inspection mandated in the final order is due within 30 days of the petition for withdrawal of probation. Having spoken with compliance officer, Ron Hinderliter, we have scheduled the final inspection for "late February or early March." CO Hinderliter has kindly indicated his willingness to assist in this matter.

Paul's Pharmacy is eligible for withdrawal of probation on March 18, 2025, and is preparing to submit a formal request to withdraw probation with the assistance of counsel, Stephanie Eckerle. We respectfully request to be placed on the March 11, 2025, Board of Pharmacy agenda.

Compliance with Terms of Final Order "Agreed Disposition" executed August 18, 2023

- **Agreement 1:** The Board has jurisdiction over Respondent and the subject matter in this disciplinary action.
 - **No additional action required.**
- **Agreement 2:** The parties execute this Agreement voluntarily.
 - **No additional action required.**

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

- **Agreement 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.
 - **No additional action required.**
- **Agreement 4:** Petitioner agrees to the terms of this Agreement will resolve any and all pending claims or allegations relating to disciplinary action against Respondent's pharmacy license.
 - **No additional action required.**
- **Agreement 5:** Respondent's pharmacy license shall be placed on INDEFINITE PROBATION for NOT LESS THAN EIGHTEEN (1S) MONTHS from the date of the final order.
 - **No additional action required.**
- While on probation:
 - **Agreement 5(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.
 - **Action Completed: The first inspection has been successfully passed, and another will be scheduled in collaboration with Ron Hinderliter at the appropriate time.**
 - **Agreement 5(b):** Respondent shall keep the facility's contact information up to date with the Board.
 - **Action Completed: There have been no changes to the contact information, therefore, none was reported.**
 - **Agreement 5(c):** Respondent shall keep the Board informed of the facility's management of the pharmacy.
 - **Action Completed: There have been no changes in management therefore, none was reported.**
 - **Agreement 5(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

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

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.

- **Action Completed: Typed bi-monthly reports, detailing remediation updates and documentation of bimonthly audits, have been submitted to the indicated email address as required. The first was submitted within 2 months of the issuance of the final order. This is the seventh bimonthly report, and all reports have been typed, timely, and complete.**
- **Agreement 5(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.
 - **Action Completed: The required Plan of Remediation was submitted in October 2023 which was within 1 month of the final order which was executed August 18, 2023. This plan of remediation was provided to CO Ron Hinderliter prior to the first inspection and was also available at the time of the inspection. It will be available at the next inspection as well.**
 - **Action Completed: Gap analyses have been conducted and included in each bi-monthly report detailing actions taken and compliance with the final order.**
- **Agreements 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 by personal check, cashier's check, or money order.
 - **Action Completed: The \$5 fee was paid as stipulated.**
- **Agreements 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.
 - **Action Completed: The \$4,000 fine was paid as stipulated.**

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Remediation Progress Summary

The remediation plan encompasses four core elements:

1. **Policies and Procedures:** Paul's Pharmacy implemented updated policies and procedures in 2023, designed to address concerns raised in the Administrative Complaint. These policies have been reviewed regularly for effectiveness and updated as needed.
2. **Continuing Education and Training:** Staff members have participated in ongoing education related to compliance, regulatory matters, and compounding.
3. **Comprehensive Gap Analysis:** Regular gap analyses have been conducted, with results submitted in each report. The latest analysis is included as Attachment 1 herewith.
4. **Chief Compliance Officer/Chief Operating Officer:** In my role as CCO/COO, I have actively overseen the implementation and execution of the remediation plan, gap analyses, communication with the Board, and as indicated in each bi-monthly report.

Final Remarks

Paul's Pharmacy has enthusiastically complied with each condition of probation. Successfully passing the first inspection was a significant milestone but it is only a small piece of the 18-month long polish of Paul's Pharmacy's compliance program. We are grateful for the Board's grace and support, and we commit to sustaining the advances in our culture of compliance.

Should you have any questions or require additional information, please do not hesitate to contact me at 812-426-5033 ext. 308 or via email at deborah@paulsrx.com.

Thank you for your continued partnership and collaboration.

Sincerely,

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Deborah Larison, PharmD, CPh
COO/CCO
Paul's Pharmacy
Evansville, IN

Postscript – January 31, 2025

As part of our heightened monitoring plan, Paul's Pharmacy has progressed from conducting weekly active inventory audit spot checks 18 months ago to bi-monthly audits today.

On Monday, January 27, 2025, after this document was completed, a pharmacy intern, Collin Fiorentini, and I conducted a comprehensive audit of 100% of active inventory medication shelves, compounded preparations, and API active inventory for expired medications.

Notably, we did not find a single expired medication in active inventory areas. Additionally, there were no "soon-to-expire" containers with expiration dates within the next 60 days. Only six stock bottles of commercially purchased medications were identified with expiration dates between 60 and 90 days in the future.

I wanted to share this achievement with the board as a testament to the dedication and diligence of the pharmacy staff throughout the probation period.

Best regards,

Deborah Larison, PharmD, CPh

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Cover Sheet

Attachment 1 – Gap Analysis and Heightened Monitoring

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Heightened Monitoring Compliance Program – Periodic Gap Analysis

Completed 01/16/2025

Count 1: Adulterated Drugs: Expired Drugs in the Pharmacy Area 7/26/2022.

Count 2: Adulterated Drugs: Expired Drugs in the Pharmacy Area 2/1/2023.

