SOUTH DAKOTA BOARD OF PHARMACY

July 18, 2025

<u>Unapproved Draft Minutes</u>

9:00 am CDT

Public Board Meeting

Board members present: Shane Clarambeau, Ashley Hansen, Cheri Kraemer, Tom Nelson, and Curt Rising Board staff present: Tyler Laetsch, Jenna Heyen, Melissa DeNoon, Carol Smith, Lee Cordell, Elizabeth Hallway, and Beth Windschitl

Other parties in attendance

Meeting called to order at 9:00 am by President Hansen. Voice roll call taken, mission statement read, a quorum confirmed, and introductions completed. A call for public comment was made pursuant to SDCL 1-25-1 and there was no public comment.

Motion to approve consent agenda was ratified (Kraemer/Rising/pass).

EXECUTIVE SESSION - Per SDCL1-25-2(4) to consult with legal counsel.

Motion to go into executive session was ratified (Kraemer/Rising/unanimous) 9:07 am. Board meeting resumed 9:35 am.

REPORTS

Operations

Tyler Laetsch

- Fiscal year 2026 started July 1.
- July 1st HB 1016 went into effect resulting in a new \$50 late fee charge for pharmacy and wholesale renewals, an increase of pharmacist renewal late fee to \$50, and terminology clean-up.
- Updating rules to increase in wholesale fees to \$500, implement a \$50 PIC change fee and clean-up of rules in section 20:51
- Pharmacy license renewal period ended June 30th. Non-renewed accounts were rendered inactive on July 1st. A total of 1,181 in-state and nonresident licenses were renewed.
- Part-time secretary Danelle Perrizo resigned after three months. Her last day is July 23rd.
- Legislative plans are due to the Department of Health in August. Board is discussing clean-up of 34-20E-2 PDMP data submission fields and medical cannabis indicator fields. Talks about moving the controlled substance registration from DOH to BOP continue.
- Board has assumed the responsibility from SDPhA for the payment of services provided by HPAP. A new \$10,000 contract between BOP and HPAP was executed June 1st.
- Several in-state retail pharmacies reported issues renewing entity's Minnesota license. Minnesota requires a full blueprint or VPP inspection for pharmacies performing non-sterile compounding, and deemed the inspections provided in the renewal applications as insufficient. SD board will incorporate more statements in our inspections in order to meet Minnesota's licensing inspection requirements in the future.

Inspector Highlights

Carol Smith

- Completed a total of 39 retail, hospital, AMDD and medical gas inspections; four retail inspections were conducted in Sioux Falls with P4 student Elizabeth Hallway.
- Key Findings:
 - A pharmacy staff completed biennial inventory while PIC was on vacation. Staff failed to print and sign biennial
 inventory after completion. Document was printed and signed 11 days after-the-fact. Biennial inventory must be
 signed by the persons completing the inventory on the date it was completed
 - Fielded PIC questions including if a facility CEO's name could be listed on DEA certificate instead of PIC. Yes, using a POA.
 - Hospital pharmacy incubating their room temperature petri plates samples on the counter instead and not in an incubator.
 - Prescription Audit identified multiple issues including prescription written for 46 tablets, ad 23-day supply; renewed old prescription for 60 tablets and a 30-day supply which was incorrect; wrong provide because an old prescription was renewed instead of creating a new prescription.
 - SDIIS Immunization Audit Immunizations are required to be reported to SDIIS within 14 days. Discovered two
 pharmacies who manually report immunizations that are a month behind in their reporting. Found several
 pharmacists who were locked out of the SDIIS website. Users must log in every 90 days to avoid being locked out.

