AUGUST 2022

SOUTH DAKOTA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Board Welcomes Newly Registered Pharmacists and Pharmacies

Congratulations to the following 17 candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Tosin Adelakun, Clarissa Fasbender, Anna Fathman, Khalil Ford, Vanessa Gottier, Natalie Gray, Sara Huffman, Mary Kading, Aerial Lapke, Luke Lorenz, Vishal Patel, Kayley Perkins, Caroline Shin, Jacob Steckelberg, Holly Vietor, Kasey Wagner, and Natalie Wright. Eleven of the candidates were licensed by reciprocity and were from 11 different states.

There were two new South Dakota full-time pharmacy licenses issued: Lewis Family Drug, LLC, dba Lewis Family Drug #47, License #100-2081, Harrisburg, SD, and Avera St Luke's, dba Avera Plaza Pharmacy, License #100-2080, Aberdeen, SD. There were no new part-time pharmacy licenses issued in the period.

Top 10 Inspection Findings

By Inspectors Carol Smith and Tyler Laetsch

In South Dakota, inspections are completed with in-state pharmacies on an annual basis. Over time, with staff turnover and policy changes, some items may be overlooked by pharmacy employees, and inspectors often find them. While on inspections, we discuss items that need to be addressed and areas where we have typically seen compliance issues. We use this communication to help make pharmacists aware of items to improve upon. Below is a list of the top 10 items in pharmacies that required correction. If you work in a pharmacy, this list may help you identify items that need to be corrected.

Top inspection deficiencies noted:

1. **Biennial inventories of controlled substances (CS) not completed correctly.** There are often one or

National Pharmacy Compliance News
A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

more issues with the completion of the CS inventory. Either the inventory is not all completed on the same day, it is not completed within two years of the previous inventory (annual inventories are strongly encouraged), there is no signature on the inventory, and/or it does not include prescriptions that are completed and waiting to be picked up by the patient or drugs waiting for destruction. Remember, if the CS is in your location, you must count it.

2. **Outdated medications found in stock.** Everyone is busy, and it is no fun to go through all the medications in the pharmacy. Unfortunately, there are often expired medications on shelves; usually it is just one or two, however, even one is too many for good patient care. It is recommended that all pharmacies have a policy in place to check for outdated medications minimally every quarter.

3. **CS dispensing logbook or daily printouts are not being signed.** Pharmacists are required to verify all CS prescriptions refilled during their shift. This is an issue that inspectors encounter from time to time. Surprisingly, it is often the bigger stores with multiple pharmacists that have the hardest time because not everyone works daily or closes the pharmacy. At some sites, there is only one pharmacist's signature listed when multiple pharmacists worked in a day. Other sites may have no pharmacist signatures listed for certain days.

4. **CS prescriptions are not being submitted to the South Dakota Prescription Drug Monitoring Program (PDMP) correctly.** CS prescriptions are filled under a nickname rather than the patient's legal name. Also, some pharmacies are not submitting "Schedule V" CS prescriptions. In South Dakota statutes, federal Schedule V substances are Schedule IV. PDMP rules state that all Schedule II, III, and IV prescriptions are submitted by the dispensing pharmacy. This is most likely an error in communication with software vendors and pharmacies when the vendor sets up automated submissions of dispensed medications. This is often an easy fix, but it is a good reminder to regularly spot check the pharmacy's data in PDMP.

5. **Combat Methamphetamine Certification is expired.** Each pharmacy that sells pseudoephedrine is required to have a current Combat Meth Certificate. It must be renewed annually. This is something that inspectors check for annually, and it can be easily forgotten if no reminders are set.

6. **Pharmacist's license is not printed and displayed.** When the pharmacist renews their license, they must print and display a copy of their license at each pharmacy where they regularly work. A copy of the primary source verification is not a copy of the pharmacist license.

7. **Controlled Substance Ordering System (CSOS) orders are not received electronically.** The CSOS order must be finalized electronically upon receiving and checking in the inventory. If you order electronically, you must receive the medication order documentation electronically as well.

8. **Take-back receptacle security and documentation.** Receptacles must be securely fastened to the floor or wall. The pharmacy is also required to keep a record of all receptacle liners. The

pharmacy receives a new serial-numbered liner after shipping a full liner. Records need to be kept of dates when a liner is received, placed into the receptacle, and shipped. Also, after receiving documentation that the liner and its contents have been incinerated, this must be documented in the receptacle "liner log."

9. **Refrigerator monitoring not being completed.** To ensure proper medication storage, the refrigerator temperature must be recorded manually or electronically, at least daily, when the pharmacy is open.