Policy and Procedure (P/P):

- 5.060 MAINTENANCE OF INVENTORIES

☒ All products on active inventory shelves in the pharmacy area

☒ are in date (not expired).

☒ expiring within the current calendar year have a month sticker prominently affixed.

☒ expiring within the next calendar year have a year sticker prominently affixed.

- **Note:** No advanced notice is given to the owner, pharmacists, or technicians prior to internal audits.
- **Note:** Medications are organized and have prominently affixed labels for the years 2025 (month and year or just month), 2026, and 2027, and 2028. Medications with expiration dates 2029 or longer have a green (or other color if green is depleted) dot affixed.
- **Note:** No expired products were found on active inventory shelves. No products with expirations dates within the next 90 days were found on active inventory shelves.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Count 3 Adulterated Drugs: BUDs (Beyond Use Dates) beyond USP (United States Pharmacopeia) 795 standards 7/26/2022.

Count 4 Adulterated Drugs: BUDs beyond USP 795 standards 10/12/2022.

Count 5 Adulterated Drugs: BUDs beyond USP 795 standards 2/1/2023.

Count 6 Adulterated Drugs: BUDs beyond USP 795 standards 7/26/2023.

Count 7 Misbranded Medications: BUDs beyond USP 795 standards 10/12/2022.

Count 8: Misbranded Medications: BUDs beyond USP 795 standards 2/1/2023.

Policy and Procedure (P/P):

- 9.050 ASSIGNING AND MAINTENANCE OF BEYOND-USE DATE (BUD) FOR COMPOUNDED PREPARATIONS

- ☒ All compounded products on the active inventory shelves
 - ☒ comply with the USP <795> BUDs.

Note: I audited all products in compounding active inventory. All containers have appropriate beyond-use dates (BUDs) as per USP 795.

Note: As mentioned in the previous report, we are working toward purchasing compounding software that we believe will help us manage BUDs and other compounding compliance matters more efficiently and effectively. We aim to complete this transition before April 1, 2025. Meanwhile, we continue to use PioneerRx.

Note: The BUD (Beyond Use Dates) reference charts, including Table 1 of the USP guidelines for BUD management, remain posted near the compounding area.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Count 6 Misbranded Medication: Failure to consistently label medications with appropriate BUD 7/26/2023.

Count 8 Misbranded Medication: Failure to consistently label medications with appropriate BUD 2/1/2023.

Policy and Procedure (P/P):

- 6.020 LABELING OF COMPOUNDED PREPARATIONS
- USP <795> Establishing Beyond-Use Dates: Each CNSP label must state date, or hour/date, beyond which the preparation cannot be used and must be discarded.
- ☑ All compounded products on active inventory shelves
 - ☑ have a month sticker or month and year sticker (if needed) affixed to the container which is prominently visible.
 - ☑ expiring within the current calendar month are removed from the active inventory shelves and placed in quarantine.
 - ☑ have a BUD printed or affixed to the label that is within the guidelines of the USP <795>

Note: All preparations have prominently affixed month stickers on the exterior containers.

Note: All preparations have BUD compliant with USP 795.

Note: A training module titled "Labeling – Annual Review" was recently launched on ConnectTeam®, our training and communication app, to reinforce best practices for labeling, beyond-use dating (BUD), and expiration dates. This training has been assigned to pharmacists, compounding staff, and lead technicians.

To date, 12 of 13 team members have fully completed the training, including all compounding pharmacists. A screen shot of the administrator view of the module is attached herewith. Note, the pharmacist that has not completed the training is a PRN pharmacist who works at a non-compounding location of Paul's Pharmacy. He works approximately half shift once every 2 weeks to cover for pharmacy manager meetings.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Count 6 Misbranded Medications: Inappropriate return-to-stock procedures for the ScriptPro machine 7/26/2023.

Policy and Procedure (P/P):

- 4.290 USE AND MAINTENANCE OF THE SCRIPT PRO MACHINE
- 5.060 MAINTENANCE OF INVENTORIES

- ☒ Return to stock containers for medication located in the script pro machine (SPM)
 - ☒ are placed on the active inventory shelf (not back in the SPM).
 - ☒ the cartridge for the medication to be returned to stock is pulled from the SPM and placed on the active inventory shelf beside or under the product container.
 - ☒ SPM has no greater than 12-month expiration date on medications placed in each cartridge.
- **Note:** The script pro policy has been regularly evaluated for appropriateness, and it is being diligently followed; we have been auditing this process for months and continue to audit the process at least every other month.
- **Note:** Manufacturer cleaning logs are in use and complete.
- **Note:** I audited every SPM cartridge, and each cartridge has an expiration date of less than 12 months.
- **Note:** I audited every return to stock bottle for medications in the SPM. Bottles have been properly initialed by a pharmacist and were placed on a shelf for the next use.

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: Failure to maintain essential documentation.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to consistently label medications with appropriate BUD.

Count 9 Failure to Keep Abreast of Current Professional Theory and Practice: failure to create necessary policies and procedures.

Policy and Procedure (P/P):

- 2.010 EMPLOYEE ORIENTATION AND TRAINING
- 2.020 COMPOUNDING PERSONNEL ORIENTATION PROGRAM
- 2.040 NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

☒ All products with an extended BUD have appropriate documentation on file by a peer-reviewed study, by stability study, or by documentation from a compounding agency like PCCA. **(PLEASE NOTE: This is not applicable. There are no products with extended BUD's being compounded by Paul's Pharmacy).**

☒ Training completed by compounding pharmacist supervising compounding at least annually:

- ☒ USP 797 labeling.
- ☒ USP 797 Assigning BUDs.