Lee Cordell

- Completed a total of 18 pharmacy and AMDD inspections in Q2 for a total of 40 inspections year-to-date
- Key Finding:
 - Several facilities lacked proper temperature monitoring in storage areas, inadequate response to temperatures that were out of range
 - Risk assessment deficiencies staff could not locate or utilize their assessment of risk, one chain lacked appropriate risk assessments
 - Completed a joint visit with the Board of Dentistry conducted an inspection at dental facility found expired medications, inaccurate controlled substance documentation, will complete a follow-up inspection at location.
 - Controlled substance discrepancies (CS) Missing CS with no DEA form 106 as required
 - o Complaint reviewed film to resolve and confirmed no counseling occurred during designated period
 - Biennial inventory not being completed when PIC changes; when counts are off the responsible party is the new PIC that is taking over

Jenna Heyen

- Completed 50 inspections in Q2 25 retail, 13 hospitals, remaining were wholesale and medical gas
- Key Findings:
 - Accompanied DEA on an inspection. DEA highlighted documentation issues with drug take back at locations registered as collectors (signatures required for all boxes, Triology paperwork deemed inadequate from DEA's perspective). Found at several locations. Will work with Triology to get paperwork compliant.
 - o A variety of expired licenses at locations
 - Several cases where education was provided regarding repackaging/labeling, dating of repackage items, and items store in non-USP compliant packaging
 - Removed outdate medications at several locations; one with a significant number of outdates and site follow-up was required and complete inventory done.
 - A couple occurrences where POA was still in play, but the designated POA person had quit; sites where actively
 working to revoke.
 - Sites where will-call bin was not included in inventory
 - Assisted a couple sites with proper voiding of triplicate DEA 222 forms
 - Upon review of CSOS orders for a site they had not been accepted for six days
 - o Incidents where controlled substances were not stored properly
 - Accountability for med dispensing machine access; movement of controls in and out of machine; policies and procedures not being followed.
 - Issues with Beyond Use Dates (BUD) for compounded products, inadequate compounding records and labeling
 - o Facility whose overall pharmacy space is not 797 compliant; follow-up plan for site initiated to get them compliant
 - o Today is SDSU P4 student Elizabeth Hallway's last day of her five-week rotation with the board.
 - Attended the two-day KPIC training for compounding focused on 797 and 800. There are some states that have not adopted 797.

Prescription Drug Monitoring Program - Melissa DeNoon

- Ongoing focus on data integrity inspectors pull ten controlled substance prescriptions per inspection and the data on the hard copy is being checked against the data submitted to the PDMP.
- Providers can have multiple DEA numbers and DEA numbers are state specific. If a provider practices in a state, they need a DEA for that state unless they are doing telehealth which currently allows for one DEA for all states; however, these telehealth Covid flexibilities end as of 12/31/25.
- Best practice for pharmacy staff is to enter and verify prescribers of controlled substance prescriptions by their DEA number.
- Issues were discovered with Trilogy's drug take-back liner tracking logs (two signatures required); new DEA compliant log requiring four signatures was made by Trilogy and has been implemented.
- Unused drug take-back receptacle liners and those sealed liners awaiting return for destruction are required to be included in the controlled substance biennial inventory (21 CFR Part 1304).
- The SD PDMP user guide has been replaced by an online user site available through user accounts. A site for program admins is currently under development by the program vendor, Bamboo Health.
- Program statistics on prescription count of controlled substances to SD patients by drug schedule was shown and reviewed.

Complaints, Disciplinary Actions, and Loss/Theft Reports - Board Staff

Refer to audio record for compliant specific information.

- Complaint 2025-0004, Pharmacy
- Complaint 2025-0006, Pharmacy
- Complaint 2025-0007, Pharmacy
- Complaint 2025-0008, Pharmacy
- Complaint 2025-0009, Pharmacy
- Complaint 2025-0010, Pharmacy
- Complaint 2025-0011, Pharmacy
- DEA Form 106, Thrifty White Deadwood

- DEA Form 106, Lewis Southwest Sioux Falls
- DEA Form 106. Lewis Aberdeen
- DEA Form 106, Genoa healthcare Huron
- DEA Form 106, Walgreens Mt View Rd Rapid City
- DEA Form 106, Walgreens Yankton
- DEA Form 106, Lewis Family Drug Chamberlain
- DEA Form 106, Medicine Shoppe Rapid City
- Discipline, Walgreens #5643, Rapid City / Motion
 - a. Complaint 2025-0003 (executive session)

A motion to accept the recommendations of the disciplinary committee against Walgreens Pharmacy #5643 which includes (1) a two-year probation period, (2) undergo increased inspections, and (3) the sending of a letter to all persons who received an immunization from Walgreens Pharmacy #5643 in the last year stating person may have received a vaccination from an unqualified person was ratified. (Kraemer/Clarambeau/Pass), Rising obtain.