10. **Compounding documentation is lacking significant information.** Sometimes there is a failure to document cleaning of the primary engineering control and anteroom. This is especially true with monthly cleaning. Inspectors have seen a lack of documentation for staff competencies and compounding records that do not have complete information. It is important to remind everyone of United States Pharmacopeia <795> and <797> requirements and the need for proper compounding documentation.

Hopefully, this article will remind staff to reflect upon whether the pharmacy is in compliance with laws and regulations and if there is anything that should be improved. If you work in a South Dakota pharmacy, please know that inspectors will look for these items and others during your next inspection.

PDMP Update – Data Integrity

By Melissa DeNoon, PDMP Director

Ensuring accuracy of the data contained in a PDMP is critically important as health care practitioners use this tool in clinical decision making when providing patient care.

PDMP staff is currently focusing on data submission compliance and database error correction. South Dakota law and rule require dispensers to submit dispensed Schedule II, III, and IV prescriptions at least every 24 hours or by midnight of the next business day after dispensing. If a pharmacy is found to be out of compliance with these data submission requirements, the pharmacist-in-charge (PIC) will be contacted by the PDMP assistant with information on how to come into compliance.

PDMP database errors fall into two categories:

- dispensation records in the database, and
- dispensation records not in the database.

Dispensation records that meet the specifically identified data elements adopted by the South Dakota State Board of Pharmacy and are contained in the 2011 version of the electronic reporting standard for PDMPs, version 4.2 of the American Society for Automation in Pharmacy (ASAP v4.2), will be in the database and viewable on patient reports. These records, however, may contain errors that occurred during prescription data entry and were not identified and corrected prior to dispensing, ie, incorrect prescription written date or incorrect prescriber Drug Enforcement Administration number. PDMP

staff is typically made aware of these errors by PDMP users after viewing the record on a patient report. South Dakota law requires that reported errors are corrected and that PDMP staff members work with PICs to accomplish this. This corrective action always involves submission of the corrected information into South Dakota's data submission site, PMP Clearinghouse. It is important to note that making the correction to the prescription within the patient's profile does not automatically resubmit the corrected record; PICs must check with their pharmacy dispensing software vendors for their record correction process to ensure resubmission.

Dispensation records that do not meet the Board-adopted ASAP v4.2 data elements will not be in the database and therefore will be missing on patient reports. These data elements can be found in Administrative Rules of South Dakota 20:51:32:03. It is a PIC's responsibility to know what these required data elements are and to ensure that their pharmacy dispensing software vendor and party responsible for their data submissions do as well. Data submission error reports are generated by PMP Clearinghouse upon file submission. These error reports must be promptly reviewed, and the necessary corrections made, so that the file can be resubmitted. If data submissions are performed by the pharmacy dispensing software vendor, the PIC must also make sure that these error reports are forwarded to them for review and correction, and then sent back to the vendor for resubmission.

Best practice for PICs in both noncompliance and error correction is to perform a patient query after the corrective action is taken to confirm that the missing record is now in the database, or the incorrect record is now updated with the correct information. Please email questions to PDMP staff at sdpdmp@state.sd.us.

Board Meeting Dates

Please check the Board's website for the time, location, and agenda for future Board meetings.

Board of Pharmacy Members

- Ashley Hansen, Aberdeen, SD
- Cheri Kraemer, Parker, SD
- Tom Nelson, Spearfish, SD
- Curtis Rising, Rapid City, SD
- Dan Somsen, Yankton, SD

Board of Pharmacy Staff Directory

- **Board Office General Email:** PharmacyBoard@state.sd.us
- **Office Phone:** 605/362-2737; **Office Fax:** 605/362-2738
- **Kari Shanard-Koenders, MSJ, RPh, Executive Director:** kari.shanard-koenders@state.sd.us
- **Melissa DeNoon, RPh, PDMP Director:** melissa.denoon@state.sd.us
- **Tyler Laetsch, PharmD, RPh, Pharmacy Inspector:** tyler.laetsch@state.sd.us

- **Lee Cordell, PharmD, RPh, Pharmacy Inspector:** lee.cordell@state.sd.us
- **Carol Smith, RPh, Pharmacy Inspector:** carol.smith@state.sd.us
- **Beth Windschitl, Senior Secretary:** beth.windschitl@state.sd.us
- **Melanie Houg, PDMP Assistant:** melanie.houg@state.sd.us
- **Rhea Kontos, Senior Secretary:** rhea.kontos@state.sd.us
- **PDMP Sign-up and Data Access Website:** *https://southdakota.pmpaware.net/login*

The South Dakota State Board of Pharmacy News is published by the South Dakota State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Kari Shanard-Koenders, MSJ, RPh - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager

4001 W Valhalla Blvd, Suite 106 | Sioux Falls, SD 57106 | 605/362-2737 | www.pharmacy.sd.gov