☒ Training completed by compounding technician at least annually:

- ☒ Re: USP 797 labeling.
- ☒ USP 797 Assigning BUDs.

☒ USP 795 Figure 1 posted in plain view for compounding team.

As previously mentioned, the following chart is posted:

Table 1. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or Compounded Nonsterile Preparation (CNSP)-Specific Stability Information ^a		
Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms ^b	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (Non-aqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms ^c	180	Controlled room temperature or refrigerator
^a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table.		
^b Emulsions, gels, creams, solutions, sprays, or suspensions.		
^c Capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.		

☒ Necessary policies related to counts 1-9 and listed within this document are reviewed at least annually and updated as needed.

Note: See previous note regarding Labeling training in ConnectTeam ®

Cover Sheet

Attachment 2 – Related Policy and Procedures

(nothing new attached today)

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Cover Sheet

Attachment 3 – New Training Certificates

Labeling - Annual Review

Published

Course admins

Edit

Settings

Options

Overall course statistics

Search

Why take this course?

Explanation

USP 1-Dec-2025

USP <7> Labeling

DEFINITIONS

Label vs Labeling

Shipping containers

BUD vs Expiration Date

LABELING DETAILS

Names and strengths

Exceptions to Name and Stre...

Leading and Terminal Zeros

Units

LABELS AND LABELING FOR INJECT...

Labeling - Annual Review

Completion

Preview

92% 12 / 13 Have completed

0% 0 / 13 Are in progress

8% 1 / 13 Have not started

Filter View Table

Search

Export

	First name	Last name	Last viewed	Status	Last status change
	Deborah	Larison	11/25/2024 02:23 PM	Completed	11/25/2024 02:23 PM
	Laura	Ziliak	10/15/2024 01:55 PM	Completed	10/15/2024 01:55 PM
	Brandt	Kolb	11/25/2024 02:49 PM	Completed	11/25/2024 02:49 PM
	Tricia	Britton	11/25/2024 02:19 PM	Completed	11/25/2024 02:19 PM
	Claire	Schmitt	11/25/2024 02:13 PM	Completed	11/25/2024 02:13 PM
	Ryan	Anslinger	11/26/2024 05:51 PM	Completed	11/26/2024 05:51 PM
	Scott	Schutte	11/29/2024 11:19 AM	Completed	11/29/2024 11:19 AM
	Jon	Robb	11/25/2024 06:54 PM	Completed	11/25/2024 06:54 PM
	Jonathan	Garvey	09/16/2024 09:37 PM	Completed	09/16/2024 09:37 PM
	Ashley	Gibson	09/28/2024 05:07 PM	Completed	09/28/2024 05:07 PM
	Jacob	Mayer	11/25/2024 01:02 PM	Completed	11/25/2024 01:02 PM
	Joy	Caldwell	12/01/2024 09:26 AM	Completed	12/01/2024 09:26 AM
DS	David	Smith	--	Not started	--

Note: David Smith is a PRN pharmacist who works at a non-compounding location once every other week for a half day to cover manager meetings.

Cover Sheet

Attachment 4 – Board of Pharmacy Inspection Report 10/31/2024

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072
Indianapolis, IN 46204

FACILITY

Paul's Pharmacy
2345 w franklin st.
2345 w franklin st
Evansville IN 47712
Phone: 8124254365
Owner:
Ownership Type:

LICENSE

License No: 60006286A
Profession: Pharmacy
License Type: Pharmacy
2345 W Franklin St
Evansville IN 47712
Phone: 8124254365

Inspection Type:	Pharmacy Inspection
Inspection Date:	10/31/2024 12:00:00 AM
Result:	Pass

Remarks:Renan Pharmacy Inspection conducted on 10/31/2024 by C/O Ron Hinderliter and Kim Russell, at the direction of the Indiana Board of Pharmacy as stated in the settlement agreement. Assisting in the inspection were Managing Pharmacist, Jonathan Garvey and Chief Operating Officer/Chief Compliance Officer, Deborah Larison, PharmD, CPh. No violations were observed.

Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labelling/Documentation
Non-sterile Compounding

Paul's Pharmacy - West

Bimonthly Report for Indiana Board of Pharmacy – January 2025

Remote Locations (Type II only)
Emergency Drug Kits/Crash Carts
Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

This alleged violation(s) was/were not addressed during the inspection. The alleged violator has the opportunity to submit a written Corrective Plan to the Indiana Professional Licensing Agency (PLA). If the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@plain.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 482 W. Washington St. RM W072, Indianapolis, IN 46204.



Signature of Inspector

11/1/2024 12:51:21 PM

Date/Time



Signature of Owner/Representative

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Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072
Indianapolis, IN 46204

FACILITY

Paul's Pharmacy
2345 w franklin st.
2345 w franklin st
Evansville IN 47712
Phone: 8124254365

LICENSE

License No: 60006286A
Profession: Pharmacy
License Type: Pharmacy

Inspection Type:	Pharmacy Inspection
Inspection Date:	10/31/2024 12:00:00 AM
Result:	Pass

Remarks:Return Pharmacy Inspection conducted on 10/31/2024 by C/O Ron Hinderliter and Kim Russell, at the direction of the Indiana Board of Pharmacy as stated in the settlement agreement. Assisting in the inspection were Managing Pharmacist, Jonathan Garvey and Chief Operating Officer/Chief Compliance Officer, Deborah Larison, PharmD, CPh. No violations were observed.

