JANUARY 2024

SOUTH DAKOTA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

South Dakota Board Welcomes Newly Registered Pharmacists and Pharmacies

Congratulations to the following 18 candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: I Trinity Bernier-Nachtwey, Timothy Berry, Aya Cabanban, Loretta Dy, Kimberly Dykstra, Sierrah Ellenbecker, Giby George, Ashley Howard, Roxana Joseph, Carli Krogman, Dana Moore, Josey Poppens, Karla Ruiter, Kathryn Sheetz, Lacey Steele, Renee Tichy, Sheri Woitalewicz, and Samira Zantout.

There were five new South Dakota full-time pharmacy licenses issued: Lewis Drugs, Inc, dba Falls Community Health – Lewis Drug #29, Sioux Falls, SD, License #100-2092; SD Department of Corrections Pharmacy – Pierre Women's Prison, Pierre, SD, License #100-2093; Lewis Drugs, Inc, dba Lewis Drug #17, Sioux Falls, License #100-2094; Monument Health Nuclear Pharmacy, Rapid City, SD, License #100-2095; and Avera McKennan, dba Avera Long-Term Care Pharmacy – Rapid City, License #100-2096. There were no South Dakota part-time pharmacy licenses issued. There was one new South Dakota wholesaler license issued: Helget, Inc, dba Helget Home Medical, Sioux Falls, License #600-3582.

Board Approves Policy Statement on USP Compounding Chapters

During the September 14, 2023 South Dakota Board of Pharmacy meeting, the Board adopted a policy statement to clarify the expectations for pharmacies to follow the new United States

National Pharmacy Compliance News
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Pharmacopeia (USP) standards. Board Policy Statement #23-09-14 can be found on the Board website. The Board expects all pharmacies that are compounding or handling hazardous drugs to follow the latest USP Chapters <795>, <797>, <800>, and <825>, which became enforceable on November 1, 2023. This policy statement will be used for guidance until the compounding section of the administrative rules can be updated through the full rulemaking process in the spring.

In addition, for pharmacies that regularly compound most of their business or ship compounds to other states, the National Association of Boards of Pharmacy® (NABP®) has updated the Multistate Pharmacy Inspection Blueprint Form to the current USP compounding chapters. This form is utilized by the Board's inspectors to perform annual inspections of these pharmacies. This tool has been most helpful for inspectors and for pharmacies to ensure that they are following the current compounding standards.

PDMP Assistant Hired to Replace Longtime Board Employee

As most of you know, longtime Board employee Melanie Houg has retired and is enjoying her grandchildren even more! We miss her! The Board has hired Certified Pharmacy Technician Brandi Dux as the new prescription drug monitoring program (PDMP) assistant. Brandi is highly skilled in pharmacy management and understands the pharmacy world in a very big way. She is a fantastic asset to our small Board office, and we are thrilled to have her assisting the PDMP.

Beware of Fraud and Counterfeit Popular Weight Loss Products

Food and Drug Administration (FDA) is warning of fraud in the supply chain for weight loss products in the glucagon-like peptide-1 (GLP-1) agonists (ie, semaglutide) and the glucose-dependent insulinotropic polypeptide receptor plus GLP-1 mixed (tirzepatide) receptor classes. FDA's Office of Criminal Investigations has identified cases of wholesalers selling the product and the purchaser not receiving it after they pay for it. Be sure to question any behavior that seems abnormal for these classes of agents.

These products do cause significant weight loss, are in high demand, and are on FDA's shortage list as a result. FDA allows 503B and 503A pharmacies to compound shortage list items if the active pharmaceutical ingredient (API) is not a salt or other form of the drug. For instance, semaglutide (Ozempic®) may only be compounded with the API semaglutide base. Most of the spas and wellness centers are dispensing non-FDA-approved compounded products due to this. Some send prescriptions for brand-name products to a pharmacy. This is preferred. The Board is aware of one adverse reaction in South Dakota due to a patient misunderstanding the dose and taking 10 times the amount prescribed. Additionally, wherever there is high demand, it provides the opportunity for potential criminal activity. Thirty-eight cases of counterfeit semaglutide that caused adverse events were reported to the FDA Adverse Event Reporting System (FAERS) since 2020. The majority of these were serious adverse drug reactions. One syringe was found to contain insulin glargine. The FAERS has

limitations, due to the reports being voluntary, so there may be many more cases. Be on the lookout for counterfeit products. Notable characteristics of counterfeits are that labels have poor quality, boxes may have grammatical or spelling errors, boxes may lack a tamper-resistant system, and the batch number on the counterfeit box might not correspond to the product strength listed on the same box and pen.

PharmaDrop Drug Take-Back Program

By Melissa DeNoon, PDMP Director

The Board established a drug take-back program in 2017 to reduce the avenue of diversion created by unused, unwanted, and expired drugs in an individual's medicine cabinet. Trilogy MedWaste's PharmaDrop receptacles were placed in South Dakota hospitals and retail pharmacies. This program was initially funded through a federal PDMP grant and is currently being funded through a South Dakota Department of Social Services federal grant. Since its inception, the program has placed 89 **permanent drug take-back receptacles** across South Dakota and enrolled an additional five locations that already had their own receptacles to the South Dakota PharmaDrop program, bringing the total number of locations managed through the program to 94. A comprehensive list of permanent drug take-back sites can be found at *AvoidOpioidSD.com* under the Take Action heading by selecting Safe Medication Disposal. This program provides an option for the safe disposal of an individual's nonprescription and prescription drugs, including controlled substances, and is a key component in South Dakota's strategy to address the state's misuse, abuse, and diversion of controlled prescription drugs. If your pharmacy is not currently participating and would like to, please email Melissa.DeNoon@state.sd.us.

Board Meeting Dates

Please check the Board of Pharmacy page on the Boards and Commissions Portal for the time, location, and agenda for future Board meetings.

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Tom Nelson, Spearfish, SD

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PDMP Sign-up and Data Access Website: *https://southdakota.pmpaware.net/login*

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