OTHER REPORTS

SD Pharmacists Association – Amanda Bacon Executive Director

- Highlights
 - July 1 marks an historic shift for SDPhA due to statute changes
 - Working on setting a strong foundation that is a member driven model (a new structure and by-laws revisions) and founding members' campaign.
 - Spring district meetings are done
 - Quarterly journal email topics focus on transparent and developing the new SDPhA roadmap for the future
 - There is renewed interest in revitalizing the SDAPT technician association and relaunch.
 - Watch for a communication preferences survey from SDPhA
 - o 139th annual convention September 19-20, 2025, in Deadwood, SD with great CE opportunities
 - SDPhA will host a symposium, ahead of the upcoming legislative session, focused best practices and contracting by retail entities

SD Society of Health System Pharmacists - (none)

SDSU College of Pharmacy - Jeremy Daniel, PharmD, Avera, SDSU Faculty, and SDPhA

- One hundred percent, first time NAPLEX pass rate for SDSU 2024 pharmacist graduate class. National pass rate is 77.4%
- SDSU Pharmacy program selected as the number one most affordable College of Pharmacy in the United States.
- Faculty working on curriculum revisions starting with P1 class
- SDSU Metro Center in Sioux Falls at 33rd Street and Minnesota will house multiple health professions.
- Class enrollment numbers P4 (38), P3 (31), P2 (50), and P1 (60)
- Pre-pharmacy numbers are back to pre-COVID level

SD Association of Pharmacy Technicians (none)

- Entity has been dormant for three years.
- SD Pharmacists Association is examining how to help SDAPT get back up and going in the future.

OLD BUSINESS

Wellbeing First Champion Challenge - Jenna Heyen / Tyler Laetsch

- Application updates
 - o Board submitted updated application questions to the Lorna Breen Foundation for review
 - Updated questions were also provided to the board's licensing platform vendor for inclusion in both the pharmacist and technician applications.

NEW BUSINESS – Tyler Laetsch

Legislative Update

HB 1016

- Changed our statutes starting July 1, 2025
- See Operations Report section of minutes for HB1016 changes

Rules Update Process (no comments)

SB 74

Open Meeting Laws Review - Annual Discussion

SDCL 125:13 - New law effective July 1, 2025, requires all agencies and boards to provide annually a copy of the open
meeting laws published flyer "Conducting the Public's Business in Public" to attendees for review and discussion. No
questions.

RFP for Licensing Software

- Request for proposal (RFP) was published on June 2, 2025, on the procurement website
- Timeline of events:
 - June 20th board received 22 Letters of Intent
 - July 11th questions from offerors due
 - July 18th answers to offeror questions due
 - July 31st proposal submission begins
 - August presentations/demonstrations, technical review
 - October 1st RFP award date
 - Current vendor is phasing out they will provide services through May 2026
- If fee for using a credit card is assessed to card holder, then board must allow paper application submission.

Policy Statement - Patient Abandoned Controlled Substance Medications - Jenna Heyen

- Question what can be done with controlled medications that have been left at a facility
- DEA note limited ability to grant approval for an entity to remove or destroy medication not under the ownership of their registration
- DEA guidance turns it back to the State/local tribal authorities to determine the guidance
- A policy statement is necessary. Board will formulate a policy for review/consideration at the next meeting

OTHER BUSINESS

Recent Meeting News

<u>Future Board Meetings</u> – all held in Sioux Falls Board Room unless otherwise noted.

- October 10, 2025, 9:00 am
- January 16, 2026, 9:00 am
- April 10, 2026, 9:00 am
- July 17, 2026, 9:00 am

Upcoming Meetings

- District V NAPB/AACP 2025 Meeting, Coralville, IA August 6-8, 2025
- 139th SDPhA Annual Convention, Deadwood, SD, September 19-20, 2025
- SDSHP 50th Annual Conference, Sioux Falls, SD April 17-18, 2026
- NABP 122nd Annual Meeting, Boston, MA May 12-15, 2026

Motion to adjourn (Kraemer/Rising). Meeting adjourned at 11:07 am (CDT).