Checklist Results	
Pharmacy General Information	
1.5 County	Vandercrburgh
1.6 Telephone number	(812)425-4365
1.8 Is permit properly displayed?	Yes
1.9 Controlled Substance Registration (CSR) number	60006286B
1.10 Controlled Substance Registration (CSR) status	Active
1.11 Controlled Substance Registration expiration date	12/31/2025
1.12 DEA registration number	FP3069437
1.13 DEA registration status	Active
1.14 DEA expiration date	03/31/2027
1.15 Qualifying pharmacist name	Jonathan Garvey
1.15c - Qualifying Pharmacists's average weekly hours	Over 40
1.16 Name of pharmacist-of-record at the time of inspection	Jonathan Garvey
1.17 Name of district manager	Deborah Larison
1.18 E-mail of district manager	deborah@paulsrx.com
1.19 Size of company/number of pharmacies nationwide	Chain
1.20 Average number of prescriptions filled daily	201-300
1.21 Days and Times of operation?	Mon.-Fri. 8:00am to 6:00pm, Sat. 9:00am to 1:00pm, Closed Sunday
1.23 Total weekly hours	54

Absence of Pharmacist	
2.1 If institutional pharmacy, how are drugs obtained for patient use when pharmacy is closed?	N/A
2.2 If institutional pharmacy, is a pharmacist reconciling drug removal against the order within 24 hours?	N/A
2.3 If institutional pharmacy employs after hours pharmacy access, does only one (1) supervisory licensed nurse per shift have access?	N/A
2.3a - Is the proper drug information recorded as required by law?	N/A
2.3b - Is a copy of the drug order left in the pharmacy?	N/A
2.4 Excluding after hours access by a supervisory nurse in an institutional pharmacy, is the licensed area unoccupied when the pharmacist is absent?	N/A
2.5 If institutional pharmacy, is there an emergency access policy for closed pharmacy?	N/A
2.6 If retail pharmacy, does prescription department have appropriate signage for pharmacist absence?	Yes
Staff/Personnel	
3.1 How many pharmacists are employed by the pharmacy?	2
3.1a - Do all pharmacists possess a valid license?	Yes
3.1b - Are any of the licensees on probation?	No
3.1c - Are any of the licenses "Valid to Practice While Being Reviewed"?	No
3.2 How many technicians are employed by the pharmacy?	11
3.2a - Do all technicians possess a valid certification?	Yes
3.2b - Are any of the certifications on probation?	No
3.2c - Are any of the certifications "Valid to Practice While Being Reviewed"?	No
3.2d - What training does the pharmacy require of technicians?	Employer based
3.2e - Are all technicians wearing a nametag stating their profession?	Yes
3.2f - Are all technicians engaging in legally permitted activities	Yes
3.3 How many interns are employed by the pharmacy?	1
3.3a - Do all interns possess a valid registration?	Yes
3.3b - Are any of the registrations on probation?	No
3.3c - Are any of the registrations "Valid to Practice While Being Reviewed"?	No
3.4 Does the pharmacy have ancillary personnel working in the licensed area?	Yes
3.4a - Are ancillary personnel engaging in permitted activities?	Yes
3.4b - How many ancillary personnel are working in the licensed area at the time of inspection?	3
3.5 Are all licenses and certifications properly displayed?	Yes
3.6 Are the pharmacy technician files complete?	Yes
3.8 Do technicians properly answer the telephone stating to the caller they are a technician?	Yes
3.9 Does staff properly make an offer for counseling?	Yes

Pharmacy Equipment/Security	
4.1 Is the pharmacy area properly equipped, and include the following?	Yes
4.1a - Scale (if performing non-sterile compounding)?	Operational
4.1b - proper documentation from Department of Weights and Measures	Yes
4.1c - refrigeration	Operational
4.1d - sink (proper sewage outlet)	Operational
4.1e - hot and cold water	Operational
4.1f - stationary / immobile	Yes
4.1g - well lit	Yes
4.1h - ventilated	Yes
4.1i - sanitary	Yes
4.1j - proper temperature	Yes
4.2 Does refrigerator contain only pharmaceutical products?	Yes
4.3 Is the pharmacy properly secured?	Yes
4.3a - Does the pharmacy have a motion detector?	Yes
4.3b - Does the pharmacy have an alarm?	Yes
4.3c - Does the pharmacy have a camera(s)?	Yes
4.3d - Does the pharmacy have locking doors?	Yes
4.3e - Does the pharmacy have a panic button?	Yes
4.3f - Does the pharmacy have a locking cage/gate?	No
4.3g - List any additional security measures.	N/A
4.4 What is the method of entry into the pharmacy?	Key
4.5 Is the drive thru secure?	Yes
4.6 When closed, do non-authorized personnel have access to the perscription department?	No
4.7 What are the number of entrances to the pharmacy?	2

References	
5.1 How does the pharmacy access current Indiana pharmacy law?	internet
5.1a - Does the pharmacy have Facts and Comparisons either in digital or hard copy form?	Yes
5.1b - Does the pharmacy utilize Remington: The Science and Practice of Pharmacy?	Yes
5.1d - Does the pharmacy utilize The Merck Manual?	Yes
5.1e - Does the pharmacy utilize other on-line subscriptions (Micromedex, Clinical Pharmacology, etc)?	Yes
5.1f - If pharmacy uses on-line service, are employees able to access?	Yes
5.2 For sterile compounding, does the pharmacy have at least one of the following reference materials?	N/A
5.2a - The Handbook on Injectable Drugs	N/A
5.2b - The King's Guide to Parenteral Admixtures	N/A
5.2c - another Board approved, printed or electronic database	N/A

Automated Medication Systems & Automatic Counting	
6.1 Does the pharmacy utilize a counting device(s)?	Yes
6.2 Does the pharmacy utilize a cabinet(s)?	Yes
6.2a - Are policies and procedures in place?	Yes
6.2b - Are maintenance protocols followed and documented?	Yes
6.2c - Are quality assurance protocols followed and documented?	Yes
6.2d - Is the cabinet only accessible by authorized personnel?	Yes
6.2e - Is there proper documentation of drugs dispensed?	Yes
6.3 Does the pharmacy utilize an automated will-call machine?	No
6.3a - Are policies and procedures in place?	N/A
6.3b - Are maintenance protocols followed and documented?	N/A
6.3c - Are quality assurance protocols followed and documented?	N/A
6.3d - Is there proper documentation of drugs dispensed?	N/A
6.4 Does the pharmacy utilize another form of automation?	No
6.4a - Are policies and procedures in place?	N/A
6.4b - Are maintenance protocols followed and documented?	N/A
6.4c - Is there proper documentation for drugs dispensed?	N/A
6.4d - Are quality assurance protocols followed and documented?	N/A

AMS Automated Packaging Systems	
7.1 Is the pharmacy properly logging the lot and expiration date for the drugs?	N/A
7.2 Are the drugs properly labeled if repackaged?	N/A
7.3 Do the drugs properly fit in the bubble pack?	N/A
7.4 Does the pharmacy have written policies and procedures of operation?	N/A
7.5 Has the automation been inspected and approved by the Pharmacy Board?	N/A
7.6 Does the pharmacy have a written plan for recovery in an emergency that includes the following?	N/A
7.6a - Planning and preparation for an emergency	N/A
7.6b - Procedures for response to an emergency	N/A
7.6c - Procedures for notifying the Board, patients, and those they have contracts with	N/A
7.6d - Procedures for maintenance and testing of recovery plan	N/A
7.7 Does the pharmacy have a written policy for quality assurance that includes the following?	N/A
7.7a - Testing and accuracy of the system on a biannual basis	N/A
7.7b - Retaining all quality documents for two (2) years	N/A
7.7c - Continuous monitoring of the system	N/A
7.7d - Reporting recurring errors to the Board	N/A
7.7e - What is the protocol for measuring effectiveness of AMS?	N/A
7.8 Is all pharmacy personnel with access to AMS trained in the pharmacy's policies and procedures?	N/A
7.9 Does the pharmacy have a written program for preventative maintenance of the system?	N/A
Drug storage/labeling/destruction	
8.1 Are all drugs properly labeled including lot number and expiration or beyond use dating as required?	Yes
8.2 Have any drugs in active inventory exceeded expiration or beyond use dating?	No
8.2a - If yes, provide detailed information.	N/A
8.3 How often does the pharmacy check for expired drugs?	Monthly
8.4 Are all drugs properly stored?	Yes
8.5 Does the pharmacy properly maintain a logbook for schedule V controlled substances dispensed without a prescription?	N/A
8.6 Does the pharmacy properly maintain a logbook for syringes dispensed without a prescription?	N/A
8.7 Is the pharmacy properly reporting all sales of pseudoephedrine products to the NPLEx tracking system?	N/A
8.7a - How are ephedrine and pseudoephedrine products stored?	N/A
8.8 Are samples stored in the licensed pharmacy area?	No
8.8a - If yes, is storage and distribution in accordance with federal regulations?	N/A
8.9 Does the pharmacy have current pseudoephedrine purchasing limits posted?	N/A
Dispensing/Records Retention	
9.1 Has the data processing system been approved by the Indiana Board of Pharmacy?	Yes
9.2 What type of software application does the pharmacy use?	Pioneer RX
9.3 Does the pharmacy scan a hard copy of prescriptions?	Yes
9.4 How does the pharmacy back up files?	Off site
9.5 Does the pharmacy have internet access?	Yes
9.6 How does the pharmacy maintain daily dispensing records?	Hard copy
9.7 Does the pharmacy retain these records for five (5) years?	Yes
9.8 Are HIPAA logs verifying all drugs dispensed that day signed by the pharmacist-in-charge?	Yes
9.9 What type of auxiliary procedure does the pharmacy have in place during system down time?	Shut Down
9.10 What type of filling system is used for prescriptions?	Three file
9.11 Does the pharmacy maintain digital copies of prescriptions?	Yes
9.11a - If yes, where are the records stored?	Off site server/database
9.11b - Is the data readily retrievable by the pharmacy?	Yes
9.11c - Who may access the data?	Pharmacist

Fax/e-prescribing/Transfers	
10.1 Is the facsimile machine in the prescription department or a nonpublic area of the pharmacy?	Yes
10.1a - Does the facsimile prescription contain all information required by law (IC 25-26-13-2)?	Yes
10.1b - Excluding Rule 31 exceptions, have schedule II controlled substances been dispensed pursuant to a faxed prescription?	No
10.1c - Does original prescription have "valid only if transmitted by facsimile machine" on its face?	Yes
10.1d - If the facsimile does not contain required information, has the pharmacist verified the prescription with appropriate documentation (i.e., reduced to writing)?	N/A
10.2 Do all e-prescriptions contain all of the information required by law?	Yes
10.2a - Is the Electronic Data Intermediary (EDI) approved by the Board of Pharmacy?	Yes
10.2b - Does the pharmacy maintain policies and procedures to ensure security of all information?	Yes
10.2c - Does the manual address the safety of the prescription?	Yes
10.2d - Does the manual address the safety of the practitioner's identity and privacy?	Yes
10.2e - Does the manual address the safety of the patient's identity, privacy and confidentiality?	Yes
10.3 If observed, are pharmacists properly processing transfers?	Not Observed
10.3a - Is prescription pad form completed on transfer?	N/A
10.3b - On transfer out, is all required information recorded on the invalidated prescription?	N/A
10.3c - On transfer in, is all required information recorded on the transferred prescription?	N/A
10.3d - Does the pharmacy print out a "transfer in" and "transfer out" report to confirm it has been transmitted?	N/A
Remote Order Entry and Centralized Processing	
11.1 Is the pharmacy performing or contracting centralized processing services?	N/A
11.2 Do the parties involved have the same owner or a written contract?	
11.3 Does the pharmacy have a written policies and procedures manual for performing or contracting CPS?	N/A
11.3a - Does the manual address how the parties will comply with federal and state laws and regulations?	N/A
11.3b - Does the manual address maintenance records to identify the responsible pharmacist(s) in the dispensing and counseling processes?	N/A
11.3c - Does the manual address a mechanism for tracking the prescription drug order during each step in the dispensing process?	N/A
11.3d - Does the manual address a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order?	N/A
11.3e - Does the manual address the provision of adequate security to protect the product integrity?	N/A
11.3f - Does the manual address the provision of adequate security to prevent the illegal use or disclosure of protected health information?	N/A
11.3g - Does the manual address the maintenance of a continuous quality improvement program for centralized prescription processing pharmacy services?	N/A
Generic Substitution	
12.1 Do substitutions have proper labeling?	Yes
12.2 Was the prescription followed and generic properly substituted?	Yes
12.3 Did the pharmacist inform the customer of substitution?	Yes
12.4 Was prescription dispensed with generically equivalent drug product (A, AB)?	Yes
12.5 Did the pharmacist list the name of the manufacturer, distributor or both of the drug actually dispensed?	Yes
12.6 What resource does the pharmacy use to determine generic equivalence?	Software application

Controlled Substances	
13.1 Does the pharmacy maintain a perpetual inventory for controlled substances?	Yes
13.1a - If yes, which controlled substance schedules are inventoried perpetually?	All controlled substances
13.1b - If no, what is the date of last biennial inventory (Type II facilities and facilities without controlled substances are exempt).	01/02/2023
13.1c - Is inventory within 2 years of last biennial inventory?	Yes
13.1d - How is the inventory recorded?	Pen
13.1e - Is the inventory signed by the pharmacist with date and time?	Yes
13.1f - Is the inventory complete?	Yes
13.1g - If incomplete, provide details.	N/A
13.2 Which controlled substances are stored in a locked cabinet?	CII
13.2a - What is the method of storage?	Safe
13.2b - If method of storage is improper, provide explanation.	N/A
13.3 Who is your reverse distributor for destruction of controlled substances?	Imar
13.3a - Does the pharmacy properly maintain reverse distribution receipts?	Yes
13.4 Are controlled substance records maintained separately from all other pharmacy records?	Yes
13.5 Who is your primary Wholesale Drug Distributor for Controlled Substances?	Amerisource

DEA Forms	
14.1 Are federal DEA Forms properly kept?	Yes
14.2 Does the pharmacy retain proper copies (i.e. Copy 1 or 3) of DEA Form 222?	Yes
14.2a - Are records retained for two (2) years?	Yes
14.2b - Which type of DEA Form 222 do you use for ordering CII's?	e-form
14.2c - Is receipt of CII properly recorded?	Yes
14.2d - Are DEA Form 222's properly executed?	Yes
14.2e - Has the invoice been signed?	Yes
14.2f - Are DEA Form 222's filed separately from other drug order forms?	Yes
14.2g - Are invoices attached to DEA Form 222's?	No
14.2h - Are there discrepancies between order forms and inventory?	No
14.2i - Are unused DEA Form 222's in a secure location and unsigned?	Yes
14.2j - Does the pharmacy have power of attorney that enables employees to place the order?	Yes
14.3 Does the pharmacy maintain copies of DEA Form 106 (theft and loss), if applicable?	N/A
14.4 Does pharmacy have DEA Form 41 on file if destroyed with witness of special agent or compliance officer?	N/A
14.5 Has the pharmacy reported theft of controlled substances to DEA within one (1) business day?	N/A
14.6 Have all thefts/losses been reported to the Pharmacy Board?	N/A
14.7 How many theft/losses have occurred since the previous routine inspection?	0

INSPECT	
15.1 Is the pharmacy currently reporting all controlled substance prescription data to INSPECT within seven (7) days of dispensing to a patient?	Yes
15.1a - If yes, provide verification of previous two submissions. Enter "Automatic Submission", if applicable.	Automatic submission
15.1b - If no, has the pharmacy made arrangements with INSPECT to begin reporting?	N/A
15.2 After uploading prescription data to INSPECT, does the pharmacy regularly check to see if the system found errant records?	Yes
15.2a - If yes, does the pharmacy have an error correction procedure in place?	Yes
15.3 How many practitioners within the pharmacy utilize an individual practitioner INSPECT account?	2
15.4 Is the pharmacy part of a chain or is it a single location?	Chain
15.5 How does the pharmacy staff access the INSPECT account?	Practitioner Account only
15.5a - Does the pharmacy (or parent corporation) prohibit staff from accessing INSPECT and/or the Internet?	No Restrictions
15.6 If Agent Access, is the practitioner aware of professional liability associated with the INSPECT account?	Yes
15.7 How many employees are trained to upload dispensing data to INSPECT?	2
15.7a - Is there a standard policy in place for uploading?	Yes
15.8 Does the pharmacy have procedures to properly dispose hardcopy INSPECT reports?	Yes
15.8a - How long are hardcopy INSPECT reports saved before they are destroyed?	0 Days
15.9 Has the pharmacy copied, faxed, e-mailed or transmitted INSPECT reports in any way?	No

Sterile Compounding: Policies and Procedures

16.2e - Do the quality assurance procedures cover sterility testing or monitoring, if employed, in the case of routine bulk compounding from nonsterile chemicals-high risk level compounding?	N/A
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Sterile Compounding: Engineering Controls

17.2 What type of primary engineering control (PEC) is used?	LAFW
17.2a - Total number of PEC's used	0
17.2b - Do the PEC's maintain ISO class 5 environment during in-use activity?	N/A
17.3 Are PECs located within appropriate secondary engineering controls?	N/A
17.4 Do secondary engineering controls (buffer area, ante area) maintain appropriate ISO classification?	N/A
17.5 If using CAI, is it located in an ISO class 7 buffer room?	N/A
17.5a - If no, does pharmacy have proper manufacturer documentation that it can maintain ISO class 5 environment during use?	N/A
17.6 Is appropriate pressure differential or airflow between control environments and the general pharmacy maintained and documented at least every work shift?	N/A
17.7 Is there a cleaning log for the PEC?	N/A
17.8 Is there a daily cleaning log for the counters, floors and work surfaces?	N/A
17.9 Is there a monthly cleaning log for the walls, ceiling and shelving?	N/A
17.10 Is there a cleaning log for the cleaning of BSC between uses if preparing both hazardous and non-hazardous preparations?	N/A
17.11 Are there proper containers for disposal of waste?	N/A
17.12 Does the pharmacy have records of necessary environmental sample testing maintained for two (2) years?	N/A
17.13 Does the pharmacy have total particle counts of each ISO classified area - performed not less than every six (6) months and when PEC is moved?	N/A
17.14 Does the pharmacy have volumetric air sampling for microorganisms in each ISO classified area - performed not less than every six (6) months?	N/A

Sterile Compounding: Personnel

18.1 Is there documentation of all personnel preparing sterile pharmaceuticals?	N/A
18.2 Is there documentation of all support personnel assisting with sterile pharmaceuticals?	N/A
18.3 Are personnel assessments/competencies related to aseptic technique, garbing, and cleaning/disinfecting performed at least annually?	N/A
18.4 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to garbing (assessment: observation, gloved fingertip sampling)?	N/A
18.5 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to aseptic technique (assessment: written test, media-fill test)?	N/A
18.6 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to cleaning/disinfecting procedures (assessment: observation, surface sampling via contact plates/swabs)?	N/A
18.7 Are personnel engaging in appropriate aseptic technique, garbing, and cleaning/disinfecting at the time of inspection?	N/A

Sterile Compounding: Labeling/Documentation

19.1 Does the label on the dispensed sterile pharmaceutical contain all information required by law?	N/A
19.2 Does the label have the additional information required if dispensed at home or outside the facility?	N/A
19.3 Is there documentation of patient training by the pharmacists to patients in the home?	N/A
19.4 Are single- and multiple-dose containers (e.g., vials) being properly used and stored with appropriate BUD when applicable?	N/A
19.5 Does the pharmacy have disposable needles, syringes and other supplies needed for aseptic admixture?	N/A
19.6 Does the pharmacy have disinfectant cleaning tools and solutions (i.e. sterile 70 % IPA)?	N/A
19.7 Does the pharmacy have a hand washing agent with antibacterial action?	N/A
19.8 Does the pharmacy have disposable towels or wipes?	N/A
19.9 Does the pharmacy have filters and filtration equipment, if utilized?	N/A
19.10 Does the pharmacy have a hazardous drug spill kit if hazardous drugs are prepared?	N/A
19.11 Does the pharmacy have disposable gowns and gloves?	N/A
19.12 Does the pharmacy have a refrigerator with a thermometer and temperature log?	N/A
19.13 Does the pharmacy have an infusion device, if appropriate?	N/A
19.14 Does the pharmacy have a sink with hot and cold running water, outside of the buffer area?	N/A
19.15 Does the pharmacy use a computer system to monitor 797 compliance? (i.e. Simplify 797)	N/A

Non-sterile Compounding	
20.1 What is the pharmacy's commitment to non-sterile compounding?	Moderate
20.2 Does the pharmacy have an affiliation with a professional compounding organization?	Yes
20.2a - If yes, which one?	PCCA, PRSRX
20.3 Does the regular pharmacy software application produce formula sheets?	Yes
20.4 Does the pharmacy record lot numbers and expiration dates of medications utilized during non-sterile compounding?	Yes
20.5 Does the pharmacy label compounded pharmaceuticals in accordance with USP 795?	Yes
20.6 Does the pharmacy check expiration dates of compounding chemicals?	Yes
20.7 Does the pharmacy assign beyond use dates to the compounded pharmaceuticals in accordance with USP 795?	Yes
20.7a - If yes, where does the pharmacy obtain it's information?	USP 795/Software
20.8 Who is responsible for preparing compounded pharmaceuticals?	Pharmacist
20.8a - If technicians are preparing compounded pharmaceuticals, how were they trained?	Employer
20.8b - Does the pharmacy submit sample compounds to outside testing labs for verification of the product strength and concentration?	No
Remote Locations (Type II only)	
21.1 If hospital (Type II) pharmacy, does pharmacy operate remote location(s)?	N/A
21.1a - If yes, how many remote locations?	0
21.2 Does the remote location have a pharmacist present?	N/A
21.3 Is a mechanical device used at the remote location(s)?	N/A
21.4 Is the remote location properly secured?	N/A
Emergency Drug Kits/Crash Carts	
22.1 For hospital pharmacies, do policies and procedures include determination of drugs and quantities to be included?	N/A
22.1a - For hospital pharmacies, do policies and procedures include labeling for expiration date?	N/A
22.1b - For hospital pharmacies, do policies and procedures include process for restocking the cart(s) or box(es)?	N/A
22.1c - For hospital pharmacies, do policies and procedures include security measures to prevent unauthorized access?	N/A
22.2 For Type III and Type VI permits, is the list of drugs/quantities included in each kit reviewed at least annually?	N/A
22.2a - Does the exterior labeling of the kit(s) meet the requirements of 859 IAC 1-28.1-9?	N/A
22.2b - Are all drugs contained in the kit(s) labeled as required by 856 IAC 1-28.1-9?	N/A
22.2c - Are controlled substances contained in the kit(s) included in the pharmacy's biennial inventory?	N/A
22.2d - Is the nurse responsible for removing drugs from the kit recording the information as required by 856 IAC 1-28.1-9?	N/A
22.2e - Is the restocking and resealing of the kit(s) being performed by the pharmacy?	N/A
Quality-Related Events/Patient Own Medications	
23.1 Have any sentinel events occurred as a result of pharmacy operations since the last inspection?	No
23.1a - If yes, how many?	0
23.1b - Are records of analysis and corrective action available for review?	N/A
23.2 Have any quality-related events occurred as a result of pharmacy operations since the last inspection?	No
23.2a - If yes, how many?	0
23.2b - Are records of analysis and corrective action available for review?	N/A
23.3 Are patient's own medications maintained exclusively in the patient care area or at the bedside?	N/A
23.4 Upon discharge or death, are such medications handled according to 856 IAC 1-28.1-14?	N/A
Special Medications	
24.1 Does the pharmacy report the dispensing of clozapine within five (5) days to the CNR?	N/A
24.1a - Which method does the pharmacy use for reporting the dispensing of clozapine?	N/A
24.2 Has the pharmacy received authorization from the iPLEDGE program to dispense isotretinoin (Accutane)?	Yes
24.2a - Is the MedGuide included with the prescription?	N/A
24.2b - Does the pharmacy have a record of pharmacist training for the iPLEDGE program?	Yes
24.3 Is the authorization number on all prescriptions for Thalomid?	N/A
24.3a - Is the pharmacy registered in the STEPS program for dispensing?	N/A
24.4- Does the pharmacy dispense any other "special medications" with an RDDS program?	N/A
24.5 Does the pharmacy follow proper FDA and manufacturers practices for other "special" medications such as Ticocin?	N/A

Immunization Rule	
25.1 What type of immunizations do pharmacists administer?	Influenza/other
25.2 Does the pharmacy have a Doctor's standing order in place for influenza and/or shingles immunizations?	Yes
25.2a - If administering per a standing order, does the protocol contain all the information required by law?	Yes
25.2b - Is the protocol up to date (renewed annually)?	Yes
25.3 Have all pharmacists administering immunizations completed an ACPE accredited training program?	Yes
25.4 Is the pharmacist CPR certified?	Yes
25.5 Is the pharmacist the only person administering vaccinations within the licensed area?	Yes
25.6 What are the procedures in place to address emergency situations?	Emergency Kit
25.7 Does the pharmacy maintain records of adverse event reporting to the necessary physicians and VAERS as required?	N/A
25.8 Does the pharmacy notify the authorizing physician and the individual's primary care physician of immunization administration within 14 days?	Yes
Patient Confidentiality (HIPAA)	
26.1 How does the pharmacy dispose HIPAA trash?	Third party service
26.1a - Is the dumpster locked and secure?	Yes
26.1b - What is the name of off-site HIPAA vendor?	Piranah
26.2 Are HIPAA policies posted?	Yes
26.3 Are employees HIPAA trained?	Yes
26.3a - Is there documentation of training?	Yes
26.4 Does the pharmacy have policies and procedures in place to protect health information?	Yes
26.5 Has the pharmacy had a complaint filed with DHHS?	No
Prescription Audit	
27.1 Do all Controlled Substance prescriptions meet Indiana security feature requirements?	Yes
27.2 Do all Controlled Substance prescriptions contain all information required by law?	Yes

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.

Signature of Inspector

11/1/2024 12:51:21 PM

Date/Time

Signature of Owner/